



PB 97 of 2025

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (September Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, PBS Listing, Pricing and Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 29 August 2025

REBECCA RICHARDSON

Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division

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1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (September Update) Instrument 2025*.
- (2) This instrument may also be cited as PB 97 of 2025.

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 September 2025	1 September 2025

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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] Schedule 1, entry for Dupilumab

substitute:

Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled pen	Injection	Dupixent	C17009 C17016 C17072 C17073 C17113	See Schedule 2	See Schedule 2
	Injection 200 mg in 1.14 mL single dose pre-filled syringe	Injection	Dupixent	C15348 C15886 C15924 C17009 C17016 C17072 C17073 C17113	See Schedule 2	See Schedule 2
	Injection 300 mg in 2 mL single dose pre-filled pen	Injection	Dupixent	C17009 C17016 C17072 C17073 C17113	See Schedule 2	See Schedule 2
	Injection 300 mg in 2 mL single dose pre-filled syringe	Injection	Dupixent	C15348 C15424 C15425 C17009 C17016 C17072 C17073 C17113	See Schedule 2	See Schedule 2

[2] Schedule 1, entry for Infliximab [Brand: Inflectra]

- (a) omit from the column headed “Circumstances”: **C9668 C9669**
- (b) omit from the column headed “Circumstances”: **C9719 C9721**
- (c) omit from the column headed “Circumstances”: **C9751**
- (d) omit from the column headed “Circumstances”: **C9775**
- (e) omit from the column headed “Circumstances”: **C13691**
- (f) omit from the column headed “Circumstances”: **C13702**
- (g) insert in numerical order in the column headed “Circumstances”: **C17097 C17111 C17112 C17115 C17116 C17117 C17120 C17122**

[3] Schedule 1, entry for Infliximab [Brand: Remicade]

- (a) omit from the column headed “Circumstances”: **C9669**

- (b) omit from the column headed "Circumstances": **C9719 C9721 C9751**
- (c) omit from the column headed "Circumstances": **C13691**
- (d) omit from the column headed "Circumstances": **C13702**
- (e) insert in numerical order in the column headed "Circumstances": **C17097 C17111 C17112 C17115 C17116 C17122**

[4] Schedule 1, entry for Infliximab [Brand: Renflexis]

- (a) omit from the column headed "Circumstances": **C9668 C9669**
- (b) omit from the column headed "Circumstances": **C9719 C9721**
- (c) omit from the column headed "Circumstances": **C9751**
- (d) omit from the column headed "Circumstances": **C9775**
- (e) omit from the column headed "Circumstances": **C13691**
- (f) omit from the column headed "Circumstances": **C13702**
- (g) insert in numerical order in the column headed "Circumstances": **C17097 C17111 C17112 C17115 C17116 C17117 C17120 C17122**

[5] Schedule 1, entry for Ivacaftor

insert as first entry:

Sachet containing granules 13.4 mg	Oral	Kalydeco	C16928 C16971	See Schedule 2	See Schedule 2
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[6] Schedule 1, after entry for Lamivudine in the form Tablet 300 mg [Brand: Lamivudine Alphapharm]

insert:

Lamivudine Viatris	C4454 C4512	60	5
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[7] Schedule 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg

omit:

MycoCept	C5554 C5795 C9691 C9693	300	5
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[8] Schedule 1, entry for Omalizumab in the form Injection 75 mg in 0.5 mL single dose pre-filled syringe [Brand: Omlyclo]

- (a) omit from the column headed "Circumstances": **C15352**

- (b) omit from the column headed "Circumstances": **C15403**
- (c) omit from the column headed "Circumstances": **C16879 C16904 C16948**
- (d) insert in numerical order in the column headed "Circumstances": **C17012 C17049 C17075 C17085 C17086 C17102**

[9] Schedule 1, entry for Omalizumab in the form Injection 75 mg in 0.5 mL single dose pre-filled syringe [Brand: Xolair]

- (a) omit from the column headed "Circumstances": **C15352**
- (b) omit from the column headed "Circumstances": **C15403**
- (c) omit from the column headed "Circumstances": **C16879**
- (d) insert in numerical order in the column headed "Circumstances": **C17012 C17049 C17075 C17086**

[10] Schedule 1, entry for Omalizumab in the form Injection 150 mg in 1 mL single dose pre-filled syringe

- (a) omit from the column headed "Circumstances": **C15403**
- (b) omit from the column headed "Circumstances": **C16879 C16904**
- (c) omit from the column headed "Circumstances": **C16948**
- (d) insert in numerical order in the column headed "Circumstances": **C17012 C17049 C17075 C17084 C17096**

[11] Schedule 1, entry for Patisiran

omit from the column headed "Circumstances": **C15478**

[12] Schedule 1, entry for Peginterferon alfa-2a

substitute:

Peginterferon alfa-2a	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	C17022 C17108	8	5
	Injection 135 micrograms in 0.5 mL single use pre-filled syringe (s19A)	Injection	Pegasys (Ireland)	C17022 C17108	8	5
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	C17022 C17108	8	5
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe (s19A)	Injection	Pegasys (Ireland)	C17022 C17108	8	5

[13] 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": **C16400**

(b) insert in numerical order in the column headed "Circumstances": **C17055**

[14] Schedule 1, entry for Valaciclovir

omit:

Valaciclovir APOTEX	C5975 C9267	500	2
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[15] Schedule 2, entry for Dupilumab [Maximum quantity: 1 pack; Maximum repeats: Sufficient for 32 weeks of treatment]

insert in numerical order in the column headed "Circumstances": **C17016 C17072 C17073**

[16] Schedule 2, entry for Dupilumab [Maximum quantity: 1 pack; Maximum repeats: Sufficient for 24 weeks of treatment]

insert in numerical order in the column headed "Circumstances": **C17009 C17113**

[17] Schedule 2, entry for Infliximab [Maximum quantity: 1 dose of 3 mg per kg of patient weight; Maximum repeats: 2]

omit from the column headed "Circumstances": **C9668**

[18] Schedule 2, entry for Infliximab [Maximum quantity: 1 dose of 5 mg per kg of patient weight; Maximum repeats: 2]

(a) omit from the column headed "Circumstances": **C9669**

(b) omit from the column headed "Circumstances": **C9719 C9721**

(c) omit from the column headed "Circumstances": **C9751**

(d) omit from the column headed "Circumstances": **C9775**

(e) omit from the column headed "Circumstances": **C13691 C13702**

(f) insert in numerical order in the column headed "Circumstances": **C17097 C17111 C17112 C17115 C17116 C17117 C17120 C17122**

[19] Schedule 2, after entry for Ivacaftor

insert:

C16928 C16971	1 pack	2
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- [20] **Schedule 2, entry for Omalizumab [Maximum quantity: Sufficient for 4 weeks of treatment; Maximum repeats: 5]**
 (a) omit from the column headed "Circumstances": **C15352**
 (b) omit from the column headed "Circumstances": **C16904**
 (c) omit from the column headed "Circumstances": **C16948**
 (d) insert in numerical order in the column headed "Circumstances": **C17084 C17085 C17086 C17096 C17102**
- [21] **Schedule 2, entry for Omalizumab [Maximum quantity: Sufficient for 4 weeks of treatment; Maximum repeats: 6]**
 omit from the column headed "Circumstances": **C16879** substitute: **C17049 C17075**
- [22] **Schedule 2, entry for Omalizumab [Maximum quantity: Sufficient for up to 28 weeks of treatment; Maximum repeats: 0]**
 omit from the column headed "Circumstances": **C15403** substitute: **C17012**
- [23] **Schedule 2, entry for Patisiran**
 omit from the column headed "Circumstances": **C15478**
- [24] **Schedule 2, entry for Ravulizumab [Maximum quantity: 1 dose; Maximum repeats: 0]**
 (a) omit from the column headed "Circumstances": **C16400**
 (b) insert in numerical order in the column headed "Circumstances": **C17055**
- [25] **Schedule 3, entry for Dupilumab**
 insert in numerical order after existing text:

	C17009		Uncontrolled severe asthma Continuing treatment Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma; AND Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be aged 6 to less than 12 years. An adequate response to this biological medicine is defined as:	Compliance with Written Authority Required procedures
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		<p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p> <p>A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.</p> <p>At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks therapy.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) maintenance oral corticosteroid dose; and</p> <p>(b) Asthma Control Questionnaire (ACQ-5) score; or</p> <p>(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
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	C17016	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR</p> <p>Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre in the last 12 months; OR</p> <p>Patient must have a fractional exhaled nitrous oxide of at least 20 ppb in the last 12 months; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>Patient must be under the care of the same physician for at least 6 months; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must be aged 6 to less than 12 years.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;</p> <p>AND</p> <p>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day</p>	Compliance with Written Authority Required procedures
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			<p>maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in 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.</p> <p>The initial IgE assessment, blood eosinophil count or fractional exhaled nitrous oxide measurement must be no more than 12 months old at the time of application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),</p> <p>AND</p> <p>(b) while receiving optimised asthma therapy in the previous 12 months, 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>The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 28 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the last dose of biological medicine, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p> <p>A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2 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>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab of up to 32 weeks.</p>	
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		<p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and</p> <p>(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(c) the IgE, blood eosinophil or the fractional exhaled nitrous oxide result and date; and</p> <p>(d) Asthma Control Questionnaire (ACQ-5) score; or</p> <p>(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p>	
	C17072	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR</p> <p>Patient must have had a fractional exhaled nitrous oxide of at least 20 ppb no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>Patient must be under the care of the same physician for at least 6 months; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must be aged 6 to less than 12 years.</p>	Compliance with Written Authority Required procedures

			<p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2 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 commencement of treatment with a biological medicine under the new treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy.</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) the IgE, blood eosinophil or fractional exhaled nitrous oxide result and date; and 	
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			<p>(b) Asthma Control Questionnaire (ACQ-5) score; or</p> <p>(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p> <p>(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
	C17073		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment, or transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - Balance of Supply in a patient aged 6 to 12 years</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing and transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p>	Compliance with Authority Required procedures
	C17113		<p>Uncontrolled severe asthma</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2025; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist; (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard</p>	Compliance with Written Authority Required procedures

		<p>clinical features: (i) forced expiratory volume (FEV1) reversibility, (ii) airway hyperresponsiveness, (iii) peak expiratory flow (PEF) variability; AND</p> <p>Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS-subsidised treatment with this drug; AND</p> <p>Patient must have had a documented total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must have had a fractional exhaled nitrous oxide of at least 20 ppb in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must have been aged 6 to less than 12 years prior to starting non-PBS-subsidised treatment with this drug.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;</p> <p>AND</p> <p>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in 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.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire</p>	
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			<p>interviewer administered version (ACQ-IA) 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be demonstrated in all patients at the time of the application: (a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed prior to non-PBS-subsidised treatment with this drug for this condition (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND (b) while receiving optimised asthma therapy in the prior to non-PBS-subsidised treatment with this drug for this condition 12 months, 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>The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate 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 at least 28 weeks</p> <p>All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised treatment with this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug for this condition.</p> <p>A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2</p>	
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			<p>biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date of 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>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks of therapy.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) prior optimised asthma drug therapy (date of commencement and duration of therapy); and</p> <p>(b) IgE, blood eosinophils or fractional exhaled nitrous oxide results and date from prior to initiating non-PBS-subsidised treatment with this drug; and</p> <p>(c) date of commencing non-PBS-subsidised treatment with this drug for this condition.</p> <p>(d) If applicable, maintenance oral corticosteroid dose; and</p> <p>(e) If applicable, the Asthma Control Questionnaire (ACQ-5) scores, including the date of assessment of the patient's symptoms; or</p> <p>(f) If applicable, the Asthma Control Questionnaire interviewer administered version (ACQ-IA) scores, including the date of assessment of the patient's symptoms.</p>	
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[26] Schedule 3, entry for Infliximab

(a) *omit:*

	C9668		<p>Moderate to severe Crohn disease</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND</p> <p>Patient must have a total PCDAI score of 30 points or less; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9668</p>
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			<p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The PCDAI assessment must be no more than 1 month old at the time of prescribing.</p> <p>The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.</p> <p>Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	
	C9669		<p>Moderate to severe Crohn disease</p> <p>Balance of supply for paediatric patient</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.</p>	Compliance with Authority Required procedures

(b) omit:

	C9719		<p>Moderate to severe Crohn disease</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p>	Compliance with Written Authority Required procedures
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		<p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND</p> <p>Patient must have a total PCDAI score of 30 points or less; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.</p> <p>The PCDAI assessment must be no more than 1 month old at the time of application.</p> <p>Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
	C9721	<p>Moderate to severe Crohn disease</p> <p>First continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND</p> <p>Patient must have a total PCDAI score of 30 points or less; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.</p> <p>The PCDAI assessment must be no more than 1 month old at the time of application.</p> <p>The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.</p> <p>Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
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(c) omit:

	C9751	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include:</p>	Compliance with Written Authority Required procedures
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		<p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and</p> <p>(ii) details of prior biological medicine treatment including details of date and duration of treatment.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.</p> <p>If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
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(d) omit:

	C9775	<p>Moderate to severe Crohn disease</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9775</p>
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		<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND</p> <p>Patient must have a total PCDAI score of 30 points or less; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The PCDAI assessment must be no more than 1 month old at the time of prescribing.</p> <p>The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.</p> <p>Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	
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(e) omit:

	C13691	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p>	Compliance with Written Authority Required procedures
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			<p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
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(f) omit:

	C13702		<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR</p> <p>Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine,</p>	Compliance with Authority Required procedures
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			<p>6-mercaptopurine and methotrexate; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and</p> <p>(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.</p> <p>The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
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(g) insert in numerical order after existing text:

	C17097	<p>Moderate to severe Crohn disease</p> <p>Balance of supply for paediatric patient</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p>	Compliance with Authority Required procedures
	C17111	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR</p>	Compliance with Written Authority Required procedures

		<p>Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; OR</p> <p>Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:</p> <p>(1) details of the proposed prescription(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia</p>	
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		<p>website.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>An assessment of a patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C17112	<p>Moderate to severe Crohn disease</p> <p>First continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; OR</p> <p>Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The authority application must be made via the Online PBS Authorities System, or in writing via</p>	Compliance with Written Authority Required procedures

			<p>HPOS form upload or mail and must include:</p> <p>(1) details of the proposed prescription(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The assessment of response must be no more than 4 weeks old at the time of application.</p> <p>The application for first continuing treatment with this drug must be accompanied with the assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
	C17115		<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:</p> <p>(1) details of the proposed prescription(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Services Australia no later than 4 weeks from the date that course was ceased.</p> <p>If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>An assessment of a patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C17116	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic</p>	Compliance with Written Authority Required procedures

		<p>and/or imaging features including histological evidence; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; OR</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease that is no more than 4 weeks old at the time of application; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:</p> <p>(1) details of the proposed prescription(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>An assessment of a patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a</p>	
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			<p>response to be demonstrated.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C17117		<p>Moderate to severe Crohn disease</p> <p>Subsequent continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; OR</p> <p>Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The assessment of response must be no more than 4 weeks old at the time of prescribing.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17117</p>
	C17120		<p>Moderate to severe Crohn disease</p> <p>Subsequent continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17120</p>

		<p>Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; OR</p> <p>Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The assessment of response must be no more than 4 weeks old at the time of prescribing.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	
	C17122	<p>Moderate to severe Crohn disease</p> <p>Subsequent continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; OR</p> <p>Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:</p> <p>(1) details of the proposed prescription(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The assessment of response must be no more than 4 weeks old at the time of application.</p> <p>Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who:</p> <p>(i) received fewer than 2 repeats at the time of application; and/or</p> <p>(ii) required changes to their dosing regimen during this treatment phase.</p>	
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[27] Schedule 3, entry for Ivacaftor

insert in numerical order after existing text:

	C16928	<p>Cystic fibrosis</p> <p>Initial treatment - New patient (gating mutations)</p> <p>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,</p>	Compliance with Written Authority Required procedures
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		<p>management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR</p> <p>Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 1 month or older.</p> <p>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.</p> <p>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.</p> <p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:</p> <p>(1) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (a) the specific CFTR mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) details of the proposed prescription; and</p> <p>(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C16971	Cystic fibrosis	Compliance with Written Authority Required

		<p>Initial treatment - New patient (non-gating mutations)</p> <p>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</p> <p>Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data; AND</p> <p>Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 1 month or older.</p> <p>For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.</p> <p>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.</p> <p>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.</p> <p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:</p> <p>(1) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA-approved Product Information. Quote each of the: (a) the specific mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	procedures
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			<p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) details of the proposed prescription; and</p> <p>(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
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[28] Schedule 3, entry for Omalizumab

(a) *omit:*

	C15352	<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to omalizumab treatment is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA 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 or ACQ-IA score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.</p> <p>At the time of the authority application, medical practitioners should request the appropriate</p>	Compliance with Authority Required procedures
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			<p>quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
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(b) omit:

	C15403		<p>Uncontrolled severe allergic asthma</p> <p>Balance of supply in a patient aged 6 to 12 years</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.</p>	Compliance with Authority Required procedures
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(c) omit:

	C16879		<p>Uncontrolled severe allergic asthma</p> <p>Initial treatment</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either: a (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p>	Compliance with Written Authority Required procedures
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			<p>Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to less than 12 years.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must be under the care of the same physician for at least 6 months.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;</p> <p>AND</p> <p>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in 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.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),</p> <p>AND</p> <p>(b) while receiving optimised asthma therapy in the previous 12 months, 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>The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that</p>	
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		<p>there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.</p> <p>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and</p> <p>(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(c) the IgE result and date; and</p> <p>(d) Asthma Control Questionnaire (ACQ-5) score; or</p> <p>(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p>	
	C16904	<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to omalizumab treatment is defined as:</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 16904</p>

			<p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA 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 or ACQ-IA score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
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(d) omit:

	C16948		<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of severe allergic asthma; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 16948</p>
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			<p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to omalizumab treatment is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA 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 or ACQ-IA score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of</p>	
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			application.	
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(e) insert in numerical order after existing text:

	C17012		<p>Uncontrolled severe allergic asthma</p> <p>Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment - Balance of Supply in a patient aged 6 to 12 years</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 28 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 28 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial 1 and Initial 2 restriction; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing restriction.</p>	Compliance with Authority Required procedures
	C17049		<p>Uncontrolled severe allergic asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to less than 12 years.</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must be under the care of the same physician for at least 6 months.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 24 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date of 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>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
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			<p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) the IgE result and date; and</p> <p>(b) Asthma Control Questionnaire (ACQ-5) score; or</p> <p>(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p> <p>(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
	C17075		<p>Uncontrolled severe allergic asthma</p> <p>Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR</p> <p>Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to less than 12 years.</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for either: (i) severe asthma, (ii) severe allergic asthma.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p>	Compliance with Written Authority Required procedures

			<p>Patient must be under the care of the same physician for at least 6 months.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;</p> <p>AND</p> <p>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in 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.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),</p> <p>AND</p> <p>(b) while receiving optimised asthma therapy in the previous 12 months, 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>The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p> <p>A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine 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 2 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</p>	
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		<p>PBS-subsidised biological medicine was administered until the date of the first application for commencement of treatment with a biological medicine under the new treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and</p> <p>(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(c) the IgE result and date; and</p> <p>(d) Asthma Control Questionnaire (ACQ-5) score; or</p> <p>(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p>	
	C17084	<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17084</p>

		<p>baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p> <p>A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.</p> <p>At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
	C17085	<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii)</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17085</p>

			<p>clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p> <p>A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.</p> <p>At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
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	C17086	<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p> <p>A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.</p> <p>At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p>	Compliance with Authority Required procedures
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			<p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
	C17096		<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17096</p>

		<p>A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.</p> <p>At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
	C17102	<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p> <p>Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) 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 Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17102</p>

			<p>version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.</p> <p>A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.</p> <p>At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
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[29] Schedule 3, entry for Patisiran

omit:

	C15478		<p>Hereditary transthyretin amyloidosis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received treatment with this drug for this condition prior to 1 August 2024; AND</p> <p>Patient must continue to demonstrate clinical benefit; AND</p> <p>Patient must not be permanently bedridden; OR</p> <p>Patient must not be receiving end-of-life care.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p>	Compliance with Written Authority Required procedures
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			<p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) details of the proposed prescription; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
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[30] Schedule 3, entry for Peginterferon alfa-2a

substitute:

Peginterferon alfa-2a	C17022		<p>Chronic hepatitis C infection</p> <p>Must be treated in an accredited treatment centre.</p> <p>Patient must be at least 18 years of age; AND</p> <p>Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.</p> <p>Patient must have compensated liver disease; AND</p> <p>Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND</p> <p>Patient must have a contraindication to ribavirin; AND</p> <p>The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND</p> <p>The treatment must be limited to a maximum duration of 48 weeks.</p> <p>Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17022</p>
	C17108		<p>Chronic hepatitis C infection</p> <p>Must be treated in an accredited treatment centre.</p> <p>Patient must be at least 18 years of age; AND</p> <p>Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.</p> <p>Patient must have compensated liver disease; AND</p> <p>Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND</p> <p>Patient must have a contraindication to ribavirin; AND</p> <p>The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 17108</p>

			<p>The treatment must be limited to a maximum duration of 48 weeks.</p> <p>Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.</p>	
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[31] Schedule 3, entry for Ravulizumab

(a) *omit:*

	C16400		<p>Neuromyelitis optica spectrum disorder (NMOSD)</p> <p>Initial treatment - loading dose</p> <p>Patient must have a confirmed diagnosis of NMOSD with aquaporin-4 immunoglobulin G auto-antibody (AQP4-IgG); AND</p> <p>Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7; AND</p> <p>Patient must have had at least one relapse in the last 12 months; AND</p> <p>Patient must have experienced the most recent relapse while receiving treatment with rituximab; OR</p> <p>Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR</p> <p>Patient must have a documented contraindication to rituximab therapy; AND</p> <p>Patient must not receive more than 2 weeks of treatment under this restriction.</p> <p>Must be treated by a neurologist; OR</p> <p>Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for a single loading dose for induction therapy, according to the specified dosage in the approved Product Information (PI). Refer to the approved PI for patient weight ranges for the 100 mg/mL doses (consisting of 300 mg in 3 mL and 1.1 g in 11 mL vials).</p> <p>An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.</p> <p>Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.</p> <p>The authority application must be in writing and must include all of the following:</p> <p>(1) details of the proposed authority prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:</p> <p>(i) the patient's Expanded Disability Status Scale (EDSS) score; and</p> <p>(ii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy),</p>	<p>Compliance with Written Authority Required procedures</p>
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			or details of contraindications or developed intolerances necessitating treatment withdrawal. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
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(b) *insert in numerical order after existing text:*

	C17055		<p>Neuromyelitis optica spectrum disorder (NMOSD)</p> <p>Initial treatment - loading dose</p> <p>Patient must have a confirmed diagnosis of NMOSD with aquaporin-4 immunoglobulin G auto-antibody (AQP4-IgG); AND</p> <p>Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7; AND</p> <p>Patient must have experienced at least one relapse in the last 12 months while receiving treatment with rituximab; OR</p> <p>Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR</p> <p>Patient must have a documented contraindication to rituximab therapy; AND</p> <p>Patient must not receive more than 2 weeks of treatment under this restriction.</p> <p>Must be treated by a neurologist; OR</p> <p>Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for a single loading dose for induction therapy, according to the specified dosage in the approved Product Information (PI). Refer to the approved PI for patient weight ranges for the 100 mg/mL doses (consisting of 300 mg in 3 mL and 1.1 g in 11 mL vials).</p> <p>An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.</p> <p>Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.</p> <p>The authority application must be in writing and must include all of the following:</p> <p>(1) details of the proposed authority prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:</p> <p>(i) the patient's Expanded Disability Status Scale (EDSS) score; and</p> <p>(ii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	Compliance with Written Authority Required procedures
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