

PHARMACY POLICY STATEMENT Georgia 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 NOT MEDICALLY NECESSARY	Click Here

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/dL² 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/dL² 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 lifestyle 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-Statins 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-Statins 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: 12/01/2020

Revised date: 07/09/2020

Table 1

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