PCSK9 Inhibitors — PBS Eligibility

Evolocumab, alirocumab & inclisiran; three pathways

PBS AUTHORITY

Three PCSK9-pathway agents are now PBS-listed. Evolocumab and alirocumab are monoclonal antibodies dosed fortnightly or monthly; inclisiran is an siRNA dosed twice-yearly after an initial booster. A GP can initiate in consultation with a specialist across three pathways — ASCVD, heterozygous FH, or homozygous FH. Eligibility thresholds have changed more than once since 2021 — confirm the exact current wording at pbs.gov.au before applying.

ELIGIBILITY — THE THREE PATHWAYS

✓ **Pathway 1 — ASCVD**	Established atherosclerotic cardiovascular disease (prior myocardial infarction, ischaemic stroke, coronary revascularisation, or symptomatic peripheral arterial disease) with LDL-C above the current PBS threshold despite maximally tolerated statin ± ezetimibe (or documented statin intolerance).
✓ **Pathway 2 — HeFH**	Confirmed heterozygous familial hypercholesterolaemia (Dutch Lipid Clinic Network Score, Simon Broome criteria, or a pathogenic LDLR/APOB/PCSK9 mutation). The LDL-C threshold differs depending on whether ASCVD is also present — the exact current figures for each are not reproduced here; confirm at pbs.gov.au.
✓ **Pathway 3 — HoFH**	Confirmed homozygous familial hypercholesterolaemia (genetic testing, or a high Dutch Lipid Clinic Network Score with consistent clinical features). No LDL-C threshold applies — managed with specialist input.
✓ **GP initiation**	A GP can initiate evolocumab or alirocumab in consultation with a specialist (cardiologist, endocrinologist or lipidologist); inclisiran follows a similar model, with specialist consultation required for the first prescription. Document the consultation in the notes.

WHICH PCSK9-PATHWAY AGENT

Agent	Mechanism & dosing	Initiation
Evolocumab (Repatha)	Monoclonal antibody; SC injection fortnightly or monthly	GP-initiable in consultation with a specialist
Alirocumab (Praluent)	Monoclonal antibody; SC injection fortnightly	Similar specialist-consultation model
Inclisiran (Leqvio)	siRNA; clinician-administered SC injection, twice-yearly after an initial booster dose	Specialist consultation required for the first prescription

■ SAFETY

- Confirm the patient doesn't have a secondary or reversible cause of hypercholesterolaemia (hypothyroidism, nephrotic syndrome, cholestasis) before committing to long-term PCSK9 inhibitor therapy
- Document specialist consultation and baseline LDL-C clearly — required for the PBS authority application
- PBS thresholds and restriction wording for this drug class have changed multiple times since 2021

◆ CHECK / EXCLUDE

- Confirm current LDL-C thresholds and HeFH scoring requirements at pbs.gov.au — exact figures for each pathway are not reproduced on this sheet
- Confirm adequate statin trial (or documented intolerance to ≥2 statins) is recorded
- See CV-03B for the authority process, dosing and monitoring