CareSource Rx Innovations

# PHARMACY POLICY STATEMENT
## Arkansas PASSE

| DRUG NAME | Evkeeza (evinacumab-dgnb) |
|---|---|
| BILLING CODE | J1305 (5mg=1unit) |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Home/Office/Outpatient |
| STATUS | Prior Authorization Required |

Evkeeza (evinacumab-dgnb) 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).

Evkeeza (evinacumab-dgnb) will be considered for coverage when the following criteria are met:

## Homozygous Familial Hypercholesterolemia (HoFH)

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a lipid specialist or a cardiologist; AND
3. Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by **one** of the following:
   a) Genetic testing confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus; OR
   b) LDL-C > 500 mg/dL before any treatment or LDL-C > 300 mg/dL if treated with a lipid-lowering drug AND **one** of the following:
      i) Xanthoma before 10 years of age; OR
      ii) Evidence of heterozygous familial hypercholesterolemia (HeFH) (i.e., total cholesterol > 250 mg/dL) in both parents; AND
4. Chart notes must include documentation of baseline LDL-C level, taken within the past 90 days prior to therapy; AND
5. Member is unable to achieve LDL-C goal (see Note below) after trials with **both** of the following:
   a) 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg for 18 years or older, ≥ 20mg for under 18 years old) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe;
   b) 90-day trial with Repatha or Praluent (prior authorization required); AND
6. Evkeeza will be used as an adjunct to other lipid-lowering treatments (e.g., statins, ezetimibe, LDL apheresis), unless contraindicated or intolerant; AND
7. Prescriber attests that the member will adhere to a low-fat diet and exercise regimen; AND
8. If member is adding Evkeeza to current Juxtapid therapy, must have a 6 month trial and failure of Evkeeza with maximized statin, ezetimibe, or PCSK9 (without Juxtapid) AND a strong clinical reason why Evkeeza must be used together with Juxtapid.
9. **Dosage allowed/Quantity limit:** 15 mg/kg administered by intravenous infusion once monthly.

Note: The LDL-C goals are <100 mg/dL for adults 18 years or older, < 135 mg/dL for children, and < 70 mg/dL for adults with clinical ASCVD.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:
1. Chart notes along with recent labs have been provided showing a meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## CareSource considers Evkeeza (evinacumab-dgnb) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **03/23/2021** | New policy for Evkeeza (evinacumab-dgnb) created. |
| **02/21/2022** | Updated J code. |

References:


1. Evkeeza [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc. February 2021.
2. Raal FJ, Rosenson RS, Reeskamp LF, et al. Evinacumab for Homozygous Familial Hypercholesterolemia. *N Engl J Med*. 2020;383(8):711-720.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. *Eur Heart J*. 2014;35(32):2146-2157.
4. Doggrell SA. Will evinacumab become the standard treatment for homozygous familial hypercholesterolemia?. *Expert Opin Biol Ther*. 2021;21(3):299-302.


Effective date: 07/01/2022
Revised date: 02/21/2022