

### Clinical Pharmacy Program Guidelines for Praluent

Program	Prior Authorization
Medication	Praluent (alirocumab)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Rhode Island, Pennsylvania CHIP, South Carolina
Issue Date	5/2015
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

#### 1. Background:

Praluent™ (alirocumab) 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).

No coverage of Praluent will be provided for the primary prevention of cardiovascular events and/or for the lowering of low-density lipoprotein cholesterol in patients with primary hyperlipidemia who do not have heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease (ASCVD) as the use of PCSK9 inhibitors in this population is not supported by the 2018 American College of Cardiology/ American Heart Association Cholesterol Clinical Practice Guidelines.

#### 2. Coverage Criteria:

##### **A. Hyperlipidemia**

##### **1. Initial Therapy**

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

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

(a) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by **one** of the following\*:

i. **Both** of the following:

1. Pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age)

**-AND-**

2. **One** of the following:

- a. Family history of myocardial infarction in first-degree relative < 60 years of age
- b. Family history of myocardial infarction in second-degree relative < 50 years of age
- c. Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- d. Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
- e. Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative

**-OR-**

ii. **Both** of the following:

1. Pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age)

**-AND-**

2. Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following:

- a. Functional mutation in LDL, apoB, or PCSK9 gene\*
- b. Tendinous xanthomata
- c. Arcus cornealis before age 45

**-OR-**

(b) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by **one** of the following:

i. Acute coronary syndromes

- ii. History of myocardial infarction
- iii. Stable or unstable angina
- iv. Coronary or other arterial revascularization
- v. Stroke
- vi. Transient ischemic attack
- vii. Peripheral arterial disease presumed to be of atherosclerotic origin

**-AND-**

- (2) Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

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

**-OR-**

- (b) **Both** of the following:

- i. 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-**

- ii. **One** of the following:

- a. Patient has been receiving at least 12 consecutive weeks of **moderate-intensity statin** [i.e. atorvastatin 10-20 mg, 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] and will continue to receive a moderate-intensity statin at maximally tolerated dose

**-OR-**

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

**-OR-**

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

i. **One** of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

1. Myalgia (muscle symptoms without CK elevations)
2. Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

**-OR-**

ii. Patient has a labeled contraindication to all statins as documented in medical records

**-OR-**

iii. Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN

**-AND-**

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

(a) Submission of medical records (e.g., laboratory values) documenting **one** of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- i. LDL-C  $\geq$  100 mg/dL with ASCVD
- ii. LDL-C  $\geq$  130 mg/dL without ASCVD

**-OR-**

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

- i. Submission of medical records (e.g., laboratory values) documenting **one** of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

1. LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
2. LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

**-AND-**

- ii. Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

1. Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia<sup>®</sup>) therapy as adjunct to maximally tolerated statin therapy

**-OR-**

2. Patient has a history of contraindication or intolerance to ezetimibe

**-AND-**

- (4) Used as an adjunct to a low-fat diet and exercise

**-AND-**

- (5) Prescribed by **one** of the following:

- (a) Cardiologist
- (b) Endocrinologist
- (c) Lipid specialist

**-AND-**

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

**-AND-**

(7) 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.

\*Results of prior genetic testing can be submitted as confirmation of diagnosis of HeFH, however please note that UnitedHealthcare does not currently cover genetic testing for evidence of an LDL-receptor mutation, familial defective apo B-100 or a PCSK9 mutation.

**Authorization will be issued for 12 months**

**2. Reauthorization**

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

(1) Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

**-AND-**

(2) Patient is continuing a low-fat diet and exercise regimen

**-AND-**

(3) Prescribed by **one** of the following:

- (a) Cardiologist
- (b) Endocrinologist
- (c) Lipid specialist

**-AND-**

(4) Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C reduction while on Praluent therapy

**-AND-**

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

**-AND-**

(6) 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**

### 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.
- Supply limits may be in place.

### 4. References:

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13. 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.
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17. 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.

Program	Prior Authorization - Praluent™ (alirocumab)
<b>Change Control</b>	
Date	Change
5/2015	New program
5/2015	Added examples of atherosclerotic cardiovascular disease
8/2015	Revised clinical criteria
9/2015	Revised clinical criteria to include combination use of high-intensity statin or documented intolerance to high-, moderate- and low intensity statin therapy to achieve the maximally tolerated statin therapy.
9/2016	Annual review. Updated references and policy template.
12/2016	Modified medical record criteria to include review of prescription claims history. Updated references.
3/2017	Changed initial authorization duration to 12 months
11/2017	Updated medical record requirement, modified criteria for HeFH diagnosis, modified previous statin requirement requiring failure, intolerance to high intensity and either moderate or low intensity statin. Modified target LDL values and ezetimibe trial requirement. Extended timeline for lipid panel submission to 120 days. Added physician attestation criterion. Updated references.
11/2018	Annual review. No changes to clinical content. Updated references.



12/2019	Annual review. Updated background information without changes to clinical coverage criteria. Updated references.
2/2020	Updated criteria to provide clarity on laboratory monitoring requirements and PCSK9 therapy.
2/2021	Annual review with no change to coverage criteria. Updated reference.