UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3064-12
Program	Step Therapy
Medications	Juxtapid® (lomitapide)
P&T Approval Date	10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 7/2021, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

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) and Evkeeza® (evinacumab) unless there is a history of intolerance, failure or contraindication to Repatha and Evkeeza 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, including those with heterozygous familial hypercholesterolemia (HeFH). [1]

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.[2]
- 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 other LDL-C-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
- as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C.

Evkeeza (evinacumab) is an ANGPTL3 (angiopoietin-like 3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with HoFH.[3]

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2. Coverage Criteria[a]:

A. Homozygous Familial Hypercholesterolemia

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

   a. **Both** of the following:

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

      -AND-

      (2) History of failure, contraindication, or intolerance to Evkeeza (evinacumab)

      -OR-

   b. **Both** of the following:

      (1) Patient is currently on Juxtapid 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-

         (b) **All** 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

            -AND-

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

            -AND-

            iii. History of failure, contraindication, or intolerance to Evkeeza (evinacumab)

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Juxtapid** will be approved

Authorization will be issued for 12 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:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Prior Authorization may be in place.

4. References:

1. Juxtapid [package insert]. Cambridge, MA: Aegerion Pharmaceuticals; September 2020.
2. Repatha [package insert]. Thousand Oaks, CA : Amgen Inc.; September 2021.
3. Evkeeza [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; March 2023.

Program	Step Therapy - Juxtapid® (lomitapide)
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.
9/2019	Annual review. Renamed program to Step Therapy- Juxtapid as Kynamro removed from market.
9/2020	Annual review with no changes to coverage criteria. Updated reference.
7/2021	Added Evkeeza as step through agent to background and criteria. Added continuation of therapy coverage statement to background. Decreased authorization period to 12 months. Updated references.
6/2022	Updated background to include new indication per Repatha package insert. No changes to coverage criteria. Updated references.
7/2023	Annual review with no change to clinical criteria. Updated background and references.

7/2024	Annual review with no change to clinical criteria. Updated background.