UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 3064-13 |
| 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, 7/2025 |
| Effective Date | 10/1/2025 |

**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).

Repatha (evolocumab) is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH) 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.

UnitedHealthcare®

**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.; November 2024.
3. Evkeeza [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; March 2023.


| Program | Step Therapy - Juxtapid® (lomitapide) |
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| **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. |
| 7/2025 | Annual review with no change to clinical criteria. Updated background and reference. |