

Hypercholesterolemia Prior Authorization Guidelines

In general, the following criteria needs to be met to obtain a prior authorization approval for PCSK9 Inhibitors (Praluent® and Repatha®):

- ❑ Prescribers must be specialized in Cardiology or Lipidology; payors may potentially reject the prior authorization request if the prescribing physician is not a specialist
- ❑ Patient must have one of the following FDA-Approved Diagnoses:
 - a. Heterozygous Hypercholesterolemia (must provide documentation of genetic testing)
 - b. Homozygous Hypercholesterolemia (must provide documentation of genetic testing)
 - c. Hyperlipidemia with Atherosclerotic Cardiovascular Disease (ASCVD)- as indicated by one of the following:
 - Acute Coronary Syndrome
 - History of Myocardial Infarction
 - Stable or unstable Angina
 - Coronary or other arterial revascularization (CABG, etc.)
 - History of Stroke
 - Transient Ischemic Attack (TIA)
 - Peripheral arterial disease presumed to be of atherosclerotic origin
- ❑ Documentation of the patient's cardiac risk factors describing a categorization of ASCVD (Arteriosclerotic Cardiovascular Disease). Examples may include: Previous Stroke or TIA (Transient Ischemic Attack); PAD (Peripheral artery disease), CAD (Coronary artery disease)
- ❑ Documentation is required of prior failed therapies, specifically of treatment failure with at least **two high intensity statins** (Crestor 20mg or greater and Lipitor 40mg or greater) in combination with **Zetia 10mg**. Please specify if the patient has tried and failed therapy (was unable to meet LDL-C goal) or experienced an intolerance (myalgias, myopathy, rhabdomyolysis) to statin therapy. If the patient is contraindicated to therapy with statins and, or Zetia, please specify the reason (hepatotoxicity, etc.).
- ❑ Prescribers must include all relevant lab work and a full lipid panel within **30-90 day**. for any renewal authorization, there must be updated lab results that indicate a positive response to therapy.

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