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

Office of Pharmacy Service
Prior Authorization Criteria

PRALUENT®
(alirocumab)
Prior Authorization Request Form

Praluent® is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C).

Criteria for Approval

1) Individual is 18 years or older; **AND**

2) Must be prescribed by or in consultation with a cardiologist or lipid specialist; **AND**

3) Presence of causal mutation for familial hypercholesterolemia by genetic testing; **OR** Definitive clinical evidence supporting the diagnosis of familial hypercholesterolemia (documentation must be provided); **OR**

4) The patient must have a documented diagnosis of ASCVD[1] and an LDL of at least 130 mg/dL while on a regimen consisting of a high-intensity statin therapy (at the maximally tolerated dose) in combination with Zetia. **AND**

5) Documentation indicating that treatment with at least two 12-week trials of different high-intensity statins used concomitantly with ezetimibe (Zetia) has been ineffective. Adherence to the current statin regimen must be evidenced by consistent pharmacy claims; **AND**

6) The patient will be using Praluent concomitantly with a maximally-tolerated statin

[1]Diagnosis of ASCVD is defined as one of the following: acute coronary syndrome, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin.

Criteria for Continuation

1) Hypercholesterolemia, ASCVD: Documentation that LDL-C < 100 mg/dL or there has been at least a 40% LDL-C reduction from pre-treatment level; **AND**
2) Documentation that the member has been adherent to treatment with statin and PCSK9 inhibitor as demonstrated by consistent pharmacy claims.

References

1) Praluent package insert revised 7/2015
2) Lexi-Comp Clinical Application 09/18/2015
3) *Recommendation for the ASCVD LDL cutoff was derived from direct communication with Dr. Joseph Saheen at the 2016 ADURs conference in Scottsdale, AZ.*
4) 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.
5) 2. 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.