Commercial/Healthcare Exchange PA Criteria

Effective: May 4, 2016

Prior Authorization: Praluent (alirocumab)

Products Affected:
Praluent (alirocumab) Subcutaneous Solution (Prefilled Syringe)

Medication Description:

Praluent is a monoclonal antibody that inhibits the binding of Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) to low-density lipoprotein receptors (LDLRs) on hepatocytes, thus reducing degradation of the LDLR. Increased LDLRs are then available to clear LDL-C from circulation and lower LDL-C levels.

Praluent is indicated as an 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-C.

Covered Uses:

- Hyperlipidemia in Patients with Clinical Atherosclerotic Cardiovascular Disease (ASCVD)
- Heterozygous Familial Hypercholesterolemia (HeFH)

Exclusion Criteria:

Praluent has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Concurrent use of Praluent with Repatha (evolocumab injection for SC use), Juxtapid (lomitapide capsules) or Kynamro (mipomersen injection). Repatha is another PCSK9 inhibitor and should not be used with Praluent. Both Juxtapid and Kynamro are indicated as an adjunct to lipid-lowering medications and diet to modify lipid parameters (e.g., reduce LDL-C levels) in patients with HoFH. The efficacy and safety of Repatha, Juxtapid and Kynamro in combination with Praluent have not been established.
2. Coverage is not recommended for circumstances not listed in the **"Other Criteria"**. Criteria will be updated as new published data are available.

Required Medical Information

- Diagnosis
- Current LDL-C (within the past 90 days)
- Previous trial of high dose statins
    - rosuvastatin 40mg and atorvastatin 80mg
- Confirmation that a medication reconciliation has been performed, by the prescriber, to identify any potential drug interactions that could cause elevated statin levels

Age Restrictions:

1. **Heterozygous Familial Hypercholesterolemia (HeFH)**
    - The patient is aged ≥ 18 years
2. **Hyperlipidemia in Patients with Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**
    - The patient is aged ≥ 18 years

Prescriber Restrictions: Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders.

Coverage Duration:

- Initial Prior Authorization: 12 weeks
- Continuation of Therapy: 12 months

Other Criteria:

1. **Hyperlipidemia in Patients with Clinical Atherosclerotic Cardiovascular Disease (ASCVD).***
   Approve Praluent if the patient meets the following criteria (A, B, C, D and E):
   A) The patient is aged ≥ 18 years; **AND**
   B) The patient meets the following criteria (i and ii):
      i. The patient has a current low-density lipoprotein cholesterol (LDL-C) level ≥ 70 mg/dL within the past 90 days (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy such as Repatha) [documentation required]; **AND**
      ii. The patient has had one of the following conditions or diagnoses (a, b, c, d, or e):
         a) The patient has had a previous myocardial infarction (MI) or has a history of an acute coronary syndrome (ACS) [documentation required]; **OR**
         b) The patient has a diagnosis of angina (stable or unstable) [documentation required]; **OR**
         c) The patient has a past history of stroke or transient ischemic attack (TIA) [documentation required]; **OR**
         d) The patient has peripheral arterial disease (PAD) [documentation required]; **OR**
         e) The patient has undergone a coronary or other arterial revascularization procedure in the past (e.g., coronary artery bypass graft [CABG], percutaneous coronary intervention [PCI], angioplasty, coronary stent procedure) [documentation required]; **AND**
   C) The patient meets one of the following criteria (i or ii):
      i. The patient has tried 2 high-intensity statin therapies (i.e., atorvastatin 80 mg daily AND rosuvastatin 40 mg daily) for 8-12 continuous weeks [documentation required]; **AND** the LDL-C level remains ≥ 70 mg/dL [documentation required]; **OR**
      ii. The patient has been determined to be statin intolerant by meeting one of the following criteria (a or b):
         a) The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, acute renal failure and/or elevated creatine kinase [CK] levels [e.g., greater or equal to 10 times the upper limit of normal]) [documentation required]; **OR**
         b) The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria [(1) and (2)]:

            (1) The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) [documentation required]; **AND**
            (2) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); **AND**

D) Praluent is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders; **AND**

E) If able to tolerate statins, the patient continues to receive the maximum tolerated dose of a statin while receiving Praluent therapy.

2. Heterozygous Familial Hypercholesterolemia [HeFH].[†*]

Approve Praluent if the patient meets the following criteria (A, B, C, D and E):

A) The patient is aged ≥ 18 years; **AND**

B) The patient meets the following criteria (i and ii):

- **i.** The patient has a current low-density lipoprotein cholesterol (LDL-C) level ≥ 100 mg/dL within the past 90 days; **AND**
- **ii.** The patient's diagnosis of HeFH is defined by WHO/Dutch Lipid group criteria **OR** Simon-Broome Criteria **OR** genetic testing; **AND**

C) The patient meets one of the following criteria (i or ii):

- **i.** The patient has tried 2 high-intensity statin therapies (i.e., atorvastatin 80 mg daily AND rosuvastatin 40 mg daily) for 8-12 continuous weeks [documentation required]; **AND** the LDL-C level remains ≥ 100 mg/dL [documentation required]; **OR**
- **ii.** The patient has been determined to be statin intolerant by meeting one of the following criteria (a or b):
  - **a)** The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, acute renal failure and/or elevated creatine kinase [CK] levels [e.g., greater or equal to 10 times the upper limit of normal]) [documentation required]; **OR**
  - **b)** The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria [(1) and (2)]:
    - **(1)** The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) [documentation required]; **AND**
    - **(2)** When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); **AND**

D) Praluent is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders.

Renewal Criteria:

1. Hyperlipidemia in Patients with Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

- Lipid panel showing ≥ 40% reduction in LDL-C from baseline.
- Continued adherence to maximally tolerated statin dose.

2. Heterozygous Familial Hypercholesterolemia [HeFH]

- Lipid panel showing ≥ 40% reduction in LDL-C from baseline.
- Continued adherence to maximally tolerated statin dose.

References:

1. Praluent (alirocumab) [package insert]. Sanofi-Aventis U.S LLC; Bridgewater (NJ): July 2015
2. Mozaffarian D, et al. Heart disease and stroke statistics--2015 update: a report from the American Heart Association. Circulation. 2015 Jan 27;131(4):e29-322. doi: 10.1161/CIR.0000000000000152. Epub 2014 Dec 17.
3. Rosenson RS, et al.. Inherited disorders of LDL-cholesterol metabolism In: UpToDate, Saperia GM (Ed), UpToDate, Waltham, MA. (Accessed on Sept 9, 2015.)
4. Ferranti et al. What is the prevalence of familial hypercholesterolemia in the US? AHA 2014; 130(A19656)
5. Stone NJ, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation, 2014; 129(25 Suppl 2): S1-45.
6. Jacobson et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: Part 1 – executive
7. summary. Journal of Clinical Lipidology. 2014. Available from: http://www.sciencedirect.com/science/article/pii/S1933287414002748.
8. FDA Briefing Information: Alirocumab Injection. The Endocrinologic and MetabolicDrugs Advisory Committee Meeting. FDA Center for Drug Evaluation and Research.2015 June 9. Available fromhttp://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM449865.pdf.
9. Cannon CP. Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. NEJM. 2015 June 18.
10. Repatha (evolocumab) [package insert]. Amgen Inc.; Thousand Oaks (CA): August 2015

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/13/2016
2	Clinical Update	Clarification of covered uses, renewal criteria removed	Covered Uses, Other criteria	03/01/2016
3	Additional criteria	Medication reconciliation requirement	Required Medical Information	12/12/2017
4	Criteria Update	Clinical criteria updated	Other Criteria	5/23/2018
5	Update	Initial Coverage Duration updated	Coverage Duration	07/23/2018
6	Policy	ConnectiCare adoption of policy	All	7/25/18