Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Kynamro (mipomersen)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 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 Kynamro (mipomersen).

Kynamro (mipomersen) is indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), 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, Kynamro (mipomersen), 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 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:
    - 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 (at least 3 months) of Repatha® (evolocumab) with an inadequate response of significant side effects/toxicity or have a contraindication to this therapy
- 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 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 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Kynamro	4 vials per 28 days

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

REFERENCES

1. Kynamro [prescribing information]. Ridgefield, NJ: Genzyme Biosurgery; March 2015.
2. Raal FJ, Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. Atherosclerosis. 2012;223(2):262-268.
3. Raal F, Santos R, Blom D, et al. Mipomersen, an apolipoprotein B synthesis inhibitor, for lowering of LDL cholesterol concentratons in patients with homozygous familial hypercholesterolemia: a randomized, double-blind, placebo-controlled trial. Lancet 2010; 375:998-1006.
4. Repatha [prescribing information]. Thousand Oaks, CA: Amgen Inc; August 2015.
5. 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.

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*