**Juxtapid (lomitapide)**

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
</tr>
<tr>
<td>Step Therapy</td>
<td></td>
</tr>
<tr>
<td>Quantity Limit</td>
<td></td>
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<tr>
<th>Medications</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Juxtapid (lomitapide)</td>
<td>1 capsule per day</td>
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**APPROVAL CRITERIA**

Requests for Juxtapid (lomitapide) may be approved based on the following criteria:

I. Individual is 18 years of age or older and has a clinical diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), based on the presence of the following:

   a. Genetic confirmation of two (2) mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; **OR**
   b. An untreated LDL-cholesterol concentration > 500 mg/dL (13 mmol/L); **OR**
   c. Treated LDL-cholesterol ≥ 300 mg/dL (7.76 mmol/L) **AND** one of the following:
      i. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
      ii. Untreated LDL cholesterol levels consistent with heterozygous FH in both parents (> 190 mg/dL)

**AND**

II. Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response, despite at least 90 days of compliant therapy; **OR**

III. Repatha is not acceptable due to concomitant clinical situations, such as but not limited to a known disease state or medication contraindication which is not also associated with Juxtapid (lomitapide).

Juxtapid (lomitapide) may **not** be approved for the following:

I. Concurrent use with PCSK-9 Inhibitors.

**Note:** Juxtapid is a pregnancy category X. Juxtapid (lomitapide) has a black box warning for risk of hepatotoxicity. Juxtapid can cause elevations in transaminases. Juxtapid also increases hepatic fat (hepatic steatosis) with or without concomitant increases in transaminases. Because of the risk of hepatotoxicity, Juxtapid is only available through a restricted program, Juxtapid REMS.
**State Specific Mandates**

| N/A | N/A | N/A |

**Key References:**


DRUGDEX® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.