STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Alex J. Mayer
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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**.**