5.24 EVOLOCUMAB
Injection 140 mg in 1 mL single use pre-filled pen, Repatha®,
Amgen Australia Pty Limited

1 Purpose of Submission

1.1 The Category 4 submission requested new listings for evolocumab injection 140 mg in 1 mL single use pre-filled pen with increased maximum dispensed quantities (MDQs) consistent with the Government's 60-day prescription initiative for the treatment of homozygous familial hypercholesterolaemia (HoFH), heterozygous familial hypercholesterolaemia (HeFH) and non-familial hypercholesterolaemia (non-FH).

1.2 Listing was requested to align with the availability of other co-prescribed lipid-lowering therapies and address the current gap whereby patients on ezetimibe + evolocumab or statin + ezetimibe + evolocumab are unable to fully realise the intended benefits of the 60-day prescribing initiative.

2 Background

2.1 Evolocumab is currently listed on the PBS as an Authority Required (STREAMLINED) listing for familial homozygous hypercholesterolaemia, familial heterozygous hypercholesterolaemia, non-familial hypercholesterolaemia.

2.2 In December 2022, the PBAC considered a list of PBS medicines indicated for the treatment of chronic conditions with respect to their suitability for listing with increased MDQs per dispensing.

2.3 In making its recommendations in December 2022, the PBAC applied the following guidance criteria to identify medicines that should not be listed with higher dispensed quantities:

- Medicines where being able to stockpile large quantities could pose a risk to patient safety (for example: narcotics, paracetamol/codeine, psychostimulants, psycholeptics and psychoanaleptics).
- Medicines with a requirement for regular monitoring and frequent dose titration.
- Medicines where the drug regimen is associated with management of progressively worsening disease or the symptoms are associated with relapse of disease and the patient is not expected to be stable for the next 12 months.
- Medicines prescribed for short term management of symptoms in chronic diseases.

- Medicines in the Palliative Care section of the Schedule.
- Medicines where the PBAC has recommended a listing that enables prescribers to prescribe less than six months therapy per prescription.
- Medicines must have been PBS listed for five or more years or be generics of medicines which have been listed for five or more years, as severe but rare adverse effects frequently become evident during the first few years a drug is widely available.

2.4 Several cardiovascular medicines co-prescribed with evolocumab currently have 60-day prescriptions. This includes the statins, ezetimibe and ezetimibe plus statin combinations.

Registration status

2.5 Evolocumab 140 mg/mL and 420 mg/3.5 mL was TGA registered on 4 December 2015. Repatha is indicated for the treatment of:

- primary hypercholesterolaemia in adults (including HeFH and Non-FH) to reduce LDL cholesterol, in combination with a statin or statin with other lipid-lowering therapies, or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant.
- HoFH in adults and adolescents ≥12 years in combination with other lipid-lowering therapies.

2.6 In August 2018, an additional TGA-registered indication was added for evolocumab 140 mg/mL and 420 mg/3.5 mL, to include prevention of cardiovascular events (myocardial infarction, stroke and coronary revascularisation) in adults with established cardiovascular disease in combination with an optimally dosed statin and/or other lipid-lowering therapies.

2.7 The recommended dose for primary hypercholesterolaemia and the prevention of cardiovascular events is 140 mg every 2 weeks or 420 mg once a month. The recommended dose for HoFH is 420 mg once a month (the dose can be increased to 420 mg every 2 weeks if a clinically meaningful response is not achieved in 12 weeks).

2.8 Repatha 420 mg/3.5 mL has been discontinued by Amgen.

Previous PBAC consideration

2.9 Evolocumab 140 mg/mL was first recommended for PBS listing by the PBAC at its March 2016 meeting for HoFH (but not the broader HeFH population) (paragraph 7.1, evolocumab, Public Summary Document [PSD], March 2016 PBAC Meeting).

2.10 At its July 2017 PBAC meeting, the PBAC recommended PBS listing of evolocumab 420 mg/3.5 mL for HoFH, under the same circumstances as evolocumab 140 mg/mL

that was already listed (paragraphs 6.1 and 6.3, evolocumab, PSD, July 2017 PBAC Meeting).

2.11 At its March 2018 meeting, the PBAC recommended listing evolocumab 140 mg/mL and 420 mg/3.5 mL for the treatment of patients with both HeFH and HoFH (paragraph 5.1, evolocumab, PSD, March 2018 PBAC Meeting).

2.12 At its November 2019 meeting, the PBAC recommended the Authority Required listing of evolocumab in the following circumstances:

- Non-FH in patients with atherosclerotic cardiovascular disease (ASCVD), who have an LDL >2.6 mmol/L and additional high-risk factors; and
- Familial hypercholesterolaemia in patients with symptomatic ASCVD or HoFH who have an LDL between 2.6 and 3.3 mmol/L (paragraph 5.1, evolocumab, PSD, November 2019 PBAC Meeting).

2.13 For the non-FH and HeFH listing, the clinical criteria stated that the patient must have been treated with ezetimibe for at least 3 months and noted that the intent is that the ezetimibe trial must be completed prior to the patient commencing treatment with evolocumab (paragraph 2.8, evolocumab, PSD, November 2019 PBAC Meeting). The PBAC also recommended changes to the requested restriction, including adjusting the LDL prescriber instructions to clarify that the qualifying LDL cholesterol level must be following 3 months of treatment with a statin and ezetimibe (paragraph 5.4, evolocumab, PSD, November 2019 PBAC Meeting).

2.14 The PBAC also considered a request to change the restriction levels for evolocumab listings for familial hypercholesterolaemia, from Authority Required (Written) to Authority Required (Telephone/Online) for initial treatment, and from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for continuing treatment, at its November 2019 meeting, aligning with its requested restrictions for non-FH listings. The PBAC considered this was appropriate (paragraph 2.5, evolocumab, PSD, November 2019 PBAC Meeting).

2.15 At its July 2022 meeting, the PBAC recommended extending the PBAC listings for evolocumab to include patients who have an LDL cholesterol level between 1.8 and 2.6 mmol/L despite optimised treatment with statins and ezetimibe, and to allow initial prescribing by any medical practitioner in consultation with a specialist physician (paragraph 7.1, evolocumab, PSD, July 2022 PBAC Meeting). The PBAC considered there was a risk of use outside the restriction, but retaining an Authority Required (telephone/online) listing would help to mitigate this risk from the expanded listing (paragraph 7.15, evolocumab, PSD, July 2022 PBAC Meeting).

2.16 At its March 2023 meeting, the PBAC noted the report for evolocumab for hypercholesterolaemia from the February 2023 Drug Utilisation Sub-Committee (DUSC) meeting. The PBAC noted:

- evolocumab utilisation for non-FH was different from what was estimated.
- the restriction changes since PBS listing of evolocumab and that the restriction changes that occurred in December 2022 (initial prescribing extended to any medical practitioner in consultation with a specialist physician and changes to the LDL cholesterol level criteria) were not included as part of the review, and that the LDL cholesterol level had been revised several times since PBS listing. The PBAC commented that utilisation of evolocumab would likely increase more rapidly as clinicians became aware of these changes.
- there was a greater proportion of patients consistently supplied evolocumab for the same indication compared to Authority or Streamlined code in 2021. It considered this was likely due to prescriber error and noted the complexities with navigating the presentation of restriction and corresponding item codes in prescriber software (PBAC Consideration of the Report of the Drug Utilisation Sub-Committee, March 2023 PBAC Meeting).

2.17 At its March 2024 meeting the PBAC recommended changing the restriction level from Authority Required (telephone/online) to Authority Required (STREAMLINED) for the initial treatment listings for evolocumab 140 mg/mL single use pre-filled pen and evolocumab injection 420 mg in 3.5 mL single use pre-filled cartridge for the treatment of homozygous familial hypercholesterolaemia (HoFH), heterozygous familial hypercholesterolaemia (HeFH) and non-familial hypercholesterolaemia (non-FH) (paragraph 6.1, evolocumab, PSD, March 2024 PBAC Meeting).

3 Requested listing

3.1 The submission requested a 60-day listing for evolocumab 140 mg/mL single use pre-filled pen under the same circumstances as the existing 30-day listing but with double the maximum quantity and with the addition of the following clinical criterion:

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

3.2 As the submission requested the same restrictions as the 30-day listing for evolocumab 140 mg/mL single use pre-filled pen, the full restrictions have not been reproduced here.

3.3 The following tables represent the sponsor's proposed listings. Suggested deletions from the Secretariat are in strikethrough.

3.4 Add new 60-day listing as follows:

Non-FH and HeFH

Abridged restrictions corresponding to initial PBS listing (11484K)

~~MEDICINAL PRODUCT medicinal product pack~~	~~PBS item code~~	~~Max. qty packs~~	~~Max. qty units~~	~~№. of Rpts~~	~~Available brands~~

~~EVOLOCUMAB~~					
~~evolocumab 140 mg/mL injection, 1 mL pen device~~	~~NEW~~	4	4	~~5~~	~~Repatha~~
~~Restriction Summary / Treatment of Concept~~					
	~~Category / Program:~~ ☒ ~~GENERAL - General Schedule (Code GE)~~				
	~~Prescriber type:~~ ☒~~Medical Practitioners~~ ☒~~Nurse practitioners~~				
	~~Restriction type:~~ ☒~~Authority Required (Streamlined) [new code]~~				
	~~Indication~~ ~~Non-familial hypercholesterolaemia~~				
	~~Treatment Phase~~ ~~Initial treatment~~				
	~~Clinical Criteria:~~				
	~~The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.~~				
Abridged Restrictions					

Abridged restrictions corresponding to initial PBS listing (11484K)

~~MEDICINAL PRODUCT~~ **~~medicinal product pack~~**	**~~PBS item code~~**	**~~Max. qty packs~~**	**~~Max. qty units~~**	**~~№. of Rpts~~**	**~~Available brands~~**
~~EVOLOCUMAB~~					
~~evolocumab 140 mg/mL injection, 1 mL pen device~~	~~NEW~~	4	4	~~5~~	~~Repatha~~
~~Restriction Summary / Treatment of Concept~~					
	~~Category / Program:~~ ☒ ~~GENERAL - General Schedule (Code GE)~~				
	~~Prescriber type:~~ ☒~~Medical Practitioners~~ ☒~~Nurse practitioners~~				
	~~Restriction type:~~ ☒~~Authority Required (Streamlined) [new code]~~				
	~~Indication~~ ~~Familial heterozygous hypercholesterolaemia~~				
	~~Treatment Phase~~ ~~Initial treatment~~				
	~~Clinical Criteria:~~				
	~~The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.~~				
Abridged Restrictions					

Abridged restrictions corresponding to continuing PBS listing (11985T)

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№. of Rpts**	**Available brands**
EVOLOCUMAB					
evolocumab 140 mg/mL injection, 1 mL pen device	NEW	4	4	5	Repatha
Restriction Summary / Treatment of Concept					
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined) [new code]				

	Indication Non-familial hypercholesterolaemia
	Treatment Phase Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran
	Clinical Criteria:
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.
Abridged Restrictions	

Abridged restrictions corresponding to continuing PBS listing (11985T)

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№. of Rpts**	**Available brands**
EVOLOCUMAB					
evolocumab 140 mg/mL injection, 1 mL pen device	NEW	4	4	5	Repatha
Restriction Summary / Treatment of Concept					
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined) [new code]				
	Indication Familial heterozygous hypercholesterolaemia				
	Treatment Phase Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran				
	Clinical Criteria:				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.				
Abridged Restrictions					

HoFH

Abridged restrictions corresponding to initial PBS listing (10958R)

~~**MEDICINAL PRODUCT**~~ ~~**medicinal product pack**~~	~~**PBS item code**~~	~~**Max. qty packs**~~	~~**Max. qty units**~~	~~**№. of Rpts**~~	~~**Available brands**~~
~~EVOLOCUMAB~~					
~~evolocumab 140 mg/mL injection, 1 mL pen device~~	~~NEW~~	~~6~~	~~6~~	~~5~~	~~Repatha~~
~~**Restriction Summary / Treatment of Concept**~~					
	~~**Category / Program:** ☒ GENERAL - General Schedule (Code GE)~~				
	~~**Prescriber type:** ☒Medical Practitioners ☒Nurse practitioners~~				
	~~**Restriction type:** ☒Authority Required (Streamlined) [new code]~~				
	~~**Indication**~~ ~~Familial homozygous hypercholesterolaemia~~				
	~~**Treatment Phase**~~ ~~Initial treatment~~				
	~~**Clinical Criteria:**~~				

	~~The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.~~
Abridged Restrictions	

Abridged restrictions corresponding to continuing PBS listing (11977J)

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№. of Rpts**	**Available brands**
EVOLOCUMAB					
evolocumab 140 mg/mL injection, 1 mL pen device	NEW	6	6	5	Repatha
Restriction Summary / Treatment of Concept					
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined) [new code]				
	Indication Familial homozygous hypercholesterolaemia				
	Treatment Phase Continuing treatment				
	Clinical Criteria:				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.				
Abridged Restrictions					

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer inputs

4.2 The PBAC noted and welcomed the input from health care professionals (1) and organisations (3) via the Office of Health Technology Assessment Consultation Hub. The inputs were supportive and emphasised that increasing the MDQ of evolocumab would improve patient access and adherence by reducing the need for monthly pharmacy visits, particularly for patients in remote areas or those with complex personal responsibilities.

4.3 The PBAC noted input received from Coronary Artery Disease (CAD) Frontiers, Advara HeartCare and the Australian Atherosclerosis Society stating that a 60-day dispensing listing for evolocumab would reduce administrative burden on prescribers and assist clinicians and patients in managing cholesterol and reducing the morbidity and mortality associated with cardiovascular disease.

Request for increased MDQ

4.4 Evolocumab is a human immunoglobulin G2 monoclonal antibody directed against human proprotein convertase subtilisin/kexin type 9 (PCSK9). Evolocumab binds selectively and with high affinity to PCSK9 and inhibits circulating PCSK9 from binding to the low-density lipoprotein receptor (LDLR) on the liver cell surface, thus preventing PCSK9-mediated LDLR degradation. An increase in liver LDLR levels results in associated reductions in serum LDL-C.

4.5 Hypercholesterolaemia is a chronic and relatively stable long-term condition. The sponsor notes that enabling 60-day prescribing for evolocumab would promote consistency and equity across chronic disease treatments, with many other PBS-listed medicines, including those required to be co-prescribed with evolocumab, for chronic cardiovascular risk management already eligible for 60-day prescribing.

4.6 The sponsor notes in the submission that evolocumab meets the criteria for an increased MDQ based on the exclusion criteria that was established at the December 2022 PBAC meeting.

- Evolocumab is not a controlled drug and does not pose a safety risk if stockpiled in large quantities.
- Evolocumab prescribing consists of two stable dosage regimens with no dose titration and no dose modification requirements. For the minority of patients with HoFH (estimated at 0.6% of total Repatha patients), there is a dose increase if a clinical meaningful response is not achieved in 12 weeks.
- Hypercholesterolaemia is a chronic and relatively stable long-term condition.
- Hypercholesterolaemia is a chronic condition requiring long term management.
- Evolocumab is not in the Palliative Care section of the Schedule.
- Evolocumab is currently available with 5 repeats which provides for 6 months of therapy.
- Evolocumab has been PBS listed for 9 years.

Clinical trials

4.7 The submission was based on the latest Periodic Safety Update Report (PSUR) (covering the period from 18 July 2024 to 17 July 2025). The long-term safety of evolocumab has been established since its initial registration on the 17 July 2015 in the EU. Exposure is estimated as:

- 36,575 subjects resulting in 106,553 subject-years of exposure in Amgen-sponsored clinical trials since the beginning of the development program.
- 3,042,864 patients (1,435,808 patient-years) were exposed to evolocumab in the marketed setting.

- Cumulatively, since the International Birth Date of evolocumab up to the end of the current reporting period, an estimated 6,645,839 patients (4,384,786 patient-years) have been exposed to the product in the marketed setting.

4.8 During the reporting period of the PSUR there was no significant change in the risk profile of evolocumab. During the reporting period no significant actions were taken for safety reasons and no change was made to the Core Safety Information. The reports concludes that the benefit-risk profile of evolocumab remains favourable for the approved indications.

Estimated PBS usage and financial implications

4.9 The submission presented a market share approach proposing the evolocumab 60-day listing will substitute for existing evolocumab 30-day listings based on utilisation of evolocumab under the current listings forecast over the 2025-2031 period.

4.10 The submission states that adding 60-day prescription listings for evolocumab will result in a small increase in PBS costs, mainly due to the reduced patient copayment contribution. The submission notes there may be savings to the MBS and patients through fewer doctor visits, however this save has not been quantified in the financial analysis.

4.11 There are no changes to current price requested.

4.12 Refer to Table 1 which presents the estimated extent of use, cost of evolocumab to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

4.13 The submission estimated that 200,000 to < 300,000 scripts would be supplied of evolocumab over the first six years of listing (30,000 to < 40,000 in Year 1 to 50,000 to < 60,000 in Year 6).

4.14 The submission stated that the estimated net financial impact to the PBS/RPBS for the 60-day listing of evolocumab is $0 to < $10 million over six years (Year 1 $0 to < $10 million to Year 6 $0 to < $10 million).

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	[redacted][1]	[redacted][2]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]
Estimated financial implications of [the proposed medicine**]**						
Cost to PBS/RPBS less co-payment ($)	[redacted][4]	[redacted][5]	[redacted][6]	[redacted][6]	[redacted][7]	[redacted][7]
Net financial implications						
Net cost to PBS/RPBS ($)	[redacted][8]	[redacted][8]	[redacted][8]	[redacted][8]	[redacted][8]	[redacted][8]

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Evolocumab financial estimates UCM workbook March 2026

The redacted values correspond to the following ranges:

[1] *30,000 to < 40,000*

[2] *40,000 to < 50,000*

[3] *50,000 to < 60,000*

[4] *$20 million to < $30 million*

[5] *$30 million to < $40 million*

[6] *$40 million to < $50 million*

[7] *$50 million to < $60 million*

[8] *$0 to < $10 million*

Quality use of medicines

4.15 The sponsor claimed in the submission that the availability 60-day prescribing for evolocumab will address the current gap whereby patients on ezetimibe + evolocumab or statin + ezetimibe + evolocumab are unable to fully realize the intended benefits of the 60-day prescribing initiative. Minimising gaps in therapy through maintaining steady state exposure and reducing administrative and access barriers that can contribute to treatment interruptions, is a meaningful strategy that supports long-term cardiovascular protection.

4.16 Amgen provides tailored educational programs to specialists (cardiologists and endocrinologists), nurse practitioners and GPs through a combination of face-to-face and digital engagement. Amgen Medical Scientific Liaisons (MSLs) and sales representatives regularly engage with approximately 1,700 specialists (approximately 1400 cardiologists, 300 endocrinologists and 50 general physicians), 120 Nurse Practitioners, 30 Hospital Pharmacists and approximately 2,160 GPs with a CVD subspecialty and/or interest. These interactions focus on appropriate lipid management and upskilling clinicians on the evolocumab PBS eligibility criteria for evolocumab to support its appropriate use.

4.17 Education for specialist physicians is delivered primarily through peer-to-peer programs focused on the management of high-risk ASCVD and familial hypercholesterolaemia patients. These activities support appropriate patient identification, treatment sequencing and continuation consistent with PBS requirements.

4.18 For GPs with a specific cardiovascular interest, who are managing high-risk ASCVD patients within an existing care partnership with their specialist physician, additional training is provided on their management as well as PBS criteria, to ensure appropriate use of evolocumab under its PBS restriction. In addition, Amgen's specialist sales representatives regularly engage these GPs and reinforce appropriate prescribing of evolocumab on the PBS.

4.19 Beyond statins – Advances in CVD Risk reduction is an Amgen program designed to educate GPs in the practicalities of lowering LDL-C through PCSK9 inhibition and the use of evolocumab. It achieves this through a case-based learning approach covering risk identification and management. Management covers therapeutic approaches as per current guidelines and detailed information is provided on the use of evolocumab according to the PBS restriction criteria.

4.20 Amgen provides patient materials to support safe and appropriate use of evolocumab. These materials are made available to specialists, nurse practitioners and GPs for distribution to patients as appropriate. This includes access to the Help4U patient support program, which offers injection technique support and guidance on questions related to evolocumab administration and information contained within the Consumer Medicine Information (CMI).

5 PBAC Outcome

5.1 The PBAC recommended the Section 85 General Schedule listing of evolocumab with increased maximum dispensed quantities (MDQs) consistent with the Government's 60-day prescription initiative for the treatment of homozygous familial hypercholesterolaemia (HoFH), heterozygous familial hypercholesterolaemia (HeFH) and non-familial hypercholesterolaemia (non-FH).

5.2 The PBAC considered that a 60-day dispensing listing for evolocumab would align the medicine with other co-prescribed lipid-lowering therapies and address the current gap whereby patients on ezetimibe + evolocumab or statin + ezetimibe + evolocumab are unable to fully realise the intended benefits of the 60-day prescribing initiative.

5.3 The PBAC considered that evolocumab meets the criteria for an increased MDQ based on the exclusion criteria that was established at the December 2022 PBAC meeting when the PBAC considered a list of PBS medicines indicated for the treatment of chronic conditions for their suitability for listing with increased MDQs per dispensing.

5.4 The PBAC noted that the submission was also based on the latest Periodic Safety Update Report (PSUR) (covering the period from 18 July 2024 to 17 July 2025) and that the long-term safety of evolocumab has been established since its initial registration on the 17 July 2015 in the EU.

5.5 In relation to the proposed listing and restriction, the PBAC considered that the increased MDQ measure for evolocumab should apply only to the continuing treatment phase and not the initial treatment phase. The PBAC noted that the sponsor was amenable to this approach as stated in their pre-PBAC response. The PBAC considered that treatment should be stable before a prescriber can determine whether the increased quantity is appropriate for an individual patient. The PBAC also considered this approach to be consistent with the intent of the 60-day dispensing policy and with existing arrangements for other medicines included in the measure.

5.6 The PBAC noted that the submission presented a market share approach proposing the evolocumab 60-day listing will substitute for existing evolocumab 30-day listings based on utilisation of evolocumab under the current listings forecast over the 2025-2031 period. The PBAC considered this was appropriate.

5.7 The PBAC noted that evolocumab would be the first monoclonal antibody included under the 60-day dispensing policy and that it has a higher AEMP than other medicines currently included in the measure. The PBAC did not consider these factors, in themselves, to present a barrier to inclusion under the policy and did not identify any specific concerns arising from the medicine's status as a monoclonal antibody or its higher cost.

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

Outcome:
Recommended

6 Recommended listing

6.1 Add new 60-day listings as follows:

Non-FH and HeFH

Abridged restrictions corresponding to continuing PBS listing (11985T)

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№. of Rpts**	**Available brands**
EVOLOCUMAB					
evolocumab 140 mg/mL injection, 1 mL pen device	NEW	4	4	5	Repatha
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined) [new code]				
Variant of Restriction Summary / Treatment of Concept					
	Indication Non-familial hypercholesterolaemia				

	Treatment Phase Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran
	Clinical Criteria:
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.
Abridged Restrictions	
Variant of Restriction Summary / Treatment of Concept / Authority Required: Streamlined	
	Indication Familial heterozygous hypercholesterolaemia
	Treatment Phase Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran
	Clinical Criteria:
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.
Abridged Restrictions	

Abridged restrictions corresponding to continuing PBS listing (11977J)

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№. of Rpts**	**Available brands**
EVOLOCUMAB					
evolocumab 140 mg/mL injection, 1 mL pen device	NEW	6	6	5	Repatha
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined) [new code]				
Variant of Restriction Summary / Treatment of Concept					
	Indication Familial homozygous hypercholesterolaemia				
	Treatment Phase Continuing treatment				
	Clinical Criteria:				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.				
Abridged Restrictions					

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.