



## RX.PA.040.MPC Evkeeza (Evinacumab-dgnb)

The purpose of this policy is to define the prior authorization process for Evkeeza (evinacumab-dgnb).

Evkeeza (evinacumab-dgnb) 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

N/A

### POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process. The drug Evkeeza (evinacumab-dgnb), is subject to the prior authorization process.

### PROCEDURE

#### A. Initial Authorization Criteria:

*Must meet all of the criteria listed below::*

- Must be prescribed by or in consultation with a clinical lipidologist, cardiologist, or endocrinologist
- Must be 12 years of age or older
- Must have a diagnosis of homozygous familial hypercholesterolemia. Chart documentation of a clinical work-up to rule out other diagnoses and clinical rationale for the diagnosis and exclusion of other possible diagnoses must be provided. The diagnosis must either be confirmed by genetic testing or a clinical diagnosis defined as ONE of the four following scenarios:
  - Must have documented functional mutation(s) in both LDL receptor

- alleles or alleles known to affect LDL receptor functionality
  - Must have untreated total cholesterol (TC) >500mg/dL and triglycerides (TG) <300mg/dL and have both parents with untreated TC >250mg/dL and LDL-C level >500mg/dL
  - Must have untreated TC >500mg/dL and TG <300mg/dL and have both parents with untreated TC >250mg/dL and ONE of the following:
    - Skin fibroblast LDL receptor activity <20% normal
    - Presence of cutaneous and tendon xanthomas and corneal arcus in the first decade of life
  - Must have untreated LDL-C level >500mg/dL and ONE of the following:
    - Skin fibroblast LDL receptor activity <20% normal
    - Presence of cutaneous and tendon xanthomas and corneal arcus in the first decade of life
- Must be on at least TWO LDL-lowering medications from different classes (e.g., statins, nicotinic acid, ezetimibe)
  - One of these medications must be an HMG-CoA Reductase Inhibitor titrated to maximum tolerated dose; unless contraindicated or intolerant to at least 2 different statins
- Must have an adequate trial (of at least 3 months) of Praluent (18 years and older) or Repatha (13 years and older) with an inadequate response or significant side effects/toxicity or have a contraindication to therapy
- Must have the following baseline tests (within one month of initiation and dates of tests must be provided):
  - For females of reproductive potential:
    - Must have a negative pregnancy test prior to starting
    - Must be using effective contraception
  - LDL-C level

**B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**

**c. Evkeeza will be considered investigational or experimental for any other use and will not be covered.**

**D. Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

**MPC Renewal:**

- Member has a documented clinical improvement to therapy as determined by the prescriber.
- Documentation of reduction in LDL levels since starting treatment

- Must be prescribed by or in consultation with a clinical lipidologist, cardiologist, or endocrinologist
- Member must continue to receive 2 other lipid lowering therapies.

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
- Provider has a documented clinical response of the member's condition which has improved compared to baseline.

**Limitations:**

| Length of Authorization (if above criteria met) |                |
|---|----------------|
| Initial Authorization                           | Up to 4 months |
| Reauthorization                                 | Up to 1 year   |

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

**HCP Codes:**

| Code                        | Description                      |
|-----------------------------|----------------------------------|
| J1305<br>(previously C9079) | Injection, Evinacumab-dgnb, 5 mg |

**REFERENCES**

1. Cuchel M, Meagher E, du Toit Theron H, et al. Efficacy and Safety of a Microsomal Triglyceride Transfer Protein Inhibitor in Patients with Homozygous Familial Hypercholesterolemia: a Single Arm, Open-Label, Phase 3 Study. The Lancet. 2012; published online at [http://dx.doi.org/10.1016/S0140-6736\(12\)61731-0](http://dx.doi.org/10.1016/S0140-6736(12)61731-0).
2. Repatha [prescribing information]. Thousand Oaks, CA: Amgen Inc; August 2015.
3. Raal FJ, Honarpour N, Blom DJ et al. Inhibition of PCSK9 with evolocumab in homozygous familial hypercholesterolaemia (TESLA Part B): a randomised, double-blind, placebo-controlled trial. Lancet. 2015 Jan 24;385(9965):341-50.
4. Raal FJ, Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. Atherosclerosis 2012; 223: 262–68.

**RECORD RETENTION**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.



**REVIEW HISTORY**

| DESCRIPTION OF REVIEW / REVISION  | DATE APPROVED |
|---|---------------|
| <i>Annual Review</i>  | 02/2026       |
| <i>Annual Review</i>  | 02/2025       |
| <i>Annual Review<br/>Change in Non-MPC renewal to renewal from previous insurer</i> | 02/2024       |
| <i>Annual review</i>  | 02/2023       |
| <i>Selected Revision<br/>Addition of MPC vs Non-MPC Renewal Criteria</i>            | 09/2022       |
| <i>Annual review</i>  | 02/2022       |
| <i>Addition of dosing requirements and off-label restrictions</i>                   | 12/2021       |
| <i>P&amp;T Review</i>   | 11/2021       |
| <i>Evkeeza assigned HCPCS code update</i>   | 10/2021       |
| <i>New Policy</i>   | 11/2020       |