



RX.PA.040.CCH Evkeeza (Evinacumab-dgnb)

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

The drug, Evkeeza (evinacumab-dgnb), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be age 12 years or older
- Must be prescribed by, or in consultation with, a clinical lipidologist
- Must have a diagnosis of homozygous familial hypercholesterolemia, as confirmed by genetic testing **OR** a clinical diagnosis defined as ONE of the four following scenarios:
 - Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality
 - 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
 - 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
 - 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 unless contraindicated or intolerant
- 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 Evkeeza
 - Must be using effective contraception
 - LDL-C level

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 documentation in a reduction in LDL levels from baseline.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

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.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J1305	Evkeeza	Injection, evinacumab-dgnb, 5mg

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).

1. Juxtapid [package insert]. Cambridge, MA: Aegerion Pharmaceuticals; May 2015 .
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.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	01/2024

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.

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