SmartHealth Ascension

Evinacumab

(Evkeeza®) J1305 (5 mg)

Covered with prior authorization

Evinacumab (Evkeeza®) may be authorized when the following criteria are met:

Individual has a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) confirmed by:

- Presence of two mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene locus; **OR**
- Presence of the following:
    - An untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L); **OR**
    - Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L); **AND** one of the following:
        - Cutaneous or tendon xanthoma before age of 10 years; **OR**
        - Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL).

AND

- Individual is on high intensity statin therapy or statin therapy at the maximum tolerated dose (high intensity statin is defined as atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher); **OR**
- Individual is statin intolerant based on one of the following:
    - Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by adverse effects associated with statin therapy that resolve or improve with dose reduction or discontinuation; **OR**
    - Statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin; **OR**
    - Individual has a contraindication for statin therapy including but not limited to active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy.

AND

- Documentation is provided that individual has had a trial and inadequate response or intolerance to proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor therapy ≥ 8 continuous weeks , or is not a candidate for PCSK9 inhibitor therapy; **OR**

- Documentation is provided that genetic testing has confirmed the individual is LDLR negative.

Exclusion criteria:
Requests for Evinacumab (Evkeeza®) may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and has had a positive clinical response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

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).

References:

1. Cuchel M, Bruckert E, Ginsberg HN, et. al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. European Heart Journal. 2014; 35: 2146–2157.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
3. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. Curr Atheroscler Rep. 2015; 17(2):482.
4. Evkeeza® [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; 2023
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ ADA/AGS/APhA/ASPC/NLA/ PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019;73:e285–350.

6. Orringer CE, Jacobson TA, Saseen JJ, et. al. Update on the use of PCSK9 inhibitors in adults: Recommendations from an Expert Panel of the National Lipid Association (NLA). J Clin Lipidol. 2017 Jul-Aug;11(4):880-890.

Date	Summary of Changes
February 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
June 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
July 2023	Criteria for use summary approved by the Ascension Cardiovascular Expert Review Panel.
July 2023	Criteria for use summary approved by the Ambulatory Care Leadership Council.
August 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.