Checklist for seeking approval for a PCSK9 inhibitor

Checklist (what to put in your office note)

☐ **Indication and documentation of patient’s medical conditions and need**
  1. Clinical atherosclerotic cardiovascular disease (ASCVD) (coronary artery disease, acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease)
  2. Patients with LDL-C > 190 mg/dL, including familial hypercholesterolemia (FH - heterozygous or homozygous)
  3. These two patient groups should be on maximally tolerated statin therapy and in need of additional LDL-C lowering (to achieve goals listed below)

☐ **A recent lipid panel (< 30 days old)**

☐ **FH Documentation:** For patients with presumed FH, include documentation of all supporting elements including history of low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL, family history of first-degree relatives with premature ASCVD or elevated LDL-C, presence of tendon xanthomas or corneal arcus (≤ age 45), presence of premature ASCVD (men age ≤ 50, women age ≤ 60), or positive genetic testing indicating functional mutation (LDL receptor, apolipoprotein B, or proprotein convertase subtilisin/kexin type 9 [PCSK9]). *Always document pre-treatment LDL-C when available.*

☐ **Statin History:** Documentation of reasons patient is not on a high intensity statin, such as statin intolerance, (e.g., presence of intolerable symptoms such as muscle pain or muscle weakness) as well as the number of statins failed, including dosages and dates used.

☐ **LDL-C Goal:** Comment that the patient is not at LDL-C goal despite maximally tolerated statin therapy and specify the goal level, (e.g., < 100 mg/dL for FH without ASCVD and < 70 mg/dL for those with ASCVD). ¹ ² Alternatively, comment that patient did not achieve a ≥ 50% LDL-C reduction on maximally tolerated statin therapy with or without adjunctive therapy.

☐ **Adjunctive Therapy:** Document use of adjunctive non-statin lipid lowering therapy such as ezetimibe, bile acid sequestrant, niacin, or the use of intensive lifestyle counseling with a registered dietitian/nutritionist.

**Document, document, document, and do not give up!**


---

*This information is provided courtesy of the National Lipid Association. The checklist is based on guidance from responses received from the NLA “Challenges in Prescribing PCSK9 Inhibitors Survey.” The NLA does not guarantee any approval results. The NLA is not liable for any use of this information. Use of this checklist is at the individual user’s own risk.*