UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1053-11
Program	Prior Authorization/Notification
Medication	Juxtapid® (lomitapide)
P&T Approval Date	2/2013, 2/2014, 2/2015, 2/2016, 2/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023
Effective Date	5/1/2023; Oxford only: N/A

1. Background:

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). The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined.[1]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Initial Authorization

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

   a. Diagnosis of homozygous familial hypercholesterolemia

   -AND-

   b. Patient is on a low-fat diet

   -AND-

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

   Authorization will be issued for 7 months.

B. Reauthorization

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

   a. Patient is on a low-fat diet

   -AND-

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

-AND-

c. Documentation of positive clinical response to Juxtapid therapy

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 medical necessity may be in place.

4. Reference:

1. Juxtapid [package insert]. Cambridge, MA: Amryt Pharmaceuticals; September 2020.

Program	Prior Authorization/Notification - Juxtapid® (lomitapide)
Change Control	
2/2013	New program.
2/2014	Annual Review. Added criterion to initial authorization requiring patient to be on a low-fat diet. Added criteria to reauthorization requiring patient to be on a low-fat diet and receiving other lipid-lowering therapy.
2/2015	Annual review with no change to coverage criteria. Updated background and references.
2/2016	Annual review. Updated background and references. Changed initial authorization period to align with Kynamro.
2/2017	Annual review with no changes to coverage criteria. Updated background and references.
2/2018	Annual review with no changes to coverage criteria. Updated reference.
2/2019	Annual review with no changes to coverage criteria.
2/2020	Annual review with no changes to coverage criteria. Updated reference.
2/2021	Annual review with no changes to coverage criteria. Updated reference.
2/2022	Annual review with no changes to coverage criteria.
2/2023	Annual review with no changes to coverage criteria. Added state mandate.