CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Praluent (alirocumab)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Praluent (alirocumab) is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor indicated to 1) reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease, 2) as adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies in adults with primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C and 3) as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C. Praluent was initially approved by the FDA in 2015.

Praluent (alirocumab) will be considered for coverage when the following criteria are met:

Heterozygous Familial Hypercholesterolemia (HeFH)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a lipid specialist, cardiologist, or endocrinologist; AND
3. Member has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by one of the following:
   a) Genetic testing (presence of LDL-R, ApoB, or PCSK9 mutation)
   b) Dutch Lipid Network score greater than 8 points
   c) "Definite" per Simon Broome criteria (i.e., LDL > 190 at baseline AND tendon xanthoma OR LDL-R, ApoB, or PCSK9 mutation); AND
4. Member has a lipid panel within the past 90 days showing LDL of 100 or greater; AND
5. Member's LDL is elevated despite at least a 3-month adherent trial of high intensity or max tolerated statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); 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/Quantity Limit:** 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 (Limit: 2 injections per 28 days)

Note: If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

Homozygous Familial Hypercholesterolemia (HoFH)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a lipid specialist, cardiologist, or endocrinologist; AND
3. Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by one of the following:
   a) Genetic testing confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus; OR
   b) LDL-C > 500 mg/dL before any treatment or LDL-C > 300 mg/dL if treated with a lipid-lowering drug AND one of the following:
      i) Xanthoma before 10 years of age; OR
      ii) Evidence of heterozygous familial hypercholesterolemia (HeFH) (i.e., total cholesterol > 250 mg/dL) in both parents; 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 goal (see Note) after a 90-day trial with a high-intensity statin or max tolerated statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); AND
6. Praluent will be used as an adjunct to other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis), unless contraindicated or intolerant; AND
7. Prescriber attests that the member will adhere to a diet regimen or diet modification.
8. **Dosage allowed/ Quantity Limit:** 150 mg (1 injection of 150 mg/mL) subcutaneously once every 2 weeks
   (Limit: 2 injections per 28 days)

NOTE: The LDL-C goals are <100 mg/dL for adults 18 years or older, < 135 mg/dL for children, and < 70 mg/dL for adults with clinical ASCVD.

*NOTE: *If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.*

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

Primary Hyperlipidemia

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. 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
3. Member has a lipid panel within the past 90 days showing one of the following:

a) LDL of 70 or greater
b) LDL of 55 or greater and "very high risk," i.e., history of multiple major ASCVD events (acute coronary syndrome within past 12 months, history of MI, stroke, or symptomatic PAD) or 1 major ASCVD event and multiple high-risk conditions; AND

4. Member's LDL is elevated despite at least a 3-month adherent trial of high intensity or max tolerated statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); AND
5. Praluent will be used in combination with a statin and/or ezetimibe, unless contraindicated or intolerant; AND
6. Prescriber attests that the member will adhere to a diet regimen or diet modification.
7. **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
(Limit: 2 injections per 28 days)

Note: If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Praluent (alirocumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/09/2020	New policy for Praluent created. Retired old Biologic Cholesterol Agents policy.
04/27/2021	New indication Homozygous Familial Hypercholesterolemia (HoFH) added. Updated atorvastatin high-intensity requirement to reflect pediatric vs. adult dosing.
02/22/2022	Policy for Praluent transferred to new template. Removed specialist requirement from ASCVD indication.
09/14/2023	Updated ACC non-statin reference. Added endocrinology as accepted specialist for HeFH, HoFH. Clarified Simon-Broome criteria for HeFH, noted pertinent gene mutations. Added detail to statin intolerance note regarding low/moderate intensity and alternate dosing. Renamed "Prevention of cardiovascular events" section to "Primary hyperlipidemia." Differentiated LDL cutoff of 55 for "very high risk" population for primary hyperlipidemia.

References:

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3. 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.
4. McGowen, Dehkordi S, Moriarty P, et al. Diagnosis and treatment of heterozygous familial hypercholesterolemia. J Am Heart Assoc. 2019 Dec 17;8(24):e013225.
5. Kastelein JJ, Ginsberg, HN, Langslet G, et al. ODYSSEY FH I and FH II: 78 week resuls with alirocumab treatment in 735 patients with heterozygous familial hypercholesterolemia. Eur Heart J. 2015 Nov 14;36(43):2996-3003.
6. 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.
7. Blom DJ, Harada-Shiba M, Rubba P, et al. Efficacy and Safety of Alirocumab in Adults With Homozygous Familial Hypercholesterolemia: The ODYSSEY HoFH Trial. *J Am Coll Cardiol*. 2020;76(2):131-142.
8. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35(32):2146-2157.
9. Lloyd-Jones DM, Morris PB, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee [published correction appears in J Am Coll Cardiol. 2023 Jan 3;81(1):104]. *J Am Coll Cardiol*. 2022;80(14):1366-1418. doi:10.1016/j.jacc.2022.07.006

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