

**6.14 INCLISIRAN,
Injection 284 mg in 1.5 mL single use pre-filled
syringe,
Leqvio[®],
NOVARTIS PHARMACEUTICALS AUSTRALIA PTY
LIMITED**

1 Purpose of Submission

- 1.1 The Category 4 submission requested an amendment to the Pharmaceutical Benefits Scheme (PBS) listings of inclisiran (Leqvio[®]) to allow nurse practitioners (NPs) to initiate and continue treatment of inclisiran, in consultation with a specialist physician, for the treatment of familial heterozygous hypercholesterolaemia (HeFH) and non-familial hypercholesterolaemia (non-FH).

2 Background

- 2.1 Inclisiran is currently listed on the PBS for the treatment of HeFH and non-FH as:
- Authority Required (Online/Telephone) listing for initial treatment.
 - Authority Required (STREAMLINED) listing for continuing treatment.
- 2.2 Medical Practitioners are currently the only eligible prescribers to initiate the treatment of inclisiran.
- 2.3 The current treatment criteria of inclisiran states that treatment initiation must be by a specialist physician, or by a physician who has consulted a specialist physician.
- 2.4 The PBAC recommended an amendment to the restriction level of inclisiran (284 mg/1.5 mL injection, 1.5 mL syringe) for the initial treatment of HeFH and non-FH from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) at the November 2024 meeting.

Registration status

- 2.5 Inclisiran is Therapeutic Goods Administration (TGA) registered as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with HeFH, atherosclerotic cardiovascular disease (ASCVD), or at high risk of a cardiovascular event:
- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or,

- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant.

Previous PBAC consideration

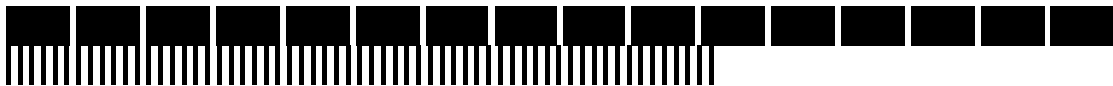
- 2.6 There were no previous submissions for inclusion of NPs as prescribers for inclisiran.
- 2.7 At its May 2023 Intracycle meeting, the PBAC recommended inclisiran for the treatment of HeFH and non-FH with ASCVD. In its consideration, the PBAC advised that, like evolocumab and alirocumab, inclisiran was not suitable for prescribing by NPs (paragraph 13.13, inclisiran (Leqvio), Public Summary Document, March 2023 PBAC Meeting with May 2023 Addendum).

Nurse practitioner prescribing on the PBS

- 2.8 NP prescribing under the PBS is currently restricted by the NP’s scope of practice, adherence to professional practice standards as set by the Nursing and Midwifery Board of Australia (NMBA), and state or territory prescribing rights. Prescribing of PBS medicines is also contingent on a prescriber being an authorised NP as required by the *National Health Act 1953*. From 1 November 2024, the legislated requirement for NPs to be in a specified collaborative arrangement with a medical practitioner to provide MBS services or prescribe PBS medicines was removed.
- 2.9 The submission noted that the Department is currently undertaking a review of PBS medicines that may be suitable for prescribing by NPs and endorsed midwives (the Review), for consideration by the PBAC. In May 2023, the Nurse Practitioner Workforce Plan was released and included a recommended action to “review NP prescribing of medicines on the PBS” with the aim to “align the medicines authorised NPs can prescribe through the PBS and the Repatriation PBS (RPBS) with their full scope of practice”. The Department is working with stakeholders to understand current gaps within the PBS that may prevent NPs and midwives from prescribing subsidised medicines within their scope of practice. The sponsor was advised by the Department that inclisiran may be included in the Review but confirmed its preference was for this submission to proceed separately.

Committee-In-Confidence information

2.10



End Committee-In-Confidence information

3 Requested listing

- 3.1 The submission requested that NPs be included as eligible prescribers for the initiation and continuation treatment of inclisiran, in consultation with a specialist physician for the treatment of HeFH and non-HF.

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3.2 Suggested additions are in italics and deletions are in strikethrough. Abridged versions of the relevant inclisiran listings are presented below.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INCLISIRAN					
inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe	14101E	1	1	1	Leqvio
Restriction Summary / Treatment of Concept:					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
	Administrative Advice: Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.				
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.				
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Administrative Advice: Special Pricing Arrangements apply.				
	Indication: Familial heterozygous hypercholesterolaemia				
	Treatment Phase: Initial treatment				
	Treatment criteria:				
	Must be treated by a specialist physician; or				
	Must be treated by a physician who has consulted a specialist physician				
	<i>Must be treated in consultation with a specialist physician</i>				
Restriction Summary / Treatment of Concept:					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
	Indication: Non-familial hypercholesterolaemia				
	Treatment Phase: Initial treatment				
	Treatment criteria:				
	Must be treated by a specialist physician; or				
	Must be treated by a physician who has consulted a specialist physician				
	<i>Must be treated in consultation with a specialist physician</i>				

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INCLISIRAN					
inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe	14087K	1	1	0	Leqvio
Restriction Summary / Treatment of Concept:					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new/existing code]					
	Administrative Advice: Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab. or alirocumab.				
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.				
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.				
	Administrative Advice: Special Pricing Arrangements apply.				
	Indication: Familial heterozygous hypercholesterolaemia				
	Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PSCK9) for this PBS indication				
	Clinical criteria:				
	Patient must have previously received PBS-subsidised treatment with this drug for this condition; or				
	Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication				
	AND				
	Clinical criteria:				
	The treatment must be in conjunction with dietary therapy and exercise				
	AND				
	Clinical criteria:				
	Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication				
	Treatment criteria:				
	<i>Must be treated by a medical practitioner; or</i>				
	<i>Must be treated by nurse practitioner in consultation with a specialist physician</i>				
Restriction Summary / Treatment of Concept:					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new/existing code]					
	Indication: Non-familial hypercholesterolaemia				

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	Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCK9) for this PBS indication
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition; or
	Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication
	AND
	Clinical criteria:
	The treatment must be in conjunction with dietary therapy and exercise
	AND
	Clinical criteria:
	Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication
	Treatment criteria:
	<i>Must be treated by a medical practitioner; or</i>
	<i>Must be treated by nurse practitioner in consultation with a specialist physician</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INCLISIRAN					
inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe	14152W	1	1	0	Leqvio

Restriction Summary / Treatment of Concept:

	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Administrative Advice: Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab, or alirocumab.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Indication: Familial heterozygous hypercholesterolaemia
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements
	Treatment criteria:
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician
	<i>Must be treated in consultation with a specialist physician</i>

Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Indication: Non-familial hypercholesterolaemia
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements
	Treatment criteria:
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician
	<i>Must be treated in consultation with a specialist physician</i>

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted and welcomed input from four health care professionals and two organisations via the Consumer Comments facility on the PBS website. The comments from health care professionals including NPs and an interventional cardiologist stated that there was little downside to allowing NPs to prescribe inclisiran given the need for patient access, noting that the indications are clearly outlined in the PBS restrictions, there are minimal contraindications and the side effect profile of inclisiran is favourable. The hearts4heart organisation noted that allowing NPs to prescribe inclisiran would optimise use of skilled healthcare workers to provide more efficient care and reduce the burden on doctors. The Heart Support Australia organisation noted that patients may face difficulties in obtaining GP and cardiologist appointments especially in rural and regional areas, and by allowing NPs to prescribe inclisiran, this would reduce the burden on primary care.

Basis of the request

- 4.3 The submission stated the proposed amendment to the listing of inclisiran would streamline patient's journey with hypercholesterolaemia, reduce health care utilisation costs and time commitment for patients, reduce cardiologist and GP appointments and administration, and provide continuity of care for patients with their NP.
- 4.4 The submission stated that in private settings such as GP and cardiologist clinics, NPs in consultation with the GP and cardiologist, are often the primary healthcare professional responsible for reducing the patient's LDL-C. However, NPs currently cannot issue prescriptions for the initiation or continuation of inclisiran treatment on

the PBS. If patients require treatment with inclisiran, the NP must refer the patient back to the GP where they are either prescribed inclisiran after consultation with a specialist physician, or they are referred by the GP directly to a cardiologist for treatment initiation.

- 4.5 The submission stated that, in public hospital settings, the management and reduction of cardiovascular (CV) risk factors are primarily managed by NPs for patients who have been hospitalised due to CV events as part of ongoing outpatient follow-up clinics for the first 12 months until their care is transferred back to a GP or cardiologist. NPs will review the patient's lipid medication and, if patients require treatment with inclisiran, the NP must then find a specialist physician, or another physician (in consultation with a specialist physician) to review the patient again in order to initiate treatment with inclisiran. The submission contended that this duplication of effort is inefficient, resulting in additional appointments and costs for the patient, and potential delay to treatment. Enabling NPs to prescribe inclisiran may consequently free up both cardiologist and GP time.
- 4.6 The pre-PBAC response reiterated that NPs play a vital role in the healthcare of patients with HeFH and non-FH and the requested change to allow NPs to initiate and continue treatment of inclisiran in consultation with a specialist physician supports the Nurse Practitioner Workforce Plan and the Department's review to enable NPs to utilise their specialist knowledge to prescribe to their full scope of practice.

Estimated PBS usage and financial implications

- 4.7 The submission stated HeFH and non-FH with ASCVD are well understood diseases with strict PBS and diagnostic criteria; thus, the amendment would not lead to an increase in prescribing of inclisiran. The submission anticipated there to be no change to the utilisation of inclisiran and therefore a nil financial impact to the PBS and RPBS.

5 PBAC Outcome

- 5.1 The PBAC recommended the amendment to the PBS listings of inclisiran to allow nurse practitioners (NPs) to initiate and continue treatment of inclisiran, in consultation with a specialist physician for the treatment of familial heterozygous hypercholesterolaemia (HeFH) and non-familial hypercholesterolaemia (non-FH).
- 5.2 The PBAC noted the submission did not propose any changes to the price of inclisiran and anticipated the proposed prescriber change will not lead to an increase in prescribing of inclisiran because HeFH and non-FH with atherosclerotic cardiovascular disease (ASCVD) are well understood diseases with strict PBS and diagnostic criteria.
- 5.3 The PBAC considered adding NPs as eligible prescribers to the PBS listings could potentially lead to an increase in the treated population initially due to improved access. However, it considered that the increase in utilisation would be expected to align with the intended population estimates when inclisiran was first listed for HeFH and non-FH. The PBAC further noted the risk sharing arrangements in place for

inclisiran. The PBAC therefore considered the change was likely to result in a nil financial impact to the PBS and RPBS.

- 5.4 The PBAC noted the submission’s proposed amendments to the listing of inclisiran would reduce the administrative burden for prescribers and patients receiving treatment under NP’s and provide continuity of care for patients with their NP.
- 5.5 The PBAC recommended the restriction changes to NP prescribing arrangements of inclisiran flow-on to evolocumab indicated for the treatment of HeFH and non-FH on the PBS. The PBAC noted alirocumab is not eligible for flow-on recommendations as it is currently in Supply Only until 1 February 2025 after which it will be delisted from the PBS.
- 5.6 The PBAC found 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 in the circumstances of its recommendation for amendment to the NP prescribing arrangements of inclisiran for the treatment of HeFH and non-FH, the amendment is not expected to address a high and urgent unmet clinical need.
- 5.7 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Amend Nurse Practitioner prescribing arrangements:

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INCLISIRAN					
inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe	14101E	1	1	1	Leqvio
Restriction Summary / Treatment of Concept:					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
	Administrative Advice: Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.				
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.				
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.				
	Administrative Advice:				

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	No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Indication: Familial heterozygous hypercholesterolaemia
	Treatment Phase: Initial treatment
	Treatment criteria:
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician
	<i>Must be treated in consultation with a specialist physician</i>
Restriction Summary / Treatment of Concept:	
)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Indication: Non-familial hypercholesterolaemia
	Treatment Phase: Initial treatment
	Treatment criteria:
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician
	<i>Must be treated in consultation with a specialist physician</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INCLISIRAN					
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Restriction Summary / Treatment of Concept:					
	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
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	Administrative Advice: Special Pricing Arrangements apply.				
	Indication: Familial heterozygous hypercholesterolaemia				

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	Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCK9) for this PBS indication
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition; or
	Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCK9) for this PBS indication
	AND
	Clinical criteria:
	The treatment must be in conjunction with dietary therapy and exercise
	AND
	Clinical criteria:
	Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCK9) for this PBS indication
	Treatment criteria:
	<i>Must be treated by a medical practitioner; or</i>
	<i>Must be treated by nurse practitioner in consultation with a specialist physician</i>
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new/existing code]
	Indication: Non-familial hypercholesterolaemia
	Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCK9) for this PBS indication
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition; or
	Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCK9) for this PBS indication
	AND
	Clinical criteria:
	The treatment must be in conjunction with dietary therapy and exercise
	AND
	Clinical criteria:
	Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCK9) for this PBS indication
	Treatment criteria:
	<i>Must be treated by a medical practitioner; or</i>
	<i>Must be treated by nurse practitioner in consultation with a specialist physician</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INCLISIRAN					
inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe	14152W	1	1	0	Leqvio

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Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Administrative Advice: Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.
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	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Indication: Familial heterozygous hypercholesterolaemia
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements
	Treatment criteria:
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician
	<i>Must be treated in consultation with a specialist physician</i>
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Indication: Non-familial hypercholesterolaemia
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements
	Treatment criteria:
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician
	<i>Must be treated in consultation with a specialist physician</i>

6.2 Flow on changes to the NP prescribing arrangements for the following items indicated for HeFH and non-FH:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
EVOLOCUMAB					
evolocumab 140 mg/mL injection, 1 mL pen device	11484K	2	2	5	Repatha
	11985T	2	2	5	
evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge	11485L	1	1	5	Repatha
	11986W	1	1	5	

6.3 Flow on changes for removal of alirocumab from the Administrative Advice (AA) 31785 will occur following the completion of alirocumab’s Supply Only period. This flow on change will be applied to all PBS items with AA 31785.

Administrative Advice: Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab .
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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.