Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

PRALUENT® (*alirocumab*) PA CRITERIA:

PRALUENT® (*alirocumab*) is a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) in adults at increased risk for these events.
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:
  - adults with hypercholesterolemia.
  - adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
  - adults with homozygous familial hypercholesterolemia (HoFH).

Prior authorization is required for PRALUENT®. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation (e.g., chart notes, lab results, etc.).

Initial Authorization: 12 Months

1. Age of the patient is within the age range as recommended by the FDA label.

   -AND-

2. Documented diagnosis of ONE of the following:
   a. Severe primary hypercholesterolemia with LDL-C ≥190 mg/dL

   -OR-

   b. At high risk for major adverse CV events, defined as 10-year ASCVD risk percent of ≥ 20%

   -OR-

   c. HoFH as evidenced by:
      i. Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus**; or**
      ii. An untreated LDL-C > 500 mg/dL with either:
         1. Cutaneous or tendon xanthoma before age 10 years**; or**
         2. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (≥190 mg/dL)

   -OR-

d. HeFH as evidenced by one of the following:
    i. Functional mutation in the LDLR, ApoB, PCSK9, or ARH adaptor protein (LDLRAP1) gene**; or**
    ii. Corneal arcus (seen in ages < 45 years), xanthelasma (seen in ages < 25 years), or tendon xanthomas**; or**
    iii. 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

-AND-

3. Documentation of recent (within the last 30 days) LDL-C of one of the following despite maximally tolerated lipid-lowering therapy:
    a. LDL-C ≥ 55 mg/dL AND Very High Risk ASCVD (defined as a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions)**; or**
    b. LDL-C ≥ 70 mg/dL for patients with clinical ASCVD AND not at very high risk**; or**
    c. LDL-C ≥ 100 mg/dL (or LDL ≥ 70 mg/dL for patients 40 to 75 years of age with diabetes) for severe primary hypercholesteremia (including HeFH) without ASCVD but with multiple risk factors that increase subsequent risk of ASCVD

-AND-

4. 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 creatine kinase (CK) elevations**; or**
    d. Statin intolerance due to:
        i. Myopathy: Unexplained muscle pain or weakness accompanied by CK elevations**; or**
        ii. Myalgia: Muscle symptoms without CK elevations and meets both of the following:
            1. Intolerable statin associated muscle symptoms (SAMS) persisting for at least two weeks which disappeared with discontinuation of the statin therapy and recurred with a statin re-challenge**; and**
            2. Intolerant despite re-challenge with titration from the lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly)

- AND-

5. 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-

6. The patient has at least 12 weeks trial and documented inadequate response, contraindication, or intolerance to Repatha unless restricted by age.

-AND-

7. Praluent will not be used in combination with Juxtapid (lomitapide) or another PCSK9 inhibitor.

Re-Authorization: 12 Months

1. Evidence of adherence (defined as 85% consistent pharmacy claims) to lipid lowering therapy as applicable.

-AND-

2. Lab results obtained within the last 12 weeks show an LDL-C reduction since the initiation of Praluent therapy.

PRALUENT® (*alirocumab*) Dosing:

Indication	Recommended Dosage
Adults with CV risk reduction or hypercholesterolemia or HeFH	75 mg every 2 weeks or 300 mg every 4 weeks. If LDL-C response is inadequate, the dosage may be adjusted to 150 mg every 2 weeks.
Adults with HeFH undergoing LDL Apheresis or in Adults with HoFH	150 mg every 2 weeks
Pediatric Patients with HeFH	Body Weight < 50 kg: 150 mg every 4 weeks Body Weight ≥ 50 kg: 300 mg every 4 weeks If LDL-C response is inadequate, the dose may be adjusted for patients with body weight less than 50 kg to 75 mg every 2 weeks or for patients with a body weight of 50 kg or more to 150 mg every 2 weeks.

PRALUENT® (*alirocumab*) Formulation:

- PRALUENT® is available as 75 mg/mL or 150 mg/mL in a single-dose prefilled pen.