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.

Non-MPC Renewal:

- Members who have previously been taking Evkeeza and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
- Member has not been receiving medication samples for Evkeeza; AND
- 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.

HCPCS Codes:

Code	Description
J1305 (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.
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
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*09/2022*
Annual review	*02/2022*

Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2021*
Evkeeza assigned HCPCS code update	*10/2021*
New Policy	*11/2020*