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**Office of Pharmacy Services
Prior Authorization Criteria
Effective 11/13/2024
PCSK9 INHIBITORS
PRALUENT®(alirocumab) & REPATHA® (evolocumab)**

Prior Authorization Request Form

REPATHA is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated for:

- **Atherosclerotic cardiovascular disease, primary prevention:** Adjunct to diet, alone or in combination with other lipid-lowering therapies (eg, maximally tolerated statin), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein-cholesterol (LDL-C).
- **Atherosclerotic cardiovascular disease, secondary prevention:** To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease. **Note:** Use in combination with an optimized regimen of lipid-lowering therapy (eg, high-intensity statin).
- **Familial hypercholesterolemia, heterozygous:** Adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., maximally tolerated statin) for the treatment of adults to reduce LDL-C; adjunct to diet and other lipid-lowering therapies for the treatment of pediatric patients ≥10 years of age to reduce LDL-C.
- **Familial hypercholesterolemia, homozygous:** Adjunct to other lipid-lowering therapies in pediatric patients ≥10 years of age and adults for the treatment of patients with homozygous familial hypercholesterolemia who require additional lowering of LDL-C.

PRALUENT is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- as adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C.

CRITERIA FOR APPROVAL:

- 1) Patient must meet all age and indication restrictions imposed by the current FDA-approved label;
AND
- 2) Documentation must be submitted indicating that the patient failed to reach an LDL<70 mg/dL and the goal LDL-C as set by the prescriber after an 8-week trial of either **atorvastatin 40 - 80 mg** OR **rosuvastatin 20 - 40 mg**. Note: If the patient failed to tolerate the first statin, then they must be trialed on the second statin for 8-weeks or until intolerance occurs.

Initial approval will be for 90 days.



CONTINUATION OF THERAPY CRITERIA:

- 1) Patient continues to meet all initial approval criteria; **AND**
- 2) Demonstrate continued documented compliance; **AND**
- 3) Documentation is provided showing efficacy as supported by at least a 40% in LDL-C reduction compared to pre-treatment levels.

