UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3067-12
Program	Step Therapy
Medications	Praluent® (alirocumab)*
P&T Approval Date	1/2016, 4/2018, 3/2019, 3/2020, 4/2020, 6/2021, 6/2022, 6/2023, 10/2023, 5/2024
Effective Date	8/1/2024

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 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, alone or in combination with other LDL-C-lowering therapies, for the treatment of adults with primary hyperlipidemia, including HeFH, to reduce LDL-C. Also, it is indicated as an adjunct to other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in adult patients with HoFH who require additional lowering of LDL-C and as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C.[1]

Members will be required to meet the coverage criteria below.

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 (ASCVD) (e.g., acute coronary syndromes, 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)

-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, rosuvastatin (Crestor) 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 creatine kinase (CK) elevations]
- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-AND-

(b) Patient has been receiving at least 12 consecutive weeks of **low-intensity or moderate-intensity** statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-intensity statin 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. **One** of the following:

(1) Patient is less than 10 years of age

-OR-

(2) History of failure, contraindication, or intolerance to Repatha (evolocumab) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

Authorization will be issued for 12 months.

B. Homozygous Familial Hypercholesterolemia

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

   a. Diagnosis of homozygous familial hypercholesterolemia (HoFH)

   -AND-

   b. History of failure, contraindication, or intolerance to Repatha (evolocumab) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

Authorization will be issued for 12 months.

C. Other Diagnoses

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

*Praluent is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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: Regeneron Pharmaceuticals, Inc.; March 2024.
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-cholesterol 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-cholesterol lowering

in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017; DOI: 10.1016/j.jacc.2017.07.745.
5. 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.000000000000625.

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.
6/2021	Annual review. Updated language in background to match package insert. Removed 60-day claim lookback period for continuation of coverage. Added HoFH step criteria. Added Repatha step through criteria. Added Praluent exclusion statement. Updated references.
6/2022	Annual review. Added examples of ASCVD. Modified examples of moderate and low intensity statin therapy per American College of Cardiology/American Heart Association Clinical Practice Guidelines. Condensed low intensity and moderate-intensity statin therapy sections. Updated exclusion statement and references.
6/2023	Annual review. Updated background.
10/2023	Removed “routine audit” language from criteria. Updated background.
5/2024	Added criterion for patients less than 10 years of age to align with new label for pediatric patients aged 8 years and older with HeFH. Updated background and reference.