

Lomitapide (JUXTAPID) Criteria for Use July 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive lomitapide.

- Pregnancy
- Lactating
- Concomitant use of moderate or strong inhibitors of CYP 3A4
- Patient with moderate or severe liver disease (e.g., Child-Pugh Category B or C) or patient with active liver disease, including those with unexplained persistent elevation of serum transaminases.

Inclusion Criteria

All of the following criteria must be met.

- Provider is certified to prescribe lomitapide due to increased risk of hepatotoxicity.
- Diagnosis of homozygous familial hypercholesterolemia (HoFH) ^{^1-2}
- Patient has been educated regarding the need to follow a low-fat diet and is willing and able to follow a diet consisting of <20% of daily calories from fat.
- PCSK9 inhibitor (e.g., alirocumab) provided insufficient reduction in low density lipoprotein cholesterol (LDL-C).
- Receiving LDL-C apheresis, if a candidate for and if therapy is accessible.
- Negative pregnancy test confirmed, if applicable.

^{^1} Diagnosis of HoFH confirmed with 1) genetic testing (mutation in LDL receptor: true homozygote or double heterozygote), **OR** 2) Untreated LDL of >500 mg/dL **OR** 3) Receiving maximal treatment with lipid-lowering therapy and LDL >300 mg/dL (adherence is confirmed), **AND** Physical findings including tendon xanthomas at any age, arcus corneae in patients <45 years or tuberous xanthomas or xanthelasma in patients <20 years.

^{^2} Safety and efficacy of lomitapide has not been established in patients without HoFH and therefore, lomitapide should only be used in patients where a diagnosis of HoFH is confirmed.

Additional Inclusion Criteria

- For females who can become pregnant: Pregnancy must be excluded prior to receiving lomitapide.
- For females who can become pregnant: Counseling has been provided on the potential risks vs benefits of treatment and the use of effective contraception during therapy lomitapide.