

Montana Healthcare Programs Physician Administered Drug Coverage Criteria

EVKEEZA™ (evinacumab-dgnb)

I. Medication Description

Evkeeza™ is an ANGPTL3 (angiopoietin-like 3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH).

Limitations of Use:

- The safety and effectiveness of Evkeeza™ have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).
- The effects of Evkeeza™ on cardiovascular morbidity and mortality have not been determined.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- 12 years of age or older
- Medication prescribed by or in consult with a cardiology specialist or endocrinology specialist
- Must have diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
- Has an LDL-cholesterol equal to or greater than 70mg/dl.
- Evkeeza™ will be used as adjunctive therapy.
- Must have had an inadequate response (trial of at least 12-weeks duration), intolerance or contraindication to **ALL** the following medications:
 - **TWO** high-intensity statins (12-week trial each)
 - Ezetimibe
 - PCSK9 Inhibitor
- Must continue background lipid-lowering therapies in combination with Evkeeza™
- *Females only*: Provider attests that member of childbearing age has been counseled on use of contraception while using Evkeeza™ due to potential fetal harm.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Has experienced a positive clinical response
- Has been adherent to Evkeeza™ and all additional lipid-lowering agents the member was taking at initiation of Evkeeza™ therapy
- Annual specialist consult provided if prescriber not a specialist.

V. Quantity Limitations

Max 15mg/kg IV every 4 weeks

VI. Coverage Duration

- Initial approval duration: 6 months
- Renewal approval duration: 1 year