

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:

- Member is 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).
- Member has an LDL-Cholesterol equal to or greater than 70mg/dl.
- Evkeeza™ will be used as adjunctive therapy.
- Member 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
- Member 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:

- Member has experienced a positive clinical response.
- Member 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