LOMITAPIDE

Generic	Brand	HICL	GCN	Exception/Other
LOMITAPIDE	JUXTAPID	39883		

***********Customer Service/PAC Alert************
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
   - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #3.
   If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Juxtapid?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has had a previous trial of Repatha (evolocumab)
   - The patient lacks functioning LDL receptors

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?
   - Simon Broome diagnostic criteria (definite)
   - Dutch Lipid Network criteria with a score of at least 8
   - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**
   - **Juxtapid 5mg (GPID 33909): #45 per 30 days.**
   - **Juxtapid 10mg (GPID 33912): #30 per 30 days.**
   - **Juxtapid 20mg (GPID 33913): #90 per 30 days.**
   - **Juxtapid 30mg (GPID 38574): #30 per 30 days.**
   - **Juxtapid 40mg (GPID 38571): #30 per 30 days.**
   - **Juxtapid 60mg (GPID 38573): #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

DENIAL TEXT: The guideline named **LOMITAPIDE (Juxtapid)** requires a diagnosis of homozygous familial hypercholesterolemia (HoFH). The following criteria must also be met:
- The diagnosis of homozygous familial hypercholesterolemia (HoFH) is determined by meeting **ONE** of the following criteria:
  - Simon Broome diagnostic criteria (definite)
  - Dutch Lipid Network criteria with a score of at least 8
  - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents
- The agent is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
- The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment
- The patient has had a previous trial of Repatha (evolocumab) unless the patient lacks functional LDL receptors

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

For statin tolerant patients, approval also requires the following:

- The patient meets **ONE** of the following criteria:
  - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
  - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient will continue statin treatment in combination with Juxtapid

For statin intolerant patients, approval also requires ONE of the following:

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

RATIONALE

Ensure appropriate utilization of Juxtapid according to approved indications, dosing, clinical trial data, and national treatment guidelines.

FDA APPROVED INDICATIONS

Juxtapid is 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).

Limitations of use:

- The safety and effectiveness 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

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FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Initiate treatment at 5 mg once daily. Titrate dose based on acceptable safety/tolerability: increase to 10 mg daily after at least 2 weeks; and then, at a minimum of 4-week intervals, to 20 mg, 40 mg, and up to the maximum recommended dose of 60 mg daily.

Take once daily, whole, with water and without food, at least 2 hours after evening meal.

REFERENCES

- Juxtapid [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/18

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