PRIOR AUTHORIZATION DESCRIPTION
Praluent® (Alirocumab)

Background information:

Per the 2018 ACC/AHA national cholesterol treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed.

For primary prevention in patients with LDL-C of 190mg/dL or higher, high-intensity statin therapy is recommended to reduce LDL-C by more than 50% and to less than 100 mg/dL.

- High-risk patients should initiate statin therapy with a goal of more than 50% LDL-C reduction.
- Patients aged 40 to 75 years who also have diabetes and LDL-C of 70 mg/dL or higher should receive moderate-intensity statin therapy.

For primary prevention in all other patients aged 40 to 75 years, the decision to actively treat lipids is largely based on the updated ASCVD Risk Estimator Plus. Access to 10-year ASCVD risk estimator:

- https://www.acc.org/ASCVDApp

Note: The ACVD Risk Estimator Plus provides sex and race specific equations for 4 groups: white men, white women, black men, black women; uncertain utility in other racial/ ethnic groups. For individuals outside this age range, simultaneous 10-year and life-time risk assessment is reasonable for clinician/individual patient discussions.

10-year risk for ASCVD is categorized as:

- Low risk= < 5% over 10 years, borderline risk = 5% - 7.4%, intermediate risk= 7.5% -19.9%, high risk= ≥ 20%
  - Patients with high risk of ASCVD include the following:
    - History of clinical atherosclerotic cardiovascular disease
    - Diabetes with an estimated 10-year ASCVD risk ≥ 7.5% for adults 40-75 years of age
    - Untreated LDL ≥ 190 mg/dL
  - Patients with moderate risk of ASCVD include the following:
    - Diabetes with an estimated 10-year ASCVD risk < 7.5% for adults 40-75 years of age
    - Estimated 10-year ASCVD risk ≥ 5% for adults 40-75 years of age

Clinical ASCVD: Pharmacologic lipid management is strongly recommended, even without risk calculation, in patients with clinical ASCVD. Stratified LDL-C goals have been reintroduced for patients with clinical ASCVD.

- First, reduce LDL-C by greater than 50% using high-intensity statins.
- Reduction of LDL-C level to target is a secondary goal after reduction of LDL-C percentage is achieved.
- Patients with very high risk ASCVD have a second goal of reducing LDL-C to less than 70 mg/dL. If this cannot be achieved with a high intensity statin, ezetimibe or a PCSK9 inhibitor (alirocumab/evolocumab) is recommended.
  - ✓ Very high-risk includes:
    - History of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.

Clinical Atherosclerotic Cardiovascular Disease (ASCVD) includes acute coronary syndrome (ACS), those with history of myocardial infarction (MI), stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral artery disease (PAD) including aortic aneurysm, all of atherosclerotic origin.

- Reference: Circulation 2019;139:e1082–e1143. DOI: 10.1161/CIR.0000000000000625 https://www.ahajournals.org/doi/10.1161/CIR.0000000000000624

CRITERIA/ADDITIONAL DOCUMENTATION

Praluent® (Alirocumab)

MISSISSIPPI DIVISION OF MEDICAID

BENEFICIARY INFORMATION	
Beneficiary ID:____ ____ ____ - ____ ____ ____ - ____ ____ ____	**DOB:**____ ____ /____ ____ /____ ____ ____ ____
Beneficiary Full Name:	

PRALUENT is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- as adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C.
- as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia to reduce LDL-C.

PRALUENT® (ALIROCUMAB) Criteria	
Initial Approval Criteria: May be approved when the below criteria are met: **(12 weeks approval duration)**	
☐ Yes ☐ No	Age of patient is within the age range as recommended by the FDA label;
AND	
☐ Yes ☐ No _____	Prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist;
1. ☐ Yes ☐ No 2.☐ Yes ☐ No 3.☐ Yes ☐ No	**Diagnosis of one of the following:** **1. Severe Primary Hypercholesterolemia, including heterozygous familial hypercholesterolemia [HeFH]), at high risk for ASCVD defined a 10-year ASCVD risk percent of ≥ 20% or patients ages 40-75 yrs with diabetes and 10 yr ASCVD risk > 7.5%, LDL 80-189) (https://www.acc.org/ASCVDApp)** **Diagnosis of HeFH (one of the following):** a. Functional mutation in the LDLR, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene; **OR** b. Corneal arcus (seen in ages < 45 years), or xanthelasma, or tendon xanthomas; **OR** c. Clinical diagnosis based on the World Health Organization Dutch Lipid Clinical Network criteria with a "probable familial hypercholesterolemia" score of ≥ 6 points **OR** *definite* diagnosis by Simon Broom criteria; **OR** **2. Established Atherosclerotic Cardiovascular Disease (ASCVD);** **OR** **3. Homozygous Familial Hypercholesterolemia (HoFH);**
AND	
☐ Yes ☐ No	Documentation of recent (within the last 30 days) LDL-C of one of the following (a or b) despite maximally tolerated lipid lowering therapy: a. LDL-C: > 70 mg/dl and Very High Risk ASCVD; ***OR*** b. LDL-C: > 100 mg/dL for severe primary hypercholesterolemia (including HeFH) without ASCVD but with multiple risk factors that increase subsequent risk of ASCVD; **LDL-C:_____ Lab date: _____**
AND	

CRITERIA/ADDITIONAL DOCUMENTATION

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☐ Yes ☐ No	Adherence (defined as 85% by consistent pharmacy claims) to a high intensity statin regimen for at least 12 weeks or to a moderate intensity statin for at least 12 weeks if unable to tolerate a high intensity statin, unless one of the following applies: a. Statin therapy is contraindicated; **OR** b. Documented statin risk factors; **OR** c. Rhabdomyolysis or muscle symptoms with statin treatment with CK elevations; **OR** d. Statin intolerance due to: ▪ Myopathy: unexplained muscle pain or weakness accompanied by CK elevations; **OR** ▪ Myalgia: muscle symptoms without CK elevations and meets both of the following: **i.** Intolerable statin associated muscle symptoms (SAMS) persisting at least two weeks which disappeared with discontinuation of the statin therapy and recurred with a statin re-challenge; **AND** **ii.** Intolerant despite re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly)
AND	
☐ Yes ☐ No	Adherence (defined as 85% by consistent pharmacy claims) to Zetia (ezetimibe) therapy used concomitantly with a statin at the maximally tolerated dose over the past 12 weeks, unless one of the following applies: a. Zetia therapy is contraindicated; **OR** b. History of Zetia intolerance (e.g. associated diarrhea or upper respiratory tract infection); **OR** c. If ≥ 15% LDL-C reduction is required despite adherence with statin therapy, use of Zetia is ***not*** required;
AND	
☐ Yes ☐ No	Praluent will be used concomitant with a maximally-tolerated statin and Zetia unless contraindicated, intolerant or Zetia use is not required as ≥ 15% LDL-C goal attainment is needed;
☐ Yes ☐ No	Not used in combination with Juxtapid® (lomitapide) or another PCSK9 inhibitor.

Recommended Praluent Dosing Regimen

Diagnosis	Praluent Dosing Regimen	Diagnosis	Praluent Dosing Regimen
• Established ASCVD • Primary Hypercholesterolemia	Starting dose of 75mg SC every 2 weeks up to a maximum dose of *150mg SC every 2 weeks* ***OR*** 300mg SC every 4 weeks (once monthly)	• HeFH undergoing LDL apheresis • HoFH	150mg SC every 2 weeks

Reauthorization Criteria: (52 weeks approval duration)

☐ Yes ☐ No	Prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist;
AND	
☐ Yes ☐ No	Evidence of adherence (defined as 85% consistent pharmacy claims) to ongoing concomitant lipid lowering therapy as applicable;
AND	
☐ Yes ☐ No	Lab results within the last 12 weeks demonstrate additional LDL-C reduction since initiation of Praluent therapy. **LDL-C:**_____ **Date:**_____
AND	
☐ Yes ☐ No	Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and that they understand that the Mississippi Division of Medicaid may perform a routine audit and request the medical information necessary to verify the accuracy of information provided.

BACKGROUND INFORMATION/ASCVD RISK CALCULATOR CAN BE FOUND IN THE INSTRUCTION SHEET