Premier Health Plan

# POLICY AND PROCEDURE



**POLICY TITLE:** ***Juxtapid (lomitapide)***
**DEPARTMENT:** **Clinical Pharmacy Services- Utilization Management**
**ORIGINAL DATE:** ***January 2013 (as adopted from UPMC Health Plan)***

**Last P & T Committee Approval Date:** *February 2018*

**Product Applicability:** *mark all applicable products below:*

| | |
|---|---|
| **COMMERCIAL** | [ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x ] All |
| **OTHER** | [ x ] Self-funded/ASO |

## PURPOSE

The purpose of this policy is to define the prior authorization process for Juxtapid (lomitapide).

Juxtapid (lomitapide) is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-denisty lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) in patients 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, Juxtapid (lomitapide), is subject to the prior authorization process.

## PROCEDURE

**Initial Authorization Criteria:**

*Must meet all of the criteria listed below:*

- Must be prescribed by or in consultation with a clinical lipidologist
- Must be age 18 years and 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 both parents with documented untreated TC >250mg/dL AND untreated LDL-C level >500mg/dL
    - Must have untreated total cholesterol (TC) >500mg/dL and triglycerides (TG) <300mg/dL and both parents with documented 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 have the following baseline (within one month) tests:
    - For females of reproductive potential:
    - Must have a negative pregnancy test prior to starting lomitapide (Juxtapid); the date of the test must be provided.
    - Must be using effective contraception

  - Transaminase (ALT and AST), alkaline phosphatase, and bilirubin levels. The date of the tests must be provided.
  - LDL-C level. The date of the test must be provided
- Must be on at least two LDL-lowering medications from different classes. One of these medications must be an HMG-CoA Reductase Inhibitor unless contraindicated or intolerant [such as, but not limited to, nicotinic acid or ezetimibe (Zetia®)]
- Must have an adequate trial (of at least 3 months) of Repatha® (evolocumab) with an inadequate response or significant side effects/toxicity or have a contraindication to therapy
- Must not be on concomitant treatment with moderate or strong CYP3A4 inhibitors (amprenavir, aprepitant, atazanavir, ciprofloxacin, crizotinib, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil, boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole)
- Must not have moderate or severe hepatic impairment (Child-Pugh category B or C) or active liver disease

**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 following:

- Documentation of improvement in the condition based upon the prescriber's assessment while on treatment
- Documentation of laboratory monitoring of transaminase, alkaline phosphatase, and bilirubin levels during treatment
- Documentation of reduction in LDL levels since starting treatment

**Limitations:**

| **Length of Authorization (if above criteria met)** | |
|---|---|
| Initial Authorization | Up to 4 months |
| Reauthorization | Up to 1 year |
| **Quantity Level Limit** | |
| Juxtapid | 30 capsules per 30 days |

If the established criteria are not met, the request is referred to a Medical Director for review.

## 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. Juxtapid [package insert]. Cambridge, MA: Aegerion Pharmaceuticals; May 2015 .
3. Repatha [prescribing information]. Thousand Oaks, CA: Amgen Inc; August 2015.
4. Raal FJ, Honarpour N, Blom DJ et al. Inhibition of PCSK9 with evolocumab in homozygous
5. familial hypercholesterolaemia (TESLA Part B): a randomised, double-blind, placebo-controlled
6. trial. Lancet. 2015 Jan 24;385(9965):341-50.
7. 5. 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 |
|---|---|
| *Criteria update* | *02/17* |
| *Annual review* | *02/16, 02/18* |