UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3067-7
Program	Step Therapy
Medications	Praluent™ (alirocumab)
P&T Approval Date	1/2016, 4/2018, 3/2019, 3/2020, 4/2020
Effective Date	7/1/2020; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member with a diagnosis of primary hyperlipidemia, heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD) that require additional lowering of low density lipoprotein cholesterol (LDL-C) with a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor to document the trial of maximally tolerated statin therapy prior to the use of Praluent™ (alirocumab).

Praluent (alirocumab) is a PCSK9 inhibitor antibody indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease, and as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C). [1]

Members will be required to meet the coverage criteria below. Members, who have received Praluent in the past 60 days as documented in claims history, will be allowed continued coverage of their current therapy.

2. Coverage Criteria[a]:

A. Hyperlipidemia

1. Praluent will be approved based on **all** of the following criteria:

a. Diagnosis of **one** of the following:

(1) Primary hyperlipidemia

(2) Heterozygous familial hypercholesterolemia

(3) Atherosclerotic cardiovascular disease

-AND-

b. **One** of the following:

(1) Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy and will continue to receive high-intensity statin [i.e., atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at maximally tolerated dose

-OR-

(2) **Both** of the following:

(a) Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:
- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-AND-

(b) **One** of the following:

i. Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin therapy and will continue to receive a moderate-intensity statin [i.e., atorvastatin 10-20 mg, Crestor (rosuvastatin) 5-10 mg, simvastatin ≥ 20 mg, pravastatin ≥ 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) ≥ 2 mg] at maximally tolerated dose

-OR-

ii. Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy and will continue to receive a low-intensity statin [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] at maximally tolerated dose

-OR-

(3) Patient is unable to tolerate **low or moderate-, and high-intensity statins** as evidenced by **one** of the following:

(a) One of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:
- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations < 10 times upper

limit of normal [ULN])

-OR-

(b) Patient has a labeled contraindication to all statins

-OR-

(c) Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN

-AND-

c. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Authorization will be issued for 12 months.

B. <u>Other Diagnoses</u>

1. Praluent will be approved

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity, Notification, and/or Supply limits may be in place.

4. References:

1. Praluent [package insert]. Tarrytown, NY/Bridgewater, NJ : Regeneron pharmaceuticals/ sanofiaventis U.S. LLC ; April 2019.
2. Lloyd-Jones D, Morris P, Ballantyne C, et al. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholersterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2016;68:92-125.
3. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American association of clinical endocrinologists and American college of endocrinology guidelines for management

of dyslipidemia and prevention of cardiovascular disease. Endocr Pract. 2017; Suppl 2;23:1-87.
4. Lloyd-Jones D, Morris P, Ballantyne C, et al. 2017 Focused update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholersterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017; DOI: 10.1016/j.jacc.2017.07.745.
Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2018; DOI: 10.1161/CIR.0000000000000625.

Program	Step Therapy- Praluent™ (alirocumab)
Change Control	
1/2016	New program.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
4/2018	Updated background and coverage criteria to include coverage for patients with primary hyperlipidemia. Modified previous statin requirement requiring failure, intolerance to high intensity and either moderate or low intensity statin. Removed Zetia trial requirement. Added physician attestation criterion. Updated state mandate verbiage. Updated references.
3/2019	Annual review with no changed to coverage criteria. Updated references.
3/2020	Annual review with no change to clinical coverage criteria. Updated reference.
4/2020	Updated program to include 60 day claim lookback period for continuation of coverage.