ALASKA MEDICAID
Prior Authorization Criteria

Evkeeza™ (evinacumab-dgnb)

FDA INDICATIONS AND USAGE[1]

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). The safety and effectiveness of Evkeeza™ have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).

APPROVAL CRITERIA[1,2,3,4,5]

1. Patient is 12 years of age or older **AND**;
2. Prescribed by or in consultation with, a specialist in cardiology, lipidology, or endocrinology **AND**;
3. Patient has a diagnosis of **homozygous** familial hypercholesterolemia (HoFH) confirmed by:
    a. Genetic confirmation of two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus **OR**;
    b. Patient has untreated LDL-C > 500 mg/dL or treated LDL-C ≥ 300 mg/dL **and** had clinical manifestation of homozygous familial hypercholesterolemia (HoFH) before the age of 10 years **or** both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH) **AND**;
4. Patient has tried and failed at least a 3 month trial of adherent therapy with ezetimibe used in combination with the highest available or maximally tolerated dose of atorvastatin or rosuvastatin or has a contraindication to statin use **AND**;
5. Patient has tried and failed at least a 3 month trial of adherent therapy with combination therapy consisting of the highest available or maximally tolerated dose of atorvastatin OR rosuvastatin, ezetimibe, AND a PCSK9 inhibitor indicated for HoFH (I.E., evolocumab), unless contraindicated **AND**;
6. Despite pharmacological treatment with a PCSK9 inhibitor, statin, and ezetimibe, the patient's LDL-C is ≥ 100 mg/dL or ≥ 70 mg/dL for patients with clinical atherosclerotic cardiovascular disease **AND**;
7. Female patients must have a negative pregnancy test and have been counselled to use effective contraception during treatment.

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DENIAL CRITERIA [1,3]

1. Failure to meet approval criteria **OR**;
2. Patient has heterozygous familial hypercholesterolemia (HeFH) or other form of hypercholesterolemia **OR;**
3. Patient does not have baseline LDL cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs documented prior to initiating treatment **OR**;
4. Patient is not using in conjunction with a low fat or heart healthy diet.

CAUTIONS[1]

- Monitor for serious hypersensitivity reactions and treat according to standard-of-care until symptoms resolve.
- Evkeeza™ may cause fetal harm based on animal studies. Advise patients who may become pregnant to use contraception during treatment and for at least 5 months following the last dose.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if the prescriber documents the patient's current LDL-C reduction from baseline and the patient has continued a lipid lowering diet and therapy.

QUANTITY LIMIT

- 345 mg/2.3 mL vial: 2 vials per 28 days
- 1,200 mg/8 mL vial: 1 vial per 28 days
- Max dose 1,890mg per 28 days

REFERENCES / FOOTNOTES:

1. Evkeeza™ [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; February 2021.
2. Raal FJ, Rosenson RS, Reeskamp LF, et al, for the ELIPSE HoFH investigators. Evkeeza for homozygous familial hypercholesterolemia. N Engl J Med. 2020;383 (8):711-720.
3. Rosenson RS, Burgess LJ, Ebenbichler CF, et al. Evkeeza in patients with refractory hypercholesterolemia. N Engl J Med. 2020;383(24):2307-2319.
4. Liu, Z, Peng, J, Wang, S, et al. Characterization of coronary atherosclerotic plaques in a homozygous familial hypercholesterolemia visualized by optical coherence tomography. J Geriatr Cardiol. 2018; 15: 738-743.
5. Doggrell, S. Will evinacumab become the standard treatment for homozygous familial hypercholesterolemia? Expert Opin Biol Ther. 2021; 21(3): 299-302.