PCSK9 Inhibitors — Authority & Monitoring

Streamlined continuing authority since Jul 2024

PBS AUTHORITY

Continuing PCSK9 inhibitor treatment now uses a streamlined authority (no phone call) once an adequate LDL-C response is documented, following the listing change effective 1 July 2024. No routine LFT or CK monitoring is needed — check LDL-C at 4–6 weeks after starting, then 3–6 monthly.

AUTHORITY PROCESS

✓ **Initial treatment**	Apply via PBS Online (real-time) or telephone authority. Document the ASCVD/FH diagnosis, baseline LDL-C, statin dose and duration (or documented intolerance), ezetimibe use, and the specialist consultation details.
✓ **Continuing treatment**	A streamlined authority applies (no phone call) once an adequate LDL-C response is documented — confirm the exact current wording and response threshold at pbs.gov.au, as the listing was last revised effective 1 July 2024.

DOSING ACROSS THE CLASS

Agent	Usual dosing	Practical notes
Evolocumab	140mg SC fortnightly, or 420mg SC monthly	Self-administered; rotate injection sites; allow to reach room temperature before injecting
Alirocumab	75mg or 150mg SC fortnightly, per response	Self-administered; similar storage and site-rotation advice
Inclisiran	284mg SC at baseline, 3 months, then 6-monthly	Administered by a clinician — reduces the adherence burden of self-injection

LDL TARGETS & MONITORING

Very-high-risk ASCVD: LDL-C<1.4mmol/L and ≥50% reduction from baseline (or <1.8mmol/L if a lower target isn't achievable), per the ESC/EAS 2025 focused update (numeric targets unchanged from 2019). HeFH without ASCVD: target <2.5mmol/L. Most patients on a PCSK9 inhibitor reach LDL-C<1.0mmol/L, with no lower safety threshold identified to date. Check LDL-C at 4–6 weeks to confirm an adequate response (needed for the continuing authority), then 3–6 monthly; no routine LFT or CK monitoring is required for any of the three agents.

■ SAFETY

- Injection-site reactions are the most common side effect with evolocumab/alirocumab — usually mild redness, itching or swelling, not associated with serious allergy in trials
- No myopathy or hepatotoxicity signal with any PCSK9-pathway agent — a useful option in statin-intolerant patients
- Very low LDL-C appears safe in long-term follow-up, with no excess cognitive, neurological or adrenal effects identified to date

◆ CHECK / EXCLUDE

- Inadequate response → confirm adherence and injection technique before assuming treatment failure
- Consider one-off Lp(a) testing when assessing residual cardiovascular risk, per the ESC/EAS 2025 update
- See CV-03A for eligibility pathways and the agent comparison