

## PHARMACY POLICY STATEMENT Indiana Medicaid

DRUG NAME	Praluent (alirocumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior authorization required (Non-preferred product) QUANTITY LIMIT – 2 injections per 28 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Praluent (alirocumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a lipid specialist or a cardiologist; AND
3. Member has a diagnosis of heterozygous familial hypercholesterolemia (FeFH) confirmed by **one** of the following:
  - a. Dutch Lipid Network Criteria score of 9 or higher;
  - b. Genetic testing confirmation;
  - c. “Definite” Simon Broome Criteria (see Table 1 to determine eligibility, if not submitted with chart notes); AND
4. Chart notes must include documentation of baseline LDL-C level, taken within the past 90 days; AND
5. Member is unable to achieve LDL < 100 mg/dL<sup>2</sup> after a 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe; AND
6. Praluent will be used in combination with a statin and/or ezetimibe, unless contraindicated or intolerant; AND
7. Prescriber attests that the member will adhere to a diet regimen or diet modification.
8. **Dosage allowed:** 75 mg (1 injection of 75 mg/mL) every 2 weeks OR 300 mg (2 injections of 150 mg/mL) every 4 weeks OR 150 mg (1 injection of 150 mg/mL) every 2 weeks.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes along with recent labs have been provided showing a meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

### PREVENTION OF CARDIOVASCULAR EVENTS

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a lipid specialist or a cardiologist; AND

3. Member has a history of clinical atherosclerotic cardiovascular disease (ASCVD) (e.g. angina, coronary or other arterial revascularization, MI, stroke, transient ischemic attack, peripheral arterial disease, etc.); AND
4. Chart notes must include documentation of baseline LDL-C level, taken within the past 90 days; AND
5. Member is unable to achieve LDL-C < 70 mg/dL<sup>2</sup> after a 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe; AND
6. Praluent will be used in combination with a statin and/or ezetimibe, unless contraindicated or intolerant; AND
7. Prescriber attests that the member will adhere to a diet regimen or diet modification.
8. **Dosage allowed:** 75 mg (1 injection of 75 mg/mL) every 2 weeks OR 300 mg (2 injections of 150 mg/mL) every 4 weeks OR 150 mg (1 injection of 150 mg/mL) every 2 weeks.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes along with recent labs have been provided showing a meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Praluent (alirocumab) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
07/09/2020	New policy for Praluent created. Retired old Biologic Cholesterol Agents policy.

References:

1. Praluent [Package Insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2020.
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. JACC. 2018;73(24)doi:10.1016/j.jacc.2018.11.002.
3. Lloyd-Jones DM, Morris PB, Ballantyne CM, 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. JACC. 2017;70(14):1785-1822.
4. Harada M, Arai H, Ishigaki Y, et al. Guidelines for diagnosis and treatment of familial hypercholesterolemia 2017. J Atheroscler Thromb. 2018 Aug 1; 25(8): 751–770.
5. McGowen, Dehkordi S, Moriarty P, et al. Diagnosis and treatment of heterozygous familial hypercholesterolemia. J Am Heart Assoc. 2019 Dec 17;8(24):e013225.
6. Kastelein JJ, Ginsberg, HN, Langslet G, et al. ODYSSEY FH I and FH II: 78 week results with alirocumab treatment in 735 patients with heterozygous familial hypercholesterolemia. Eur Heart J. 2015 Nov 14;36(43):2996-3003.
7. Lloyd-Jones DM, Morris PB, Ballantyne CM, 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: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. J Am Coll Cardiol. 2017;70(14):1785-1822.
8. Pignone M. Management of elevated low density lipoprotein-cholesterol (LDL-C) in primary prevention of cardiovascular disease. In: Freeman MW, ed. *UpToDate*. Waltham, MA.; UpToDate; 2020. www.uptodate.com. Accessed July 09, 2020.

Effective date: 02/01/2021

Revised date: 07/09/2020

Table 1

<b>Simon Broom Criteria</b>
<ul style="list-style-type: none"><li>• Total cholesterol level &gt; 290 mg/dL OR LDL-C &gt; 190 mg/dL at baseline AND</li><li>• <u>One</u> of the following:<ul style="list-style-type: none"><li>○ Physical finding of tendon xanthomas in 1<sup>st</sup> or 2<sup>nd</sup> degree relative;</li><li>○ Confirmation by gene or receptor testing (presence of LDL-R, ApoB, or PCSK9 mutation)</li></ul></li></ul>