Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 242.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Evkeeza (evinacumab-dgnb)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Evkeeza (evinacumab-dgnb)

II. Purpose/Objective:
To provide a policy of coverage regarding Evkeeza (evinacumab-dgnb)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Evinacumab-dgnb is a recombinant human monoclonal antibody that binds to and inhibits angiopoietin-like protein 3 (ANGPTL3). ANGPTL3 inhibits lipoprotein lipase (LPL) and endothelial lipase (EL). ANGPTL3 inhibition by evinacumab results in increased lipid metabolism, leading to decreased low-density lipoprotein-cholesterol (LDL-C), high-density lipoprotein-cholesterol (HDL-C), and triglycerides (TG). Evinacumab-dgnb reduces LDL-C independent of the presence of LDL receptor by promoting very low-density lipoprotein processing and clearance upstream of LDL formation. Evinacumab-dgnb blockade of ANGPTL3 lowers TG and HDL-C by rescuing LPL and EL activities, respectively.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Evkeeza (evinacumab-dgnb) will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
- Medical record documentation of <u>one</u> of the following:
    - Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (ApoB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
    - Diagnosis made based on history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age OR evidence of heterozygous familial hypercholesterolemia (HeFH in both parents)

  AND
- Medical record documentation that Evkeeza is prescribed by a lipidologist or cardiologist **AND**
- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose AND ezetimibe defined as:
    - Greater than or equal to 130 mg/dL in pediatric patients greater than or equal to 5 years of age and less than 18 years of age OR
    - Greater than or equal to 100 mg/dL in adult patients without cardiovascular disease OR
    - Greater than or equal to 70 mg/dL in adult patients with established cardiovascular disease

AND

- Medical record documentation of Evkeeza to be used in adjunct with maximum tolerated statin dose **AND**
- For members greater than or equal to 10 years of age, medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor **AND**
- If the request is for use in combination with Juxtapid:
    - Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with a minimum 6-month trial of maximum tolerated Juxtapid dose without the concomitant use of Evkeeza

AUTHORIZATION DURATION: Initial authorization will be for a period of six (6) months. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year, requiring medical record documentation that current medical necessity criteria are met and that therapy has been effective.

Evkeeza (evinacumab-dgnb) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
- Medical record documentation of one of the following:
    - Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (ApoB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
    - Diagnosis made based on history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age OR evidence of heterozygous familial hypercholesterolemia (HeFH in both parents)

AND

- Medical record documentation that Evkeeza is prescribed by a lipidologist or cardiologist **AND**
- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels, defined as:
    - Greater than or equal to 130 mg/dL in pediatric patients greater than or equal to 5 years of age and less than 18 years of age OR
    - Greater than or equal to 100 mg/dL in adult patients without cardiovascular disease OR
    - Greater than or equal to 70 mg/dL in adult patients with established cardiovascular disease

AND

- Medical record documentation of Evkeeza to be used in adjunct with other low-density lipoprotein-cholesterol (LDL-C) lowering therapies.

AUTHORIZATION DURATION: Initial authorization will be for a period of six (6) months. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year, requiring medical record documentation that current medical necessity criteria are met and that therapy has been effective.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Evkeeza [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; March 2023.
2. 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. Circulation. 2019;139(25):e1082-e1143 [cited 2023 Dec 12]. Available from: https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000625?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org
3. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022;80(14):1366-1418 [cited 2023 Dec 26]. Avialable from: https://www.clinicalkey.com/#!/content/playContent/1-s2.0-S0735109722055942?returnurl=https:%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0735109722055942%3Fshowall%3Dtrue&referrer=https:%2F%2Fpubmed.ncbi.nlm.nih.gov%2F

This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/31/21

Revised: 3/15/22 (Dx edit, ezetimibe add, apheresis delete), 3/14/23 (LOB carve out, Medicaid business segment), 8/25/23 (age), 12/28/23 (references added), 8/19/24 (LOB table, taglines)

Reviewed: 7/25/25

MA UM Committee approval: 12/31/23, 12/31/24, 9/10/25