PHARMACY POLICY STATEMENT
North Carolina 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 l(h)-14( )] T 0.0000091r

For

a) LDL of 70 or greater
b) /'/ RI RU JUHDWHU DQG ³YHU\ KLJK ULVN´ LH KLVWR 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. 0HPEHU¶V /'/ LV HOHYDWHG GHVSLWH DGKHUHQFH ZLWK D KLJK LQWHQVLW\ RU PD statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication ² 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

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

Effective date: 01/01/2024
Revised date: 09/14/2023