Medical Policy

Evkeeza™ (evinacumab)	
MEDICAL POLICY NUMBER	Med_Clin_Ops_069
CURRENT VERSION EFFECTIVE DATE	March 1, 2023
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Evkeeza™ (evinacumab) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Evkeeza will be provided for 12 months and may be renewed.
Dosing Limitation: Dose to not exceed 1890 mg every 28 days

Homozygous Familial Hypercholesterolemia (HoFH)

Initial Therapy

1. Patient is 12 years of age or older; **AND**

2. Evkeeza is prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who specializes in the treatment of cardiovascular risk management and/or lipid disorders; **AND**
3. Patient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH), through **ONE** of the following (a., b., or c.)
    a. Documented 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 an **untreated** low-density lipoprotein cholesterol (LDL-C) level > 500 mg/dL **AND** meets **one** of the following (i. **or** ii.):
        i. Patient had clinical manifestation of homozygous familial hypercholesterolemia (HoFH) before the age of 10 years (e.g., cutaneous xanthomas, tendon xanthomas, acrus cornea, tuberous xanthomas, or xanthelasma); **OR**
        ii. Both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH) (untreated total cholesterol >290 mg/dL or untreated LDL-C >190 mg/dL); **OR**
    c. Patient has a **treated,** with at least one antihyperlipidemic agent, low-density lipoprotein cholesterol (LDL-C) level ≥ 300 mg/dL **AND** meets one of the following (i. or ii.):
        i. Patient had clinical manifestation of homozygous familial hypercholesterolemia (HoFH) before the age of 10 years; **OR**
        ii. Both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH); **AND**
4. Patient meets **one** of the following criteria (a. **or** b.):
    a. Patient meets **all** of the following criteria (i. and ii.):
        i. Patient is currently receiving maximally tolerated statin therapy plus ezetimibe (as a single entity or as a combination product); **AND**
        ii. LDL-C goal of less than 70 mg/dL; **OR**
    b. Patient has been determined to be statin intolerant by meeting one of the following criteria (i. or ii.):
        i. Patient experienced statin-related rhabdomyolysis; **OR**
        ii. Patient meets **all** of the following criteria (1., 2., **and** 3.):
            1. Patient experienced skeletal-related muscle symptoms (myopathy or myalgia); **AND**
            2. The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products); **AND**
            3. When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms resolved upon

discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); **AND**

5. Patient meets **one** of the following (a. or b.):
    a. Patient meets **both** of the following (i. **and** ii.):
        i. Patient has tried a PCSK9 inhibitor for at least 3 months; **AND**
        ii. The low-density lipoprotein cholesterol (LDL-C) level after this PCSK9 inhibitor therapy remains ≥ 100 mg/dL; **OR**
    b. Patient is known to have two LDL-receptor negative alleles

Continuation Therapy

1. Documentation of a positive clinical response to therapy from pre-treatment baseline; **AND**
2. Patient continues treatment with other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., statin, ezetimibe) in combination with Evkeeza; **AND**
3. Evkeeza will not be used in combination with Juxtapid (lomitapide)

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).

BACKGROUND

Evkeeza is 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).

DEFINITIONS

1. EVKEEZA™ (evinacumab-dgnb) injection, for intravenous use. Initial U.S. Approval: 2021
    a. EVKEEZA (evinacumab-dgnb) injection is a clear to slightly opalescent, colorless to pale yellow solution. It is supplied as one single-dose vial per carton.
        i. 345 mg/2.3 mL (150 mg/mL) NDC 61755-013-01
        ii. 1,200 mg/8 mL (150 mg/mL) NDC 61755-010-01

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CODING

Applicable NDC Codes	
61755-0013-01	EVKEEZA 345 mg/2.3 mL (150 mg/mL
61755-0010-01	EVKEEZA 1200 mg/8 mL (150 mg/mL

Applicable Procedure Code	
J3490	Unclassified drugs (When utilized for Evkeeza [evinacumab])
J3590	Unclassified biologics (When utilized for Evkeeza [evinacumab])

Applicable ICD-10 Codes	
E78.01	Familial hypercholesterolemia

EVIDENCE BASED REFERENCES

1. Product Information: EVKEEZA(TM) intravenous injection, evinacumab-dgnb intravenous injection. Regeneron Pharmaceuticals Inc (per manufacturer), Tarrytown, NY, 2021.

POLICY HISTORY

Original Effective Date	July 19, 2021
Revised Date	November 1 2021 Added J-Code (J1305): Injection, evinacumab-dgnb, 5mg. Effective date: 10/01/2021 November 8, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UMC (no changes made) January 1, 2024
Approval Body	Pharmacy and Therapeutics Committee

Approved by Pharmacy and Therapeutics 11/8/2022