7.04 PEGCETACOPLAN, Solution for subcutaneous infusion 1,080 mg in 20mL, Empaveli®, Swedish Orphan Biovitrum Pty Ltd.

1 Purpose

1.1 The early re-entry resubmission sought the PBS listing of pegcetacoplan for the treatment of complement 3 glomerulopathy (C3G) and primary-immune complex membranoproliferative glomerulonephritis (IC-MPGN).

1.2 The resubmission was based on the PBAC decision to not recommend pegcetacoplan for this indication at its March 2026 meeting. This resubmission addressed some of the issues raised by PBAC; see table below.

Table 1: Summary of key matters to be addressed

Matter of concern	Response	Addressed?
Revisions to the proposed listing (para 7.5)		
Additional eligibility criteria for post-transplant patients should be revised such that eligibility requires biopsy-proven disease recurrence.	The submission proposed separate listings for post-transplant patients, requiring confirmation of recurrence of primary C3G or PIC-MPGN established by kidney biopsy.	Y
Addition of a criterion requiring patients to have proteinuria ≥1.0 g/day under the initial treatment restriction, consistent with the trial population.	This criterion was added to the proposed initial treatment restrictions and the grandfather restrictions.	Y
Addition of a treatment criterion requiring continued use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2), consistent with clinical guidelines and with the trial population.	This criterion was added to the proposed initial, continuing, and grandfather restrictions.	Y
The first continuing restriction should specify that patients must demonstrate evidence of improvement or stabilisation of disease defined as a ≥50% reduction in FMU UPCR or a ≤15% decrease in eGFR from baseline after 16 weeks of treatment. For subsequent continuing restrictions demonstration of improvement or stabilisation of disease based on clinician judgement would be appropriate, given the progressive nature of C3G and primary IC-MPGN.	The proposed continuing restrictions included criteria requiring a clinical improvement or stabilisation of the condition. The proposed restrictions no longer included a separate first continuing listing and there was no definition of improvement/stabilisation for assessment at 16 weeks included in the proposed restrictions.	N
Economic evaluation		
A substantial reduction in the cost of pegcetacoplan would be required for pegcetacoplan to be considered cost-effective (para 7.12).	The resubmission proposed a [redacted]% price reduction from the previous submission (from $[redacted] to $[redacted] ex-man).	-

Matter of concern	Response	Addressed?
A simplified cost-effectiveness analysis including cost per responder analyses with interpretation of the ratio(s) provided (para 7.13)	The resubmission presented a cost per responder and stepped economic evaluation with a one-year time horizon. Response was defined as the achievement of ≥50% reduction in uPCR compared to baseline. Additional analyses included cost offsets from dialysis and kidney transplants avoided. The cost per patient per year in the resubmission was $[redacted][1] per responder in year 1, which decreased in subsequent years to $[redacted][1] for responders only and $[redacted][1] per year if adjusted for reduction in dialysis and transplant costs.	Y
Financial estimates		
The PBAC agreed with the Sub-Committees that a combined prevalence and incidence approach would be more appropriate to capture initiation and continuation of treatment. The PBAC considered that the adjustments of the prevalent patient numbers to account for diagnosis rates and patients with subclinical disease were not reasonable as prevalence rates would already account for these factors. The PBAC considered that the proportion of patients assumed to be ineligible due to stage 5 CKD was uncertain and should be revised …, and that the proportion of patients who require treatment following a kidney transplant should also be explicitly considered (para 7.14)	The resubmission presented revised financial estimates using a combined prevalence and incidence approach with changes to eligibility, and with treatment discontinuation and adherence modelled transparently.	Y
RSA		
Proposal of an RSA to address the risk of use in a much larger population than expected, or for longer than expected and in the context of highly uncertain cost-effectiveness for pegcetacoplan (para 7.15).	The submission proposed a tiered RSA informed by updated prevalence estimates with reimbursement of [redacted]% above Tier 1, [redacted]% above Tier 2 (midpoint) and [redacted]% above Tier 3. The submission predicted that if all Tier 3 caps were met in the proposed RSA, the total cost of pegcetacoplan could be reduced by an additional [redacted]% over the forward estimates.	Y

Source: Sections 1.4, 3 and Section 4 of the of the resubmission
The redacted values correspond to the following ranges:
[1] $155,000 to < $255,000

2 Background

2.1 Pegcetacoplan (Empaveli®) was TGA registered on 19 December 2025 for the treatment of adults and adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerunephritis (IC-MPGN). The PICO from the resubmission is presented below.

Table 2: Key components of the clinical issue addressed by the submission (as stated in the submission and resubmission)

Component	Description
Population	Patients aged ≥12 years with C3G or primary IC-MPGN with native kidneys or disease recurrence following a kidney transplant
Intervention	Pegcetacoplan 1,080 mg in 20 mL twice weekly subcutaneous infusion for adults and adolescents with ≥50 kg body weight. Weight-based dosing is recommended in adolescents with <50 kg body weight [a]
Comparator	Main comparator: standard of care consisting of RAAS blockade (ACEI/ARB), SGLT2i and lifestyle measures, with or without immunosuppressive therapies (corticosteroids, mycophenolate mofetil) Near market comparator: iptacopan 200 mg orally twice daily
Outcomes	Clinically meaningful reduction in proteinuria (≥50%) with improvement (or stabilisation) of renal function, as measured by eGFR
Clinical claim	In adolescent and adult patients (≥ 12 years) with C3G or pIC-MPGN, pegcetacoplan is superior to best supportive care in terms of effectiveness and non-inferior but manageable in terms of safety

Source: Table 1, p15 of the submission, Table 1.1 of the resubmission
Abbreviations: ACEI/ARB, angiotensin converting enzyme inhibitor or angiotensin receptor blocker; C3G, complement 3 glomerulopathy; eGFR, estimated glomerular filtration rate; IC-MPGN, immune-complex membranoproliferative glomerulonephritis; RAAS, renin-angiotensin-aldosterone-system; SGLT2i, sodium glucose co-transporter 2 inhibitor
[a] Adolescents with 35 to <50 kg body weight: twice weekly starting with a first dose of 648 mg then 810 mg subsequently; adolescents with 30 to <35 kg: twice weekly starting with 540 mg for the first two doses then 648 mg subsequently
Blue shading is used to indicate where text is unchanged from the March 2026 submission.

3 Requested listing

3.1 The resubmission stated that the sponsor incorporated advice from the PBAC and Secretariat from the March 2026 submission including the consolidation of First and Subsequent Continuing restrictions and separating the listings for native (transplant naïve) and transplanted kidney patients. Secretariat suggested additions are in italics and deletions are in strikethrough.

Transplant naive patients

Initial/Grandfather treatment phase:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
PEGCETACOPLAN					
Pegcetacoplan 1.08 g/20 mL injection; 20 mL vial	NEW (Public) NEW (Private)	8	8	3	Empaveli
Concept ID	**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – *Public/Private* (Code HB)				
	Prescriber type: ☒ Medical Practitioners				
	Benefit type: ☒ Authority Required (FULL assessment) in writing only via OPA/post/HPOS upload)				
	Authority type: ☒ Complex Authority Required (CAR)				
	Prescribing rule level:				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Administrative Advice:				

	No increase in the maximum quantity or number of units may be authorised.
	Caution: This drug increases the risk of encapsulated bacterial infections. Consult the approved PI for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan
	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
	Administrative Advice: Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.
	Restriction Summary 1 / Treatment of Concept: 1A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: Initial treatment – *transplant naive patients*
	Clinical criteria:
	Patient must not have received prior treatment with this drug for this condition
	AND
	Clinical criteria:
	Treatment must not be in combination with a ~~Complement inhibitor~~ *Complement 5 (C5) inhibitor for this condition*
	AND
	Clinical criteria:
	Patient must have a confirmed diagnosis of primary C3G or pIC-MPGN established by kidney biopsy
	AND
	Clinical criteria:
	Patient must have *abnormal* proteinuria (uPCR) ≥ *1000mg/*~~day~~ *24 hours*
	AND
	Clinical criteria:
	Patient must not have an eGFR less than 30 mL/min/1.73 m2
	AND
	Clinical criteria:
	Patient must not have received prior kidney transplant
	AND
	Clinical criteria:
	Patient must not be undergoing dialysis
	~~**AND**~~

	~~**Clinical criteria:**~~
	~~Patient must continue use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2)~~
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases; or
	Must be treated by a non-specialist medical physician who has consulted a nephrologist on the patient's drug treatment details.
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be aged 12 years and older
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	Prescribing Instructions: At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) uPCR (mg/g) (ii) eGFR (mL/min/1.73 m^2)
	Prescribing Instructions: *Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.*
	Prescribing Instructions: An outcome on the authority application is not immediate but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.
	Restriction Summary 2 / Treatment of Concept: 2A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment – Grandfather arrangement – *transplant naive patients*
	Clinical criteria:
	Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to [date of listing]
	AND
	Clinical criteria:
	Treatment must not be in combination with a ~~Complement inhibitor~~ *Complement 5 (C5) inhibitor) for this condition*
	~~**AND**~~
	~~**Clinical criteria:**~~
	~~Patient must not have received any treatment for this condition prior to commencing non-PBS-subsidised treatment with this drug~~
	AND
	Clinical criteria:
	Patient must have a confirmed diagnosis of primary C3G or pIC-MPGN established by kidney biopsy
	AND

	Clinical criteria:
	Patient must not have received prior kidney transplant
	AND
	Clinical criteria:
	Patient must not have an eGFR less than 30 mL/min/1.73 m2 prior to commencing non-PBS subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	Patient must not be undergoing dialysis
	AND
	Clinical criteria:
	Patient must have had abnormal proteinuria (uPCR) ≥ 1000mg/day 24 hours prior to commencing non-PBS subsidised treatment with this drug for this condition
	~~Patient must have experienced a clinical improvement as a result of treatment with this drug~~
	~~**AND**~~
	~~**Clinical criteria:**~~
	~~Patient must continue use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2)~~
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases; or
	Must be treated by a non-specialist medical physician who has consulted a nephrologist on the patient's drug treatment details.
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be aged 12 years and older
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	Prescribing Instructions: At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) uPCR (mg/g) (ii) eGFR (mL/min/1.73 m^2)
	Prescribing Instructions: *Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.*
	Prescribing Instructions: An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.
	Administrative advice: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.
	Prescribing Instructions:

	A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Continuing treatment phase:

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PEGCETACOPLAN					
Pegcetacoplan 1.08 g/20 mL injection; 20 mL vial	NEW (Public) NEW (Private)	8	8	3	Empaveli

	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – *Public/Private* (Code HB)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (FULL assessment) in writing only via OPA/post/HPOS upload)
	Authority type: ☒ Complex Authority Required (CAR)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Caution: This drug increases the risk of encapsulated bacterial infections. Consult the approved PI for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan
	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
	Administrative Advice: Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan
	Restriction Summary 1 / Treatment of Concept: 1A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)

	Treatment Phase: Continuing treatment – *transplant naive patients*
	Clinical criteria:
	Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' *or* 'Grandfather' restriction
	AND
	Clinical criteria:
	Treatment must not be in combination with a ~~Complement inhibitor~~ *Complement 5 (C5) inhibitor) for this condition*
	~~**AND**~~
	~~**Clinical criteria:**~~
	~~Patient must continue use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2)~~
	AND
	Clinical criteria:
	Patient must not be undergoing dialysis
	AND
	Clinical criteria:
	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
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases; or
	Must be treated by a non-specialist medical physician who has consulted a nephrologist on the patient's drug treatment details.
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be aged 12 years and older
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	~~**Prescribing Instructions:**~~ ~~At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:~~ ~~(i) uPCR (mg/g)~~ ~~(ii) eGFR (mL/min/1.73 m^2)~~
	Prescribing Instructions: *Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.*
	Prescribing Instructions: An outcome on the authority application is not immediate but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.

Post-transplant patients

Initial/Grandfather restrictions:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
PEGCETACOPLAN					
Pegcetacoplan 1.08 g/20 mL injection; 20 mL vial	NEW (Public) NEW (Private)	8	8	3	Empaveli

	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – *Public/Private* (Code HB)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (FULL assessment) in writing only via OPA/post/HPOS upload)
	Authority type: ☒ Complex Authority Required (CAR)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Caution: This drug increases the risk of encapsulated bacterial infections. Consult the approved PI for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan
	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
	Administrative Advice: Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.
	Restriction Summary 1 / Treatment of Concept: 1A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: ~~Initial treatment~~ *Recommencement of treatment - post kidney transplant*
	~~**Clinical criteria:**~~
	~~Patient must not have received prior treatment with this drug for this condition~~
	~~**AND**~~
	Clinical criteria:

	Treatment must not be in combination with a ~~Complement inhibitor~~ *Complement 5 (C5) inhibitor) for this condition*
	AND
	Clinical criteria:
	Patient must have a confirmed diagnosis of primary C3G or pIC-MPGN *disease recurrence* established by a biopsy *in the transplanted kidney*
	AND
	Clinical criteria:
	Patient must not have an eGFR less than 30 mL/min/1.73 m2
	AND
	Clinical criteria:
	Patient must have *abnormal* proteinuria (uPCR) ≥ *1000mg/*~~day~~ *24 hours*
	AND
	Clinical criteria:
	Patient must not be undergoing dialysis
	~~**AND**~~
	~~**Clinical criteria:**~~
	~~Patient must continue use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2)~~
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases; or
	Must be treated by a non-specialist medical physician who has consulted a nephrologist on the patient's drug treatment details.
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be aged 12 years and older
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	Prescribing Instructions: *Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.*
	Prescribing Instructions: An outcome on the authority application is not immediate but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.
	Restriction Summary 2 / Treatment of Concept: 2A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment – Grandfather arrangement – *Post kidney transplant*
	Clinical criteria:
	Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to [date of listing]

	AND
	Clinical criteria:
	Treatment must not be in combination with a ~~Complement inhibitor~~ *Complement 5 (C5) inhibitor) for this condition*
	~~**AND**~~
	~~**Clinical criteria:**~~
	~~Patient must not have received any treatment for this condition prior to commencing non-PBS subsidised treatment with this drug~~
	AND
	Clinical criteria:
	Patient must have a confirmed diagnosis of primary C3G or pIC-MPGN *disease recurrence* established by a biopsy *in the transplanted kidney*
	AND
	Clinical criteria:
	Patient must not have an eGFR less than 30 mL/min/1.73 m2 prior to commencing non-PBS subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	Patient must not be undergoing dialysis
	AND
	Clinical criteria:
	Patient must have had abnormal proteinuria (uPCR) ≥ 1000mg~~/day~~ 24 hours prior to commencing non-PBS subsidised treatment with this drug for this condition
	~~Patient must have experienced a clinical improvement as a result of treatment with this drug~~
	~~**AND**~~
	~~**Clinical criteria:**~~
	~~Patient must continue use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2)~~
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases; or
	Must be treated by a non-specialist medical physician who has consulted a nephrologist on the patient's drug treatment details.
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be aged 12 years and older
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	Prescribing Instructions: At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) uPCR (mg/g) (ii) eGFR (mL/min/1.73 m^2)
	Prescribing Instructions:

	An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.
	Prescribing Instructions: *Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.*
	Administrative advice: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.
	Prescribing Instructions: A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Continuing treatment phase:

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PEGCETACOPLAN					
Pegcetacoplan 1.08 g/20 mL injection; 20 mL vial	NEW (Public) NEW (Private)	8	8	3	Empaveli

	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – *Public/Private* (Code HB)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (FULL assessment) in writing only via OPA/post/HPOS upload)
	Authority type: ☒ Complex Authority Required (CAR)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Caution: This drug increases the risk of encapsulated bacterial infections. Consult the approved PI for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan
	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826

	HOBART TAS 7001
	Administrative Advice: Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan
	Caution: This drug increases the risk of encapsulated bacterial infections. Consult the approved PI for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.
	Restriction Summary 1 / Treatment of Concept: 1A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: Continuing treatment – *Post kidney transplant*
	Clinical criteria:
	Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' *or* 'Grandfather' restriction
	AND
	Clinical criteria:
	Treatment must not be in combination with a ~~Complement inhibitor~~ *Complement 5 (C5) inhibitor) for this condition*
	~~**AND**~~
	~~**Clinical criteria:**~~
	~~Patient must continue use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2)~~
	AND
	Clinical criteria:
	Patient must not be undergoing dialysis
	AND
	Clinical criteria:
	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
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases; or
	Must be treated by a non-specialist medical physician who has consulted a nephrologist on the patient's drug treatment details.
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be aged 12 years and older
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	~~**Prescribing Instructions:**~~

	~~At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:~~ ~~(i) uPCR (mg/g)~~ ~~(ii) eGFR (mL/min/1.73 m^2)~~
	Prescribing Instructions: *Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.*
	Prescribing Instructions: An outcome on the authority application is not immediate but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.

3.2 The re-submission proposed a [redacted]% price reduction in the effective ex-man price compared with the previous submission (from $[redacted] to $[redacted] per vial). The DPMQ was reduced from $[redacted] to $[redacted] for public patients and from $[redacted] to $[redacted] for private patients[1].

3.3 To address the PBAC's advice that additional eligibility criteria for post-transplant patients should be revised such that eligibility requires biopsy-proven disease recurrence (paragraph 7.5, pegcetacoplan ratified minutes, March 2026 PBAC Meeting) the resubmission proposed initial, continuing, and grandfather restrictions for patients with prior kidney transplant, identical to the native kidney/transplant naïve listing above, with the exception of the following changes:

~~**AND**~~
~~**Clinical criteria:**~~
~~Patient must not have received prior kidney transplant~~
Clinical criteria:
Patient must have received prior kidney transplant
AND
Clinical criteria:
Patient must have confirmed recurrence of primary C3G or pIC-MPGN established by kidney biopsy

3.4 The resubmission included a criterion requiring patients to have proteinuria ≥1.0 g/day under the initial and grandfather treatment restrictions, consistent with the PBAC's advice (paragraph 7.5, pegcetacoplan ratified minutes, March 2026 PBAC Meeting).

3.5 The resubmission included a treatment criterion requiring continued use of supportive measures as appropriate (optimised use of ACEI/ARB +/- SGLT2), consistent with clinical guidelines and the with trial population, as advised by the PBAC (paragraph 7.5, pegcetacoplan ratified minutes, March 2026 PBAC Meeting). The Secretariat

[1] These prices reflect the economic evaluation. The requested effective DPMQ as reported in the resubmission main body (Table 1.6) was slightly different at $[redacted] (public) and $[redacted] (private).

proposed that this should be a prescribing instruction rather than a treatment criterion.

3.6 Following the advice of the Sub-Committees in March 2026, the resubmission revised the first and subsequent continuing restrictions, combining them into to a single continuing restriction. The resubmission also included a continuing restriction with a criterion for improvement or stabilisation of disease, which would be required after approximately 16 weeks of treatment as 3 repeats were proposed for the initial treatment phase. However, the restrictions did not include a definition of response/stabilisation as advised by the PBAC: a >50% reduction in FMU UPCR or a <15% decrease in eGFR from baseline after 16 weeks of treatment (paragraph 7.5, pegcetacoplan ratified minutes, March 2026 PBAC Meeting). Combining the first and subsequent continuing restrictions did not allow for assessment of improvement or stabilisation of disease based on clinician judgement in order for patients to progress under the subsequent continuing treatment (beyond 16 weeks), as advised by the PBAC (paragraph 7.5, pegcetacoplan ratified minutes, March 2026 PBAC Meeting). The pre-PBAC response indicated that if the continuing restriction is separated into first and subsequent continuing the sponsor was willing to amend the restrictions to incorporate the definition of response/stabilisation after 16 weeks.

3.7 The pre-PBAC response also proposed two changes to the proposed restrictions based on consultation with clinicians:

- That the first continuing restriction be amended to include: a ≥50% reduction in FMU UPCR **OR a reduction in FMU UPCR to <1g/g** OR a ≤ 15% decrease in eGFR from baseline after 16 weeks of treatment.
- For the population with recurrent disease post-biopsy the requirement for a minimum proteinuria level to initiate treatment should be removed. Clinicians have indicated that they would not typically wait for proteinuria to rise significantly before initiating treatment in transplanted patients, as histopathological recurrence alone may be considered sufficient. The sponsor stated this is to prevent avoidable damage to the graft in patients who have already demonstrated aggressive disease and progression to end-stage kidney disease in the past.

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer inputs

4.2 The PBAC recalled that input from individuals, healthcare professionals and organisations regarding the previous submission for pegcetacoplan had a strong

emphasis on the importance of early and equitable access to effective treatment for CG3 and IC-MPGN. Input noted that other treatments are limited to supportive measures which do not impact the underlying mechanism, and most patients progress to end-stage kidney disease (requiring dialysis or transplant) despite these therapies. The inputs noted that reducing the incidence of kidney failure can prevent physical, mental and emotional symptoms, prevent reduced quality of life and life participation as well as reduce carer burden and loss of income for patients and their families and carers. The inputs also noted that pegcetacoplan is well tolerated and acceptable to patients despite the requirement for subcutaneous administration.

4.3 The PBAC noted that no additional consumer inputs were received for this resubmission.

Clinical evidence

4.4 The PBAC previously considered that the claim of superior comparative effectiveness over standard of care was adequately supported by the data for the surrogate measure of reduction in proteinuria, for which there is strong biological plausibility for an impact on kidney disease, however, the magnitude of change in eGFR was less certain (paragraph 7.8, pegcetacoplan ratified minutes, March 2026 PBAC Meeting). The PBAC also considered the claim of non-inferior safety was not reasonable and a claim of inferior comparative safety would be appropriate (paragraph 7.9, pegcetacoplan ratified minutes, March 2026 PBAC Meeting).

4.5 As no further comparative evidence for pegcetacoplan versus standard of care was available, the resubmission did not present any new data as part of the clinical evaluation.

Economic Analysis

4.6 In March 2026, the PBAC considered that the model presented was complex, there were limited trial data to model disease progression, and the cost-effectiveness estimate should not be considered reliable. (paragraph 7.11, pegcetacoplan ratified minutes, March 2026 PBAC meeting). The PBAC considered that in addition to the high level of uncertainty in the modelled costs and outcomes, the very high ICERs from the submission model reflect the high price requested for pegcetacoplan and advised that a substantial price reduction would be required for pegcetacoplan to be considered cost-effective (paragraph 7.12, pegcetacoplan ratified minutes, March 2026 PBAC meeting).

4.7 On balance, the PBAC considered that, given the data to inform economic models for C3G or primary IC-MPGN are limited, the uncertainty in the ICER was unlikely to be adequately resolved with further revision to the economic model. In the context of a substantial price reduction, and noting the clinical need and available evidence, the PBAC considered the cost-effectiveness may be able to be assessed using a cost/responder approach. The PBAC considered that a cost per responder approach should provide interpretation, and quantification where possible, of the clinically

meaningful benefits that are expected to result from reduced proteinuria and potential reduction in decline in eGFR response, for example, avoiding or delaying dialysis and transplants (paragraph 7.13, pegcetacoplan ratified minutes, March 2026 PBAC meeting).

4.8 The resubmission proposed an effective ex-man price for pegcetacoplan of $[redacted] per 1080 mg vial (a [redacted]% reduction compared to the ex-man price proposed in the March 2026 submission, $[redacted] effective ex-man price per 1080 mg vial).

4.9 The early re-entry submission presented a stepped economic evaluation, including an incremental cost per responder approach comparing pegcetacoplan to standard of care over 12 months. Response was defined as a ≥50% reduction in uPCR compared to baseline, at 26 weeks. The resubmission argued that uPCR was the most appropriate endpoint for response because proteinuria reduction is a valid reflection of disease activity and surrogate for long-term kidney outcomes, and clinicians have indicated that it would be the primary outcome used in practice to assess response to treatment. The resubmission argued that eGFR was not appropriate for inclusion in assessment of response as the comparative period of VALIANT was likely too short to demonstrate a meaningful difference between groups.

4.10 The analysis presented in the resubmission also attempted to quantify changes in dialysis and kidney transplants arising from the reduction in proteinuria shown in VALIANT (as shown in Table 3). The approach to this was based on the following steps:

- An analysis of the UK National Registry of Rare Kidney Diseases (RaDaR, Masoud et al., 2025) found that reduction in uPCR of 50% from baseline to 1 year is associated with a 60% reduction in the risk of kidney failure (HR 0.40; 95% CI 0.23-0.69; p-value 0.001).
- The submission stated it is generally reported that approximately 50% of patients will progress to kidney failure within 10 years of diagnosis (O'Keeffe et al., 2024). This proportion was converted into an annual rate and the HR derived from RaDaR applied to estimate the reduced risk in annual progression to kidney failure (5% difference in annual risk) and to estimate cost savings from avoided dialysis.
- Australian data show that kidney transplants occur at a rate of 11.6 per 100 patient years on dialysis (Wyld et al., 2021). The difference in annual risk of progression to kidney failure and transplants per year of dialysis was used to estimate cost savings for avoided transplants per patient year of treatment. Though not stated in the resubmission, the calculation of costs from reduced transplants were based on a 0.58% reduction in the number of patients per year receiving a transplant (5% absolute difference in annual risk x 0.116 transplants per year).

4.11 The cost per responder analysis included three steps:

1. Cost per responder in first year of treatment: Includes drug costs only (assuming 80% dose intensity), response rate at the end of initial period determined by uPCR response from VALIANT trial.
2. Cost per responder in subsequent years: Includes drug costs only, over a 1-year time horizon.
3. Cost per responder in subsequent years with cost offsets: Includes drug costs, cost of end stage kidney disease, and cost of systemic corticosteroids, over a 1-year time horizon.

4.12 The resubmission stated that the cost of pegcetacoplan for the first year of treatment was $155,000 to < $255,000 per responder, which decreased in subsequent years to $155,000 to < $255,000 in step 2 and $155,000 to < $255,000 in step 3; this decrease in cost per patient per year was attributed to non-responders not being eligible to continue treatment and cost offsets associated with end stage kidney disease and systemic corticosteroids.

Table 3: Results of stepped analysis

Step	Treatment phase	Arm	Cost	Incremental cost	Response	Incremental response	Cost per responder	Incremental Cost per responder for whole year
1	Initial	Pegcetacoplan	$[redacted]	$[redacted]	60%	55%	$[redacted][1]	$[redacted][2]
		Placebo	$0.00		5%			
	Continuing (first yr)	Pegcetacoplan	$[redacted]	$[redacted]	100%	100%	$[redacted][2]	
2	Continuing (subsequent yrs)	Pegcetacoplan	$[redacted]	$[redacted]	100%	100%	$[redacted][2]	$[redacted][2]
3	Continuing (subsequent yrs) [a]	Pegcetacoplan	$[redacted]	$[redacted]	100%	100%	$[redacted][2]	$[redacted][2]

Source: Table 3.12 resubmission

[a] Includes offsets for $5,496 ($110,220 annual dialysis costs applied to 5% of patients) and $757 ($130,831 yearly transplant costs for 0.58% patients) and $80 (systemic corticosteroids).

The redacted values correspond to the following ranges:

[1] *$75,000 to < $95,000*

[2] *$155,000 to < $255,000*

4.13 The submission also presented sensitivity analyses that showed that using the composite renal endpoint (≥50% reduction in uPCR compared to baseline, and ≤15% reduction in eGFR compared to baseline) resulted in a cost of $255,000 to < $355,000 per responder over 12 months.

Drug cost/patient/year

Table 4: Drug cost per patient per year for pegcetacoplan

	March 2026 submission	Resubmission (Step 2 economic analysis)	Financial estimates (resubmission)
Cost per 28 days (effective DPMQ for 8 × 1,080 mg vials)	$[redacted] [a]	$[redacted] [a]	$[redacted] [a]
Treatment adherence	90% [c]	80% [c]	80%
Scripts/patient/year	11.74 [d]	10.44 [e]	10.44
Cost/patient/year	$[redacted] [f]	$[redacted] [f]	$[redacted] (Tier 1) <$[redacted] (If Tier 3 is reached)

Source: Table 15 pegcetacoplan ratified minutes, March 2026 PBAC meeting, Table 4.13 pegcetacoplan resubmission
Abbreviations: DPMQ, dispensed price for maximum quantity
[a] Based on an assumed 89.74%/10.26% public/private hospital split
[b] Trial-based compliance in both treatment arms during the overall study period (total number of infusions divided by total expected number of infusions)
[c] Assumption
[d] Based on 90% adherence multiplied by 13.04 scripts per year
[e] Based on 80% adherence multiplied by 13.04 scripts per year
[f] Cost per 28 days multiplied by scripts per patient per year

Estimated PBS usage & financial implications

4.14 The PBAC noted that in the March 2026 submission, for the prevalence-based approach used to derive the financial estimates the underlying numbers of patients initiating and continuing treatment in each year of the financial estimates could not be determined and it was unclear whether the uptake rates, treatment persistence, and the proportion of patients achieving a clinical benefit with pegcetacoplan in each year were reasonable (paragraph 7.14, pegcetacoplan ratified minutes, March 2026 PBAC meeting). The resubmission stated that the financial estimates were updated with incident and prevalent populations modelled separately with changes to eligibility and treatment discontinuation and adherence modelled transparently.

4.15 The estimates were based on the revised effective AEMP for pegcetacoplan of $[redacted], a [redacted]% reduction compared with the March 2026 submission.

Table 5: Summary of changes to financial estimates in the resubmission

Data	March 2026 submission and PBAC advice	July 2026 resubmission
Approach	Prevalence-based approach. The PBAC considered a combined prevalence and incidence approach would be more appropriate to capture initiation and continuation of treatment (para 7.14).	Prevalence and incidence modelling The revised approach was complex and appears to overestimate the number of patients eligible for treatment.
Prevalence	Based on the pooled meta-analysis in Caravaca-Fontan et al. 2026: Prevalence of C3G: 20.5 per million Prevalence of IC-MPGN: 16.2 per million The PBAC considered that the prevalence of C3G and primary IC-MPGN were uncertain as no reliable Australian sources were available but the values applied by the submission	Prevalence estimates were unchanged, however the tiered RSA applied the following prevalence assumptions:

Data	March 2026 submission and PBAC advice	July 2026 resubmission
	appeared reasonable (para 7.14)	C3G: Tier 1: 8.80 per 1,000,000 Tier 2: 14.7 per 1,000,000 Tier 3: 20.5 per 1,000,000 pIC-MPGN: Tier 1: 8.80 per 1,000,000 Tier 2: 12.5 per 1,000,000 Tier 3: 16.2 per 1,000,000
Incidence	Not included	The incidence of C3G and pIC-MPGN is based on the pooled meta-analysis in Caravaca-Fontan et al. 2026, which reported an incidence of 0.33 per million for C3G and 0.36 per million of pIC-MPGN In year 1 the model also includes both a prevalent and an incident population. The incident patients are not excluded from the prevalent population; this results in double counting.
Untreated carry-over	Not applicable	85% of patients not treated initially carry over in the prevalent population eligible for treatment in the following year.
Treatment eligibility	The PBAC considered that the adjustments of the prevalent patient numbers to account for diagnosis rates and patients with subclinical disease were not reasonable as prevalence rates would already account for these factors (para 7.14) The submission assumed 60% of patients were eligible for treatment as 40% are in Stage 5 CKD. Based on Sinha 2025, the proportion of patients ineligible due to having Stage 4 or 5 CKD to be 20.4% (13.7% + 6.7%) (Table 16).	Proportion ineligible due to stage 4/5 disease updated to 20.4% as per PBAC advice. Other eligibility adjustments removed. Table 4.1 of the submission stated 20.4% was used, Table 4.3 reported that 20.6% was used. The estimates actually applied 20.6%.
Uptake rate	Yr 1: [redacted]% Yr 2: [redacted]% Yr 3: [redacted]% Yr 4: [redacted]% Yr 5: [redacted]% Yr 6: [redacted]% Uptake rates were considered by the sub-committees to be uncertain and likely to be underestimated in the initial years of listing. (para 6.96). The Sub-committees considered uptake rates be revised to [redacted]% in Years 1 and 2 and [redacted]% in Years 3-6 (Table 16). The PBAC considered it was unclear whether the uptake rates in each year were reasonable (para 7.14).	The resubmission stated there are currently few clinicians with experience in treating C3G and pIC-MPGN in Australia. As a result, uptake is likely to be limited by the number of clinicians willing to initiate treatment. It is not plausible that [redacted]% of prevalent patients will be able to initiate treatment in the first year of pegcetacoplan listing. Incident population: uptake is estimated to increase from [redacted]% initially to [redacted]% by year 6. Prevalent population: uptake is estimated from [redacted]% to [redacted]% in year 6, however 15% of patients who do not initiate treatment are removed from the eligible pool each year to account for factors such as death, disease progression and relocation.
Continuing treatment	80% While the proposed restriction requires patients to have experienced a clinical improvement as a result of treatment with	No change. It was estimated 80% of patients will meet the restriction criteria to continue treatment beyond

Data	March 2026 submission and PBAC advice	July 2026 resubmission
	pegcetacoplan, no objective response measures are included, and it is unclear how this criterion will be interpreted in clinical practice. Due to the prevalence-based approach used to derive the financial estimates, it is unclear whether the implementation of this assumption in the budget impact model was reasonable as it applies to all patients in each year of the estimates (Table 16).	the initial script. This proportion includes uPCR and eGFR response as defined in the trial, however the proposed restriction wording does not specify threshold responses for continuing treatment.
Persistence	90% Due to the prevalence-based approach used to derive the financial estimates, it is unclear whether the implementation of this assumption in the budget impact model was reasonable (Table 16).	Discontinuation explicitly modelled when estimating DTGs. Annual discontinuation of 7% for prevalent population and 3% for incident population. Persistence was assumed to account for all discontinuations unrelated to the initial response criteria, e.g. disease progression to dialysis/transplant, AEs and deaths. The resubmission stated that discontinuation was higher in the prevalent population as these patients are more likely to have more severe disease at initiation. The submission stated that based on the applied discontinuation rates, approximately 70% of prevalent patients and 86% of incident patients who continue beyond the initial script will remain on treatment after 6 years.
Treatment Compliance	90% No references to support the assumed treatment adherence rate were provided (Table 16).	Treatment adherence updated to 80% to align with evidence from other markets where pegcetacoplan is available.
Post-transplant patients	The PBAC considered the proportion of patients who require treatment following a kidney transplant should also be explicitly considered (para 7.14).	Explicitly modelled in the financial estimates. Uptake was assumed to be 100% in the eligible population (excluding stage 4/5 CKD and with proteinuria ≥1g/day). Transplant patients were removed from the prevalent population to avoid double counting. It was assumed that disease recurrence occurs within one year of receiving a transplant and that some patients in the prevalent pool would receive a transplant in future years. This cohort were estimated as the proportion of patients with Stage 4-5 CKD (i.e. receiving dialysis) who receive a transplant (10.3 per 100 patient years) and experience disease recurrence (60%).

Source: Resubmission Table 4.1, pegcetacoplan ratified minutes, March 2026 PBAC meeting
Abbreviations: AEs, adverse events; CKD, chronic kidney disease; C3G, C3 glomerulopathy; DTG, duration of treatment groups; eGFR, estimated glomerular filtration rate; pIC-MPGN, primary Immune Complex Membranoproliferative Glomerulonephritis; PNH, Paroxysmal nocturnal hemoglobinuria; uPCR, urine protein to creatinine ratio

4.16 The resubmission stated that uptake was increased to reflect PBAC and ESC advice. The Sub-Committees suggested uptake is likely to be higher than estimated in initial years of listing given there are no other complement inhibitors on the PBS for C3G and

IC-MPGN and proposed uptake rates be increased to 80% in Years 1 and 2 and 90% in Years 3-6 (Table 16, pegcetacoplan ratified minutes, March 2026 PBAC meeting). The resubmission agreed that uptake should be increased, however the sponsor considered that 80% uptake in year 1 and 2 is infeasible and does not align with experience in other markets. In addition, C3G and pIC-MPGN are rare and relatively newly characterised diseases, and there remains uncertainty in the identification and diagnosis of these patients. Further, it is likely that initially these patients will be treated at specialist centres by clinicians with experience in treating C3G and pIC-MPGN, limiting the number of patients who can be initiated on pegcetacoplan. The PBAC previously considered it was unclear whether the uptake rates in each year were reasonable (para 7.14, pegcetacoplan ratified minutes, March 2026 PBAC meeting), but did not advise that uptake should be increased.

4.17 Patients who are eligible for treatment but do not initiate in a single year were assumed to be reassessed for treatment eligibility in the subsequent year. It was assumed that a proportion of patients who did not initiate treatment would not be reassessed e.g. due to death, relocation, receiving a transplant or patient ceasing treatment with the healthcare system (5% for incident patients and 15% for prevalent patients).

Table 6: Patients initiating and continuing and scripts of pegcetacoplan

	2026	2027	2028	2029	2030	2031
Patients treated						
Total initiating	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Total initial patients continuing treatment after 16 weeks	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Total patients on treatment	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
March 2026 submission Number of patients treated	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Script numbers						
C3G scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
pIC-MPGN scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
Total	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
March 2026 submission Number of scripts dispensed [a]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]

Abbreviations: C3G, C3 glomerulopathy; pIC-MPGN, primary Immune Complex Membranoproliferative Glomerulonephritis
Source: Table 4.5 and 4.6 pegcetacoplan resubmission
[a] In each year, 4 months of initial treatment (13 scripts per year × 4/12 = 4.33 scripts) and 8 months of continuing treatment (with adjustments applied for the proportion achieving a clinical benefit and persistence; 13 scripts per year × 8/12 × 0.80 × 0.90 = 6.24 scripts) were assumed. The number of scripts was further adjusted for treatment adherence of 80%.
The redacted values correspond to the following ranges:
[1] *< 500*
[2] *500 to < 5,000*

4.18 The estimates in the resubmission were substantially higher than in the March 2026 submission, although the prevalence rates were unchanged. This was due to:

- Increased uptake rates.

- Removal of adjustment to the prevalent population to account for diagnosis rates and a proportion of patients with sub-clinical disease.
- The proportion of patients ineligible due to being Stage 4/5 CKD was decreased from 40% to 20.4%.
- A small number of additional incident patients in each year (< 500 in year 1, increasing to < 500 per year in years 3-6).
- A small number of additional post-transplant patients eligible for treatment (~< 500 - < 500 per year for years 2-6 of the estimates).

4.19 As shown in Table 6 the number of initiating patients treated in each year decreases, as the untreated prevalent pool reduces as patients take up treatment. However, the total number of patients on treatment (and the number of scripts dispensed) increases in each year as patients who continue after 16 weeks are assumed to receive 297.07 weeks (5.7 years) of treatment. Due to differences in the approach the number of scripts per patient is slightly increased in the re-submission (4,869/467=10.4 scripts per patient in Year 6) compared to the submission (2,578/271=9.5).

4.20 The resubmission estimated a net cost to the PBS of $70 million to < $80 million in Year 6 of listing, with a total net cost to the PBS of $300 million to < $400 million over the first 6 years of listing based on the values presented in the worksheet. The values in Table ES6 (and Table 4.9) of the resubmission represent the total cost for pegcetacoplan without RSA rebates.

Table 7: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated financial implications						
Cost to PBS/RPBS (as per resubmission main body)	$[redacted][1]	$[redacted][2]	$[redacted][3]	$[redacted][4]	$[redacted][5]	$[redacted][5]
Cost to PBS/RPBS (as per worksheet) [b]	$[redacted][6]	$[redacted][7]	$[redacted][8]	$[redacted][3]	$[redacted][3]	$[redacted][3]
Previous submission March 2026						
Net cost to PBS/RPBS[a]	$[redacted][9]	$[redacted][10]	$[redacted][1]	$[redacted][7]	$[redacted][8]	$[redacted][8]

Source: Table 4.9 resubmission, Attachment 4.1 – UCM Jul 26 pegcetacoplan resubmission, Table 18 pegcetacoplan ratified minute, March 2026 PBAC meeting.

Abbreviations: AEs, adverse events; CKD, chronic kidney disease; C3G, C3 glomerulopathy; DTG, duration of treatment groups; eGFR, estimated glomerular filtration rate; PBAC, pharmaceutical Benefits Advisory Committee; pIC-MPGN, primary Immune Complex Membranoproliferative Glomerulonephritis; PNH, Paroxysmal nocturnal hemoglobinuria; uPCR, urine protein to creatinine ratio

a based on an effective price of $[redacted] per vial.

b These values include RSA rebates as per Table 7 (below)

The redacted values correspond to the following ranges:

[1] *$30 million to < $40 million*
[2] *$50 million to < $60 million*
[3] *$70 million to < $80 million*
[4] *$80 million to < $90 million*
[5] *$90 million to < $100 million*
[6] *$20 million to < $30 million*
[7] *$40 million to < $50 million*
[8] *$60 million to < $70 million*
[9] *$0 to < $10 million*
[10] *$10 million to < $20 million*

4.21 The resubmission made substantial changes to the structure of the financial estimates to incorporate the requested prevalent and incident approach. The revised estimates were complex, and it was unclear whether the flow of patients who did not initiate treatment back into the eligible population was reasonable. A substantial number of issues with the financial estimates were identified and the Secretariat proposed areas that should be addressed in the pre-PBAC. The Secretariat noted that the estimates should be corrected such that incident patients are removed from the prevalent pool, and the proportion of patients ineligible due to having Stage 4 or 5 CKD to be 20.4% rather than 20.6%. The Pre-PBAC response clarified that the model intentionally reassesses all patients who have not previously initiated pegcetacoplan, irrespective of whether they were eligible in the prior year. This reflects the chronic and evolving nature of C3G and IC-MPGN, where treatment eligibility and treatment uptake may change over time. The pre-PBAC response noted that this reassessment applies only to patients who have not initiated treatment and who remain in the pool after accounting for attrition (death, migration and loss to follow-up), with retention estimated at 85% for the prevalent population and 95% for the incident population. Patients who do not respond during the initial 16-week treatment period are not returned to the untreated pool for future reassessment.

4.22 The pre-PBAC response noted that the resubmission used the same prevalence rates presented in the March 2026 submission (C3G = 20.5 per million; IC-MPGN = 16.2 per million). The resubmission stated that study reporting these values has since been published (Caravaca-Fontán et al. 2026). The mortality-adjusted prevalence rates reported in the published study for C3G and primary IC-MPGN were 12.7 (95%CI: 5.4–29.7) and 12.6 (95%CI: 6.7–23.7) per million, respectively[2].

Financial Management – Risk Sharing Arrangements

4.23 In March 2026 the PBAC considered that a resubmission for pegcetacoplan should include the proposal of an RSA to address the risk of use in a much larger population than expected, or for longer than expected and in the context of highly uncertain cost-effectiveness for pegcetacoplan (para 7.15, pegcetacoplan ratified minutes, March 2026 PBAC meeting). The PBAC also noted that the prevalence of C3G and primary IC-MPGN were uncertain as no reliable Australian sources were available (para 7.14, pegcetacoplan ratified minutes, March 2026 PBAC meeting).

4.24 The resubmission proposed an RSA with tiered expenditure caps based on different prevalence rates, stating that this was to address the uncertainty associated with unclear prevalence of C3G and IC-MPGN in Australia. A three-tier RSA was proposed,

[2] Epidemiology of C3G and primary IC-MPGN: a systematic literature review and meta-analysis | Sobi Science Library

with Tier 1 to be set at prevalence estimates for C3G and IC-MPGN of 8.8 per million each, Tier 2 to be set at a prevalence of 14.7 per million for C3G and 12.5 per million for IC-MPGN, and Tier 3 set as 20.5 per million for C3G and 16.2 per million for IC-MPGN (as per the base case financial estimates). The sponsor proposed a rebate of [redacted]% for expenditure above Tier 1, [redacted]% above Tier 2 and [redacted]% above Tier 3.

Table 8: Prevalence estimates used to inform the proposed tiered RSA cap

Data	C3G prevalence	pIC-MPGN prevalence	Source	RSA rebate above tier
Tier 1	8.8 per million	8.8 per million	Iptacopan November 2025 PSD (revised estimate). pIC-MPGN assumed equal to C3G.	[redacted]%
Tier 2	14.7 per million	12.5 per million	Midpoint	[redacted]%
Tier 3	20.5 per million	16.2 per million	Caravaca-Fontán et al. (2026 (in print))	[redacted]%

Abbreviations: C3G, C3 glomerulopathy; pIC-MPGN, primary Immune Complex Membranoproliferative Glomerulonephritis
Source: Table 4.10 pegcetacoplan resubmission

Table 9: Proposed RSA caps

	2026	2027	2028	2029	2030	2031
Total cumulative Tier 1	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Total cumulative Tier 2[a]	$[redacted]	$4[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Total cumulative Tier 3[b]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]

Source: Table 4.12 pegcetacoplan resubmission
a includes [redacted]% rebate for expenditure between Tier 1 and 2
b includes a [redacted]% rebate for expenditure between Tier 2 and 3

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

5.1 The PBAC recommended extending the listing of pegcetacoplan, for the treatment of complement 3 glomerulopathy (C3G) and primary-immune complex membranoproliferative glomerulonephritis (IC-MPGN) on the basis that it should be available only under special arrangements under Section 100 Highly Specialised Drugs Program. The PBAC recognised the high clinical need for new therapies to treat these conditions, which impact relatively young patients and cause decline in kidney function that often results in the need for dialysis or kidney transplant. The PBAC is satisfied that pegcetacoplan provides, for some patients, a significant reduction in proteinuria and evidence of a slower decline in eGFR compared to current standard of care alone, and that it is possible this improvement provides a clinical benefit for some patients in terms of slowing progression to end-stage kidney disease. The PBAC considered that the resubmission had addressed the substantive outstanding issues identified at the March 2026 PBAC meeting via presenting a cost per responder analysis and revised financial estimates. The PBAC considered the cost-effectiveness of pegcetacoplan would be acceptable with a further reduction to the price per patient per year consistent with comparable conditions in patient populations of a similar size.

The PBAC noted that the revised financial impact for pegcetacoplan had increased substantially compared with the previous submission and advised that amendments to the proposed Risk Sharing Arrangement were required to ensure that the cost-effectiveness and cost to Government for pegcetacoplan are acceptable.

5.2 The PBAC acknowledged that C3G and IC-MPGN predominantly affect adolescents and young adults and the impacts of these conditions include severely disrupting education, employment, family life and mental health. The PBAC considered that there is a high clinical need for treatments for C3G and IC-MPGN, noting that other treatments are limited to supportive measures which do not impact the underlying mechanisms of the diseases, and most patients progress to end-stage kidney disease (requiring dialysis or transplant) despite these therapies. The PBAC recalled that consumer inputs provided on the November 2025 submission allowed additional insight into the patient, carer and health care provider perspective for these rare diseases.

5.3 The PBAC noted that the proposed restrictions had addressed the changes it requested in terms of the requirement for patients to have proteinuria ≥1.0 g/day under the initial treatment restriction and inclusion of criteria requiring continued use of supportive measures. The PBAC also noted that additional eligibility criteria for post-transplant patients were included as requested, such that eligibility requires biopsy-proven disease recurrence. The PBAC considered that the sponsor's proposal that the requirement for a minimum proteinuria level to initiate treatment should be removed where there is biopsy-proven disease recurrence was reasonable and clinically appropriate.

5.4 The PBAC maintained its previous advice that the restrictions should require that patients demonstrate response/stabilisation, defined as a ≥50% reduction in FMU UPCR or a ≤15% decrease in eGFR from baseline after 16 weeks of treatment (paragraph 7.5, pegcetacoplan ratified minutes, March 2026 PBAC Meeting). The PBAC did not accept the sponsor's proposal to also include a reduction in FMU UPCR to <1g/g in the definition of response as this may not adequately reflect response to treatment and was not consistent with the response criteria applied in the clinical evidence. The PBAC considered that for ongoing treatment thereafter, response may be assessed based on clinical judgement. The PBAC considered that for grandfathered patients ongoing treatment should require response/stabilisation based on clinical judgement.

5.5 The PBAC recalled that it had previously accepted the proposed clinical place and comparator for pegcetacoplan (paragraphs 7.4 and 7.6, pegcetacoplan PSD, March 2025 PBAC meeting).

5.6 The PBAC recalled that it had previously accepted that the claim of superior comparative effectiveness over standard of care was adequately supported by the data for the surrogate measure of reduction in proteinuria, for which there is strong biological plausibility for an impact on kidney disease, however, the magnitude of

change in eGFR was less certain (paragraph 7.8, pegcetacoplan PSD, March 2025 PBAC meeting). The PBAC also recalled that it had considered that a claim of inferior comparative safety would be appropriate given the increased risk of serious infections caused by encapsulated bacteria (paragraph 7.9, pegcetacoplan PSD, March 2025 PBAC meeting).

5.7 The PBAC recalled its advice that, given the data to inform economic models for C3G or primary IC-MPGN are limited, the uncertainty in the ICER was unlikely to be adequately resolved with further revision to the economic model. In the context of a substantial price reduction, and noting the clinical need and available evidence, the PBAC considered the cost-effectiveness may be able to be assessed using a cost/responder approach (paragraph 7.13, pegcetacoplan ratified minutes, March 2026 PBAC meeting).

5.8 The resubmission proposed an effective ex-manufacturer price for pegcetacoplan of $[redacted] per 1080 mg vial (a [redacted]% reduction compared to the ex-manufacturer price proposed in the March 2026 submission of $[redacted] per 1080 mg vial). The resubmission presented a stepped economic evaluation, including an incremental cost per responder approach comparing pegcetacoplan to standard of care over 12 months. Response was defined as a ≥50% reduction in uPCR compared to baseline, at 26 weeks. The analysis presented in the resubmission also attempted to quantify changes in dialysis and kidney transplants arising from the reduction in proteinuria shown in VALIANT. Based on this analysis the cost of pegcetacoplan for the first year of treatment was $155,000 to < $255,000 per responder, which decreased in subsequent years to $155,000 to < $255,000, and $155,000 to < $255,000 when reduced costs for dialysis and kidney transplants were included. The PBAC also noted that the estimated cost per patient for pegcetacoplan was reduced from $[redacted] in March 2026 to $[redacted] per year due to the [redacted]% reduction in the proposed price and a reduction in the assumed compliance from 90% to 80%.

5.9 The PBAC accepted the cost per responder approach presented in the resubmission was reasonable but considered the quantification of avoiding or delaying dialysis or transplant remained uncertain. The PBAC considered the continuing (subsequent years) in step 2 of the analysis the most reliable estimate of the ongoing cost of pegcetacoplan per responder (see Table 3). The PBAC reflected on previous determinations made for other rare diseases where no effective alternative therapies were available. The PBAC compared the available evidence, nature of the benefits, ICERs, numbers of patients expected to be treated, the cost per responder and cost per patient per year for pegcetacoplan, with other high-cost treatments for rare diseases funded on the PBS. The PBAC considered that in this context pegcetacoplan would be considered acceptably cost-effective at a cost of not more than $[redacted] per patient per year in the continuing (subsequent years) – Step 2. This would reduce the year 1 cost per responder from $155,000 to < $255,000 to $155,000 to < $255,000.

5.10 The PBAC noted that the resubmission provided revised financial estimates using a combined prevalence and incidence approach, removing the adjustments to the

prevalent patient numbers to account for diagnosis rates and patients with subclinical disease, revising the proportion of patients assumed to be ineligible due to stage 5 CKD, and explicitly accounting for a proportion of patients who require treatment following a kidney transplant. The PBAC noted that the pre-PBAC response provided clarification of some of the changes and considered the flow of patients in the revised estimates is likely to reflect standard clinical practice and the progressive nature of these diseases. The changes in the resubmission, along with increased uptake rate assumptions, resulted in a substantial increase in the estimated financial impact of the proposed listing from $200 million to < $300 million over 6 years to $400 million to < $500 million over 6 years, despite the reduction in the proposed cost for pegcetacoplan. The PBAC noted that there were several additional corrections to the estimates required (incident patients removed from the prevalent pool, the proportion of patients ineligible due to having Stage 4 or 5 CKD to be 20.4% rather than 20.6%). The PBAC also considered that the proportion of patients with Stage 1-3 CKD should be applied to all populations, including post-transplant populations. These changes reduced the financial impact from $400 million to < $500 million to $400 million to < $500 million over 6 years.

5.11 The PBAC recalled that it previously considered that the prevalence of C3G and primary IC-MPGN were uncertain as no reliable Australian sources were available (paragraph 7.14, pegcetacoplan PSD, March 2026 PBAC meeting). The resubmission used the same prevalence rates presented in the March 2026 submission (C3G = 20.5 per million; IC-MPGN = 16.2 per million). The resubmission stated that the study reporting these values has since been published (Caravaca-Fontán et al. 2026). The PBAC noted that the mortality-adjusted prevalence rates reported in the published study for C3G and primary IC-MPGN were 12.7 (95%CI: 5.4–29.7) and 12.6 (95%CI: 6.7–23.7) per million, respectively, suggesting that the values reported in the March 2026 submission and the resubmission were substantially overestimated. The PBAC also recalled it had considered a prevalence of 8.8 per million appeared reasonable for the C3G population, based on analysis of the UK RaDaR registry (paragraph 7.7 iptacopan PSD, November 2025 PBAC meeting). The PBAC considered that, overall, the financial estimates presented in the resubmission were likely to be overestimated, mainly due to the high prevalence rates applied, and that a prevalence rate of 8.8 per million would be appropriate for C3G and IC-MPGN, as applied in tier 1 of the proposed RSA. The PBAC noted that application of the lower prevalence rates and the lower cost for pegcetacoplan (as per paragraph 5.9) reduced the financial impact from $400 million to < $500 million to $100 million to < $200 million over 6 years.

5.12 The PBAC noted that the resubmission proposed an RSA to address the risk of higher than expected utilisation of pegcetacoplan in the context of highly uncertain cost-effectiveness, as requested (paragraph 7.15, pegcetacoplan PSD, March 2026 PBAC meeting). The resubmission proposed an RSA with three tiers based on varying prevalence estimates. The resubmission stated that the total cost of pegcetacoplan could be reduced by an additional [redacted]% over the forward estimates if tier 3 is reached.

However, the PBAC considered that tiers two and three applied prevalence estimates that were higher than supported by the literature and were unlikely to be reached. The PBAC considered that an RSA with estimates based on the tier 1 prevalence of 8.8 per million (for C3G and IC-MPGN) and the lower cost for pegcetacoplan, with a high rebate (at least [redacted]%), would appropriately address the risk of higher than expected utilisation of pegcetacoplan in the context of highly uncertain cost-effectiveness.

5.13 The PBAC found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met. Specifically the PBAC found that in the circumstances of its recommendation for pegcetacoplan:

a) The treatment is not expected to provide a substantial and clinically relevant improvement in efficacy over alternative therapies, as the clinical benefit was only supported by evidence of changes in surrogate measures (reduction in proteinuria and slower decline in eGFR compared to placebo);

b) The treatment is expected to address a high and urgent unmet clinical need;

c) It was not necessary to make a finding in relation to whether it would be in the public interest for the subsequent pricing application to be progressed under Pricing Pathway A because one or more of the preceding tests had failed OR

5.14 The PBAC noted that this submission is not eligible for an Independent Review as it is a positive recommendation.

Outcome:
Recommended

6 Recommended listing

6.1 Add new item:

Initial/Grandfather treatment phase:

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PEGCETACOPLAN					
Pegcetacoplan 1.08 g/20 mL injection; 20 mL vial	NEW (Public) NEW (Private)	8	8	3	Empaveli
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: ☒ Medical Practitioners				
	Benefit type: ☒ Authority Required (FULL assessment) in writing only via OPA/post/HPOS upload)				
	Authority type: ☒ Complex Authority Required (CAR)				
	Prescribing rule level:				

	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Caution: This drug increases the risk of encapsulated bacterial infections. Consult the approved PI for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan
	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
	Administrative Advice: Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.
	Restriction Summary 1 / Treatment of Concept: 1A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: Initial treatment – transplant naive patients
	Clinical criteria:
	Patient must not have received prior PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	Treatment must not be in combination with a Complement 5 (C5) inhibitor for this condition
	AND
	Clinical criteria:
	Patient must have/have had a confirmed diagnosis of primary C3G or pIC-MPGN established by kidney biopsy at the time of treatment initiation with this drug
	AND
	Clinical criteria:
	Patient must have/have had proteinuria ≥ 1000mg/day at treatment initiation with this drug
	AND
	Clinical criteria:
	Patient must not have/have had an eGFR less than 30 mL/min/1.73 m2 at treatment initiation with this drug
	AND
	Clinical criteria:
	Patient must not have had a kidney transplant
	Treatment criteria:

	Must be treated by a nephrologist with experience in glomerular diseases.
	AND
	Treatment criteria:
	Patient must not be undergoing dialysis
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be at least 12 years of age
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	Prescribing Instructions: At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) uPCR (mg/g) (ii) eGFR (mL/min/1.73 m^2)
	Prescribing Instructions: Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.
	Prescribing Instructions: An outcome on the authority application is not immediate but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.
	Restriction Summary 1 / Treatment of Concept: 3A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: Initial or recommencement of treatment - post kidney transplant
	Clinical criteria:
	Treatment must not be in combination with a Complement 5 (C5) inhibitor for this condition
	AND
	Clinical criteria:
	Patient must have/have had a confirmed diagnosis of primary C3G or pIC-MPGN disease recurrence established by a biopsy in the transplanted kidney prior to commencing treatment with this drug
	AND
	Clinical criteria:
	Patient must not have/have had an eGFR less than 30 mL/min/1.73 m2 prior to commencing treatment with this drug
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases.
	AND
	Treatment criteria
	Patient must not be undergoing dialysis
	Population criteria:
	Patient must weigh at least 30 kg

	Population criteria:
	Patient must be at least 12 years of age
	AND
	Prescribing Instructions: The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	Prescribing Instructions: Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.
	Prescribing Instructions: At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) uPCR (mg/g) (ii) eGFR (mL/min/1.73 m^2)
	Prescribing Instructions: An outcome on the authority application is not immediate but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.

Continuing treatment phases:

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PEGCETACOPLAN					
Pegcetacoplan 1.08 g/20 mL injection; 20 mL vial	NEW (Public) NEW (Private)	8	8	3	Empaveli

Concept ID	**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (FULL assessment) in writing only via OPA/post/HPOS upload)
	Authority type: ☒ Complex Authority Required (CAR)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Caution: This drug increases the risk of encapsulated bacterial infections. Consult the approved PI for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.
	Administrative Advice Complement inhibitors are defined as eculizumab, ravulizumab or iptacopan

	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
	Administrative Advice: Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.
	Restriction Summary 1 / Treatment of Concept: 1A
	Indication: C3G or primary immune complex membranoproliferative glomerulonephritis (pIC-MPGN)
	Treatment Phase: Continuing treatment – Treatment naïve and post-transplant patients
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	Treatment must not be in combination with a Complement 5 (C5) inhibitor for this condition
	AND
	Clinical criteria:
	Patient must have experienced clinical improvement or stabilisation of the condition as a result of treatment with this drug, defined as either ~~of~~:(i) at least a 50% reduction in the first morning urine (FMU) UPCR; or (ii) no more than a 15% decrease in estimated glomerular filtration rate (eGFR) from baseline, if they have received treatment under either: (a) the 'Initial treatment – transplant naive patients' restriction or (b) the ' Initial or recommencement of treatment - post kidney transplant' restriction and this is their first continuing authority prescription; OR
	Patient must have experienced clinical improvement or stabilisation of the condition, as determined by clinical judgement, where the patient has either (i) previously received non-PBS subsidised treatment with this drug for this condition prior to [listing date] or (ii) previously received their first PBS-subsidised continuing authority prescription for this drug for this condition.
	Treatment criteria:
	Must be treated by a nephrologist with experience in glomerular diseases; or
	Must be treated by a non-specialist medical practitioner who has consulted a nephrologist on the patient's drug treatment details.
	AND
	Treatment criteria
	Patient must not be undergoing dialysis
	Population criteria:
	Patient must weigh at least 30 kg
	Population criteria:
	Patient must be at least 12 years of age
	AND
	Prescribing Instructions:

	The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: (1) details of the proposed prescription(s); 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).
	Prescribing Instructions: Patient must be receiving optimised supportive care, including either (i) an ACE inhibitor or (ii) an angiotensin II receptor blocker (ARB), with or without an SGLT2 inhibitor, unless contraindicated or not tolerated.
	Prescribing Instructions: An outcome on the authority application is not immediate but will follow in due course. Electronic upload is encouraged to reduce processing time.
	Prescribing Instructions: 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.

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.