PB 126 of 2025

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (November 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 October 2025

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

Contents

1. Name

(1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (November Update) Instrument 2025*.

(2) This Instrument may also be cited as PB 126 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 November 2025	1 November 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Eculizumab

(a) omit from the column headed "Circumstances": C13458 C13459 C13464 C13560 C13660 C13661 C13684 C13845 C13857

(b) insert in numerical order in the column headed "Circumstances": C17424 C17427 C17428 C17430 C17467 C17468 C17472 C17492 C17574

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

insert:

	Ixifi	C4524 C7777 C8296 C8844 C8881 C8883 C8940 C8941 C8962 C9065 C9067 C9068 C9111 C9188 C9472 C9559 C9584 C9602 C9632 C9677 C9732 C9754 C9779 C9783 C9787 C9803 C11158 C12003 C12025 C12042 C12043 C12049 C12051 C12059 C12063 C12069 C12074 C12313 C13518 C13526 C13584 C13586 C13587 C13639 C13640 C13641 C13692 C13719 C14359 C14360 C14502 C14504 C14505 C14507 C14544 C14546 C14547 C14548 C14585 C14597 C14615 C14623 C14638 C14667 C14683 C14689 C14701 C14705 C14707 C14716 C14718 C14723 C14724 C14737 C17097 C17111 C17112 C17115 C17116 C17117 C17120 C17122	See Schedule 2	See Schedule 2

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

insert:

	Remsima	C4524 C7777 C8296 C8844 C8881 C8883 C8940 C8941 C8962 C9065 C9067 C9068 C9111 C9188 C9472 C9559 C9584 C9602 C9632 C9677 C9732 C9754 C9779 C9783 C9787 C9803 C11158 C12003 C12025 C12042 C12043 C12049 C12051 C12059 C12063 C12069 C12074 C12313 C13518 C13526 C13584 C13586 C13587 C13639 C13640 C13641 C13692 C13719 C14359 C14360 C14502 C14504 C14505 C14507 C14544 C14546 C14547 C14548 C14585 C14597 C14615 C14623 C14638 C14667 C14683 C14689 C14701 C14705 C14707 C14716 C14718 C14723 C14724 C14737 C17097 C17111 C17112 C17115 C17116 C17117 C17120 C17122	See Schedule 2	See Schedule 2

[4] Schedule 1, entry for Lenalidomide in the form Capsule 5 mg

insert in numerical order in the column headed "Circumstances" (all instances): C17414

[5] Schedule 1, entry for Lenalidomide in the form Capsule 10 mg

insert in numerical order in the column headed "Circumstances" (all instances): C17414

[6] Schedule 1, entry for Lenalidomide in the form Capsule 15 mg

insert in numerical order in the column headed "Circumstances" (all instances): C17414

[7] Schedule 1, entry for Lenalidomide in the form Capsule 20 mg

insert in numerical order in the column headed "Circumstances" (all instances): C17414

[8] Schedule 1, entry for Lenalidomide in the form Capsule 25 mg

insert in numerical order in the column headed "Circumstances" (all instances): C17414

[9] **Schedule 1, entry for Pegcetacoplan**

omit from the column headed "Circumstances": C13616 C13655 C13710 C13743 *substitute:* C17496 C17497 C17527 C17565

[10] **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":* C13459 C14476 C14477 C14530 C14531 C14565 C14586

(b) *insert in numerical order in the column headed "Circumstances":* C17415 C17420 C17423 C17463 C17464 C17469 C17493

[11] **Schedule 2, entry for Eculizumab *[Maximum quantity: 1; Maximum repeats: 0]***

omit from the column headed "Circumstances": C13857 *substitute:* C17430

[12] **Schedule 2, entry for Eculizumab *[Maximum quantity: 6; Maximum repeats: 5]***

omit from the column headed "Circumstances": C13464 C13660 C13661 C13684 C13845 *substitute:* C17424 C17427 C17428 C17472 C17574

[13] **Schedule 2, entry for Eculizumab *[Maximum quantity: 8; Maximum repeats: 0]***

omit from the column headed "Circumstances": C13458 C13459 C13560 *substitute:* C17467 C17468 C17492

[14] **Schedule 2, entry for Lenalidomide *[Maximum quantity: 21 tablets; Maximum repeats: 2]***

insert in numerical order in the column headed "Circumstances": C17414

[15] **Schedule 2, entry for Pegcetacoplan *[Maximum quantity: Sufficient for treatment for 4 weeks; Maximum repeats: 0]***

omit from the column headed "Circumstances": C13655 C13710 *substitute:* C17527 C17565

[16] **Schedule 2, entry for Pegcetacoplan *[Maximum quantity: Sufficient for treatment for 4 weeks; Maximum repeats: 5]***

omit from the column headed "Circumstances": C13616 C13743 *substitute:* C17496 C17497

[17] **Schedule 2, entry for Ravulizumab *[Maximum quantity: 1 dose; Maximum repeats: 0]***

(a) *omit from the column headed "Circumstances":* C13459 C14477 C14565 C14586

(b) *insert in numerical order in the column headed "Circumstances":* C17420 C17423 C17469 C17493

[18] **Schedule 2, entry for Ravulizumab *[Maximum quantity: 1 dose; Maximum repeats: 2]***

(a) *omit from the column headed "Circumstances":* C14476 C14530 C14531

(b) *insert in numerical order in the column headed "Circumstances":* C17415 C17463 C17464

[19] Schedule 3, entry for Dupilumab

(a) omit entry for Circumstances Code C17016 and substitute:

C17016	Uncontrolled severe asthma Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; OR 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 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 Patient must have a duration of asthma of at least 1 year; AND 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 Patient must have blood eosinophil count of at least 150 cells per microlitre in the last 12 months; OR Patient must have a fractional exhaled nitric oxide of at least 20 ppb in the last 12 months; AND 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 Patient must not receive more than 32 weeks of treatment under this restriction; AND Patient must be under the care of the same physician for at least 6 months; AND 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. 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. Optimised asthma therapy includes: (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	Compliance with Written Authority Required procedures

Authorised Version F2025L01318 registered 31/10/2025

	used as an alternative; AND (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. 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. The initial IgE assessment, blood eosinophil count or fractional exhaled nitric oxide measurement must be no more than 12 months old at the time of application. The following initiation criteria indicate failure to achieve adequate control 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 in the previous month (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 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. 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. 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. 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. 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. 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.

	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. The authority application must be made in writing and must include: (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). The following must be provided at the time of application and documented in the patient's medical records: (a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (c) the IgE, blood eosinophil or the fractional exhaled nitric oxide result and date; and (d) Asthma Control Questionnaire (ACQ-5) score; or (e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.	

(b) omit entry for Circumstances Code C17072 and substitute:

C17072	Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) 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 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 Patient must have had a fractional exhaled nitric 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 Patient must not receive more than 32 weeks of treatment under this restriction; AND Patient must be under the care of the same physician for at least 6 months; AND 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 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 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	Compliance with Written Authority Required procedures

Authorised Version F2025L01318 registered 31/10/2025

	asthma. 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 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. 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. 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. 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. 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. 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. 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. The authority application must be made in writing and must include: (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). The following must be provided at the time of application and documented in the patient's medical records: (a) the IgE, blood eosinophil or fractional exhaled nitric oxide result and date; and (b) Asthma Control Questionnaire (ACQ-5) score; or (c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. (d) the details of prior biological medicine treatment including the details of date and duration of treatment; and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	

(c) omit entry for Circumstances Code C17113 and substitute:

C17113	Uncontrolled severe asthma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2025; AND 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: (i) forced expiratory volume (FEV1) reversibility, (ii) airway hyperresponsiveness, (iii) peak expiratory flow (PEF) variability; AND 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 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 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 Patient must have had a fractional exhaled nitric 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 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 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	Compliance with Written Authority Required procedures

	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 have been aged 6 to less than 12 years prior to starting non-PBS-subsidised treatment with this drug. Optimised asthma therapy includes: (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; AND (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. 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. An adequate response to this biological medicine is defined as: (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 (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 (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline. 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. 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 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. 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. 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. 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. 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. 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. The authority application must be made in writing and must include: (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). The following must be provided at the time of application and documented in the patient's medical records: (a) prior optimised asthma drug therapy (date of commencement and duration of therapy); and (b) IgE, blood eosinophils or fractional exhaled nitric oxide results and date from prior to initiating non-PBS-subsidised treatment with this drug; and (c) date of commencing non-PBS-subsidised treatment with this drug for this condition. (d) If applicable, maintenance oral corticosteroid dose; and (e) If applicable, the Asthma Control Questionnaire (ACQ-5) scores, including the date of

		assessment of the patient's symptoms; or (f) If applicable, the Asthma Control Questionnaire interviewer administered version (ACQ-IA) scores, including the date of assessment of the patient's symptoms.	

[20] Schedule 3, entry for Eculizumab

(a) omit:

	C13458	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses) Patient must be planning pregnancy; OR Patient must be pregnant; AND Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND The treatment must not be in combination with any of (i) ravulizumab, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.	Compliance with Written Authority Required procedures
	C13459	Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised pegcetacoplan - induction doses Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND Patient must have developed resistance or intolerance to pegcetacoplan; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed	Compliance with Written Authority Required procedures

Authorised Version F2025L01318 registered 31/10/2025

	under the 'Subsequent Continuing Treatment' criteria.	
C13464	Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, details (result and date of result) of the following	Compliance with Written Authority Required procedures

	monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C13560	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - initial 1 (new patient) induction doses Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, details (result and date of result) of the following	Compliance with Written Authority Required procedures

	monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C13660	Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 2 (transition from LSDP-funded eculizumab) Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii)	Compliance with Written Authority Required procedures

	pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C13661	Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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).	Compliance with Written Authority Required procedures
C13684	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy) Patient must be planning pregnancy; OR Patient must be pregnant; AND Patient must have received PBS-subsidised treatment with ravulizumab for this condition; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR	Compliance with Written Authority Required procedures

	Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.	
C13845	Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	Compliance with Written Authority Required procedures
C13857	Paroxysmal nocturnal haemoglobinuria (PNH) Balance of Supply (transition from non-PBS-subsidised treatment during induction phase) Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have received insufficient quantity to complete the induction treatment phase; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND	Compliance with Written Authority Required procedures

	Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)

(b) insert in numerical order after existing text:

C17424	Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 2 (transition from LSDP-funded eculizumab) Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.	Compliance with Written Authority Required procedures

Authorised Version F2025L01318 registered 31/10/2025

	The authority application must be made in writing and must include: (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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C17427	Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition	Compliance with Written Authority Required procedures

	to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C17428	Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this	Compliance with Written Authority Required procedures

	drug; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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).	
C17430	Paroxysmal nocturnal haemoglobinuria (PNH) Balance of Supply (transition from non-PBS-subsidised treatment during induction phase) Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have received insufficient quantity to complete the induction treatment phase; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic	Compliance with Written Authority Required procedures

	analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	
C17467	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan or iptacopan for pregnancy (induction doses) Patient must be planning pregnancy; OR Patient must be pregnant; AND Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

Authorised Version F2025L01318 registered 31/10/2025

	(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). Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.	
C17468	Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised pegcetacoplan or iptacopan - induction doses Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition; AND Patient must have developed resistance or intolerance to either: (i) pegcetacoplan, (ii) iptacopan; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the'Subsequent Continuing Treatment' criteria.	Compliance with Written Authority Required procedures
C17472	Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the	Compliance with Written Authority Required procedures

Authorised Version F2025L01318 registered 31/10/2025

	latest version is located on the website specified in the Administrative Advice). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	
C17492	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - initial 1 (new patient) induction doses Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND	Compliance with Written Authority Required procedures

	The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C17574	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy) Patient must be planning pregnancy; OR Patient must be pregnant; AND Patient must have received PBS-subsidised treatment with ravulizumab for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under	Compliance with Written Authority Required procedures

		the 'Subsequent Continuing Treatment' criteria.	

[21] Schedule 3, entry for Lenalidomide

insert in numerical order after existing text:

	C17414	Untreated multiple myeloma Triple combination therapy consisting of daratumumab, lenalidomide and dexamethasone Patient must be undergoing concurrent treatment with daratumumab obtained through the PBS for the treatment of transplant ineligible, newly diagnosed multiple myeloma; AND Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.	Compliance with Authority Required procedures

[22] Schedule 3, entry for Pegcetacoplan

substitute:

Pegcetacoplan	C17496	Paroxysmal nocturnal haemoglobinuria (PNH) First continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L)	Compliance with Written Authority Required procedures

	(iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	
C17497	Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.	Compliance with Written Authority Required procedures
C17527	Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised eculizumab post pregnancy or from one of the PBS-subsidised therapies for this condition, for reasons other than post pregnancy Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan or iptacopan for pregnancy (induction doses)' criteria; OR Patient must have received prior PBS-subsidised treatment with at least one drug listed for this condition and must be returning to pegcetacoplan treatment for reasons other than post pregnancy; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR	Compliance with Written Authority Required procedures

	Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.	
C17565	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment (new patient) Patient must not have received prior treatment with this drug for this condition; AND Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months; AND Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor	Compliance with Written Authority Required procedures

	demonstrated by a haemoglobin level of less than 105 g/L; OR Patient must be intolerant to C5 inhibitors as determined by the treating physician; AND Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred; AND The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	

[23] Schedule 3, entry for Ravulizumab

(a) omit:

C13459	Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised pegcetacoplan - induction doses Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition;	Compliance with Written Authority Required procedures

	AND Patient must have developed resistance or intolerance to pegcetacoplan; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.	
C14476	Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.	Compliance with Written Authority Required procedures
C14477	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 1 (new patient) induction dose Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR	Compliance with Written Authority Required procedures

	Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C14530	Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather (transition from non-PBS-subsidised treatment) Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab; AND	Compliance with Written Authority Required procedures

	Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab; AND Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH)

	(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C14531	Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	Compliance with Written Authority Required procedures
C14565	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR	Compliance with Written Authority Required procedures

	Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C14586	Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised eculizumab - induction dose Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria; AND	Compliance with Written Authority Required procedures

	The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.	

(b) insert in numerical order after existing text:

C17415	Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L)	Compliance with Written Authority Required procedures

	(vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	
C17420	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.	Compliance with Written Authority Required procedures

	The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C17423	Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 1 (new patient) induction dose Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial	Compliance with Written Authority Required procedures

	hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C17463	Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather (transition from non-PBS-subsidised treatment) Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of	Compliance with Written Authority Required procedures

	normal prior to commencing treatment with ravulizumab; AND Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m2, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L)

	(iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C17464	Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.	Compliance with Written Authority Required procedures
C17469	Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised eculizumab - induction dose Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) details of the proposed prescription; and	Compliance with Written Authority Required procedures

	(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). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.	
C17493	Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised pegcetacoplan or iptacopan - induction dose Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition; AND Patient must have developed resistance or intolerance to either: (i) pegcetacoplan, (ii) iptacopan; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (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). For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the'Subsequent Continuing Treatment' criteria.	Compliance with Written Authority Required procedures