evinacumab-dgnb (Evkeeza)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: CARDIOVASCULAR AGENTS
Mechanism of Action: ANGPTL3 (angiopoietin-like 3) inhibitor
HCPCS:
J1305:Injection, evinacumab-dgnb, 5mg
How Supplied:

- 345 mg single-dose vial
- 1,200 mg single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Homozygous Familial Hypercholesterolemia (HoFH)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS EVKEEZA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first infusion of Evkeeza or is being re-initiated on Evkeeza after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Evkeeza based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Evkeeza based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Homozygous Familial Hypercholesterolemia (HoFH)

Meets medical necessity if all the following are met:

1. Recommended by a cardiologist or endocrinologist
2. Confirmed HoFH by either positive genetic test for LDL-R genetic mutations confirming HoFH or clinical evidence supporting a diagnosis of HoFH
3. Being used in combination with a standard lipid lowering combination regimen (e.g., a high potency statin and a non-statin lipid lowering agent)
4. Meets ONE of the following:
   a. Inadequate response, intolerance, or contraindication to a PCSK9 inhibitor (e.g., Praluent, Repatha)
   b. Provider attestation that patient has homozygous null-null variants

Covered Doses:

Up to 15 mg/kg given intravenously every 4 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

E78.01

Additional Information

Diagnostic Evidence for presence of HoFH

Genetic Diagnosis	HoFH Clinical Diagnosis

Genetic confirmation of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus* *LDLR = low-density lipoprotein receptor APOB =apolipoprotein B PCSK9 = proprotein convertase subtilisin kexin type 9 LDLRPA1 = low-density lipoprotein receptor adaptor protein	A clinical diagnosis of familial hypercholesterolemia is best made with the following clinical features: • Untreated LDL-C >500mg/dL or treated LDLC >300 mg/dL and • Meets ONE of the following: o Cutaneous or tendon xanthoma before age 10 years, or o Both parents have untreated elevated LDLC levels consistent with heterozygous FH

Reference:

Cuchel M, Bruckert E, Ginsberg HN, et al, for the European Atherosclerosis Society Consensus Panel on Familial Hypercholesterolemia. Homozygous familial hypercholesterolemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel in Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35: 2146-2157.

Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Overview. In: UpToDate. Topic last updated 9/21/2020

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Evkeeza (evinacumab-dgnb) Prescribing Information. Regeneron Pharmaceuticals, Inc., Tarrytown, NY: 3/2023.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee