UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Kynamro

Program	Prior Authorization
Medication	Kynamro (mipomersen sodium)
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Kynamro (mipomersen sodium) is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis 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). The safety and efficacy of Kynamro have not been established in patients with hypercholesterolemia who do not have HoFH.

2. Coverage Criteria:

A. Initial Authorization

1. **Kynamro** will be approved based on **all** of the following criteria:

   a. Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by **both** of the following:*

      (1) **One** of the following:

         (a) Pre-treatment LDL-C greater than 500 mg/dL
         (b) Treated LDL-C greater than 300 mg/dL

-AND-

      (2) **One** of the following:

         (a) Xanthoma before 10 years of age
         (b) Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

-AND-

b. Used as an adjunct to a low-fat diet and exercise

-AND-

c. Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

-AND-

d. Prescribed by **one** of the following:

(1) Cardiologist

(2) Endocrinologist

(3) Lipid specialist

-AND-

e. History of intolerance, failure or contraindication to Repatha (evolocumab)

-AND-

f. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

-AND-

g. Not used in combination with Juxtapid (lomitapide)

*Results of prior genetic testing can be submitted as confirmation of diagnosis of HoFH, however please note that UnitedHealthcare commercial plans do not currently cover genetic testing for evidence of an LDL-receptor mutation, familial defective apo B-100 or a PCSK9 mutation.

Authorization will be issued for 12 months.

B. Reauthorization

1. Kynamro will be approved based on **all** of the following criteria:

a. Patient is continuing a low-fat diet and exercise regimen

-AND-

b. Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

-AND-

c. Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C reduction while on Kynamro therapy

-AND-

d. Prescribed by **one** of the following:

(1) Cardiologist

(2) Endocrinologist

(3) Lipid specialist

-AND-

e. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

-AND-

f. Not used in combination with Juxtapid (lomitapide)

Authorization will be issued for 12 months.

3. References:

1. Kynamro [package insert]. Cambridge, MA: Genzyme Corporation; May 2016.
2. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management: A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014; 35:2146-57.

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Change Control	
Date	Change
3/2013	New guideline
3/2014	Updated criteria to require patient to be both on a low-fat diet and receiving other lipid-lowering therapy (e.g., statin) Reformatted criteria to align with UHC standard template
10/2015	Updated initial authorization criteria to require all of the following: • Submission of medical records documenting diagnosis of HoFH as confirmed by one of the following: o Both of the following: ▪ Untreated LDL-C > 500 mg/dL, or treated LDL-C > 300 mg/dL, AND ▪ Xanthoma before 10 years of age, or evidence of HeFH in both parents • Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis) • Used as adjunct to low-fat diet and exercise regimen • Prescribed by cardiologist, endocrinologist, or lipid specialist • History of failure, contraindication, or intolerance to Repatha (evolocumab) • Not used in combination with Juxtapid (lomitapide) • Not used in combination with another PCSK9 inhibitor Updated reauthorization criteria to require all of the following: • Patient is continuing a low-fat diet and exercise regimen • Patient continues to receive other lipid-lowering therapy • Documentation of a sustained LDL-C reduction from pre-treatment baseline while on Juxtapid therapy • Prescribed by cardiologist, endocrinologist, or lipid specialist • Not used in combination with another PCSK9 inhibitor Not used in combination with Juxtapid (lomitapide)
9/2016	Updated policy template and references
3/2017	Changed initial authorization duration to 12 months
9/2017	Annual review. Removed requirement of medical record submission for diagnosis documentation.