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

Office of Pharmacy Service
Prior Authorization Criteria

PCSK9 INHIBITORS
PRALUENT®(alirocumab), REPATHA® (evolocumab)
Effective 11/21/2019

Prior Authorization Request Form

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

- *to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.*
- *as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C).*
- *as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) 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) Must be prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist; **AND**

2) Patient must meet all age and indication restrictions imposed by the current FDA-approved label; **AND**

3) Documentation must be submitted indicating that the patient failed to reach an LDL<70 mg/dL after an 8-week trial of either **atorvastatin 40 - 80 mg + ezetimibe** OR **rosuvastatin 20 - 40 mg + ezetimibe.** Note: If the patient failed to tolerate the first statin/ezetimibe combination, then they must be trialed on the second combination for 8-weeks or until intolerance occurs.

CRITERIA FOR CONTINUATION

Initial approval is for 90 days and documentation of efficacy must be supported by at least a 40% LDL-C reduction from pre-treatment level.

REFERENCES

1) Repatha package insert revised 2/2019
2) Praulent package insert revised 4/2019
3) Lexi-Comp Clinical Application reviewed 5/02/2019
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.
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
7) 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.
8) 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.
9) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. Diabetes Metab Syndr Obes. 2011; 4: 155–166.