Kynamro (mipomersen)

**Line(s) of Business:**
HMO; PPO; QUEST Integration

**Original Effective Date:**
10/01/2015

**Current Effective Date:**
03/01/2019

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indications**

Kynamro 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, and non-high density lipoprotein-cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

**B. CRITERIA FOR INITIAL APPROVAL**

**Homozygous familial hypercholesterolemia (HoFH)**

Authorization for 12 months may be granted for members who meet all of the criteria listed below:

1. Member has a diagnosis of HoFH confirmed by genetic analysis or clinical criteria (See Appendices).
2. Prior to initiation of treatment with Kynamro, patient is/was receiving a combination lipid-lowering regimen consisting of a high-intensity statin, ezetimibe, and evolocumab (Repatha).
3. Prior to initiation of treatment with Kynamro, patient is/was experiencing an inadequate response to such a combination regimen, as demonstrated a treated LDL-C of greater than or equal to 100 mg/dL (or greater than or equal to 70 mg/dL with clinical atherosclerotic cardiovascular disease [ASCVD]).

**C. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for members (including new members) who meet all initial authorization criteria and have achieved or maintained a LDL-C reduction greater than 20% from the levels immediately prior to initiation of treatment with Kynamro.

**D. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**E. ADMINISTRATIVE GUIDELINES**

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.
F. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. APPENDICES

APPENDIX A. Diagnosis of Homozygous Familial Hypercholesterolemia
- Genetic confirmation
  - Mutations in both alleles at LDL receptor, ApoB, PCSK9 or LDL receptor adaptor protein gene locus
- Clinical diagnosis
  - Untreated LDL-C > 500 mg/dL OR unknown untreated LDL-C with treated LDL-C > 300 mg/dL plus
  - One of the following:
    - Tendon or cutaneous xanthomas at age 10 or younger
    - Diagnosis of familial hypercholesterolemia (FH) by Simon-Broome Diagnostic Criteria or Dutch Lipid Clinic Network Criteria (See Appendix B) in both parents
    - Evidence of FH in both parents with a history including any of the following:
      - Total cholesterol ≥ 310 mg/dL
      - Premature ASCVD (before 55 years in men and 60 years in women)
      - Tendon xanthoma
      - Sudden premature cardiac death

APPENDIX B: Diagnosis of familial hypercholesterolemia (FH)
A diagnosis of FH is made when one of the following diagnostic criteria is met:
- Genetic confirmation
  - An LDL-receptor mutation, familial defective apo B-100, or a PCSK9 gain-of-function mutation
- Simon-Broome Diagnostic Criteria for FH
  - Total cholesterol > 290 mg/dL or LDL-C > 190 mg/dL in patients over 16 years of age or total cholesterol > 260 mg/dL or LDL-C > 155 mg/dl in patients less than 16 years of age and one of the following
- Tendon xanthomas in the patient, first (parent, sibling or child) or second degree relative (grandparent, uncle or aunt)
- Family history of myocardial infarction in a first degree relative before the age of 60 or in a second degree relative before the age of 50
- Total cholesterol greater than 290 mg/dL in an adult first or second degree relative
- Total cholesterol greater than 260 mg/dL in a child, brother, or sister aged younger than 16 years
- Dutch Lipid Clinic Network Criteria for FH
  - Total score > 5 points

H. REFERENCES
## Document History

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