



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Services  
Prior Authorization Criteria

PCSK9 INHIBITORS  
PRALUENT<sup>®</sup>(alirocumab) & REPATHA<sup>®</sup>(evolocumab)  
Effective 11/15/2023

[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  $\geq 10$  years of age to reduce LDL-C.
- **Familial hypercholesterolemia, homozygous:** Adjunct to other lipid-lowering therapies in pediatric patients  $\geq 10$  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 goal LDL-C 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**.

Additional coverage may be granted with documentation of efficacy supported by at least a **40% LDL-C** reduction from pre-treatment level. Maintenance therapy may be requested by any willing prescriber.

**REFERENCES:**

- 1) Repatha package insert revised 2/2019, 11/2023.; Praluent package insert revised 4/2019, 11/2023
- 2) Lexi-Comp Clinical Application reviewed 5/02/2019
- 3) American Academy of Cardiology 2018 Guideline on the Management of Blood Cholesterol (updated June 2019)
- 4) AACE 2017 Guidelines: American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease. Endocrine Practice Vol 23 (Suppl 2) April 2017.



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- 5) *UpToDate* clinical article: Management of low density lipoprotein cholesterol (LDL-C) in secondary prevention of cardiovascular disease (last update 7-25-2017)
- 6) Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; N Engl J Med 2017; 376:1713-1722  
Stone, N. J., Robinson, J., Lichtenstein, A. H., et al. 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Retrieved from: <http://circ.ahajournals.org>.
- 7) Goldberg, A. C., Hopkins, P. N., Toth, P. P., et al. Familial hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J. of Clinical Lipidology* 2011 Volume 5, Number 3S.
- 8) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. *Diabetes Metab Syndr Obes*. 2011; 4: 155–166.
- 9) Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2022.