

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3064-6
Program	Step Therapy
Medications	Lipid Lowering Therapies for Homozygous Familial Hypercholesterolemia - Juxtapid® (lomitapide), Kynamro® (mipomersen sodium)
P&T Approval Date	10/2015, 9/2016, 9/2017, 9/2018
Effective Date	12/1/2018; Oxford: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member with homozygous familial hypercholesterolemia to use Repatha™ (evolocumab) unless there is a history of intolerance, failure or contraindication to Repatha therapy.

Juxtapid (lomitapide) is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid lowering treatments, including LDL apheresis where available, to reduce low-density 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). The safety and efficacy of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH. ¹

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

Repatha™ (evolocumab) is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C).
- as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C. ³

Members will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

A. Homozygous Familial Hypercholesterolemia

1. **Juxtapid or Kynamro** will be approved based on one of the following criteria:

- a. History of failure, contraindication, or intolerance to Repaththa (evolocumab)

-OR-

b. **Both** of the following:

- (1) Patient is currently on Juxtapid or Kynamro therapy

-AND-

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

- (a) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office or a 30 day free trial from a pharmacy as a means to establish as a current user of Juxtapid or Kynamro

-OR-

(b) **Both** of the following:

- i. Patient has received a manufacturer supplied sample at no cost in prescriber office or a 30 day free trial from a pharmacy as a means to establish as a current user of Juxtapid or Kynamro

-AND-

- ii. History of failure, contraindication, or intolerance to Repaththa (evolocumab)

Authorization will be issued for 24months.

B. Other Diagnoses

1. **Juxtapid or Kynamro** will be approved

Authorization will be issued for 24 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

Supply limits and/or Prior Authorization may be in place.

4. References:

1. Juxtapid [package insert]. Cambridge, MA: Aegerion Pharmaceuticals; August 2017.
2. Kynamro [package insert]. Cambridge, MA: Genzyme Corporation; May 2016.
3. Repatha [package insert]. Thousand Oaks, CA : Amgen Inc. ; December 2017.

Program	Step Therapy - Lipid Lowering Therapies for Homozygous Familial Hypercholesterolemia - Juxtapid® (lomitapide), Kynamro® (mipomersen sodium)
Change Control	
10/2015	New step therapy program that requires the use of Repatha for treatment of homozygous familial hypercholesterolemia before other treatments are covered.
7/2016	Added Indiana and West Virginia coverage information.
9/2016	Annual update. Decreased authorization period to 24 months. Updated references.
11/2016	Administrative change. Added California coverage information.
9/2017	Annual review with no change to criteria. Updated state mandate verbiage.
9/2018	Annual review with no change to criteria. Updated background and references.