UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2015 P 2062-1
Program	Prior Authorization/Medical Necessity
Medication	Praluent™ (alirocumab)
P&T Approval Date	5/2015
Effective Date	7/27/2015; Oxford only: 7/27/2015

1. Background:

Praluent™ (alirocumab) 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, who require additional lowering of LDL-cholesterol (LDL-C).

2. Coverage Criteria:

A. **Primary Hyperlipidemia**

1. **Initial Therapy**

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

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

a. Heterozygous familial hypercholesterolemia

-OR-

b. Atherosclerotic cardiovascular disease

-AND-

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

a. Patient is currently receiving and will continue to receive high-intensity statin [i.e. atorvastatin, Crestor (rosuvastatin)] at maximally tolerated dose

-OR-

b. If unable to tolerate high-intensity statin, patient is receiving or will continue to receive low- or moderate-intensity statin (e.g., simvastatin, pravastatin) at maximally tolerated dose

-AND-

(3) Submission of medical record (e.g., laboratory values) documenting **one** of the following LDL-C values while adherent to the current statin therapy for at least 8 consecutive weeks:

a. LDL-C greater than 130 mg/dL with atherosclerotic cardiovascular disease

-OR-

b. LDL-C greater than 160 mg/dL without atherosclerotic cardiovascular disease

-AND-

(4) Patient has received comprehensive counseling regarding appropriate diet

-AND-

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

(a) a. Cardiologist

(b) b. Endocrinologist

(c) c. Lipid specialist

2. **Reauthorization**

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

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

(a) a. Patient continues to receive high-intensity statin [i.e. atorvastatin, Crestor (rosuvastatin)] at maximally tolerated dose

-OR-

(b) b. If unable to tolerate high-intensity statin, patient continues to receive low- or moderate-intensity statin (e.g. simvastatin, pravastatin) at maximally tolerated dose

-AND-

(2) Patient continues to receive comprehensive counseling regarding appropriate diet

-AND-

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

(a) a. Cardiologist

(b) b. Endocrinologist

(c) c. Lipid specialist

-AND-

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

Authorization will be issued for 12 months

3. Additional Clinical Rules:

Supply Limits and Step Therapy may be in place.

4. References:

1. Praluent [package insert]. Tarrytown, NY/Bridgewater, NJ : Regeneron Pharmaceuticals/sanofi-aventis U.S. LLC ; July 2015

Program	Prior Authorization/Medical Necessity - Praluent™ (alirocumab)
Change Control	
5/2015	New program.