UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1166-11
Program	Prior Authorization/Notification
Medication	Praluent® (alirocumab)*
P&T Approval Date	8/2015, 7/2016, 7/2017, 7/2018, 7/2019, 7/2020, 6/2021, 6/2022, 6/2023, 2/2024, 5/2024
Effective Date	8/1/2024

1. Background:

Praluent (alirocumab) is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated[1]:

- 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 low-density lipoprotein cholesterol (LDL-C)-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C.
- As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
- 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.

2. Coverage Criteria[a]:

A. **Hyperlipidemia**

1. **Initial Authorization**

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

(1) **One** of the following diagnoses:

(a) Primary hyperlipidemia

-OR-

(b) Heterozygous familial hypercholesterolemia (HeFH)

-OR-

(c) 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-

(2) Patient has received comprehensive counseling regarding appropriate diet

-AND-

(3) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

-AND-

(4) Not used in combination with Leqvio (inclisiran)

Authorization will be issued for 12 months

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Praluent* therapy

-AND-

(2) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

-AND-

(3) Not used in combination with Leqvio (inclisiran)

Authorization will be issued for 12 months

B. **Homozygous Familial Hypercholesterolemia**

1. **Initial Authorization**

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

(1) Diagnosis of homozygous familial hypercholesterolemia

-AND-

(2) Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

-AND-

(3) Patient has received comprehensive counseling regarding appropriate diet

-AND-

(4) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

-AND-

(5) Not used in combination with Juxtapid (lomitapide)

Authorization will be issued for 12 months

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Praluent* therapy

-AND-

(2) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

-AND-

(3) Not used in combination with Juxtapid (lomitapide)

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, Supply Limits and Step Therapy may be in place.

4. References:

1. Praluent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals; March 2024.

Program	Prior Authorization/Notification – Praluent® (alirocumab)
Change Control	
8/2015	New program.
7/2016	Annual Review. Updated reference.
7/2017	Annual review with no changes to coverage criteria. Updated reference.
7/2018	Annual review with no changes to coverage criteria. Updated reference.

7/2019	Annual review. Updated background and criteria aligning with new label for the prevention of cardiovascular events in patients with established ASCVD and in patients with primary hyperlipidemia alone or in combination with other therapies. Updated reference.
7/2020	Annual review with no changes to coverage intent. Changed initial authorization to 12 months. Updated reference.
6/2021	Annual review. Updated background and added criteria to align with new label for homozygous familial hypercholesterolemia. Added Praluent exclusion statement. Updated references.
6/2022	Annual review with no changes to coverage criteria. Added state mandate footnote and updated exclusion statement.
6/2023	Annual review. Updated background. Added criteria that Praluent is not to be used in combination with Leqvio.
2/2024	Simplified reauthorization criteria.
5/2024	Updated background to align with new label for pediatric patients aged 8 years and older with HeFH. Updated reference.