Commercial/Healthcare Exchange PA Criteria

Effective: February 2013

Prior Authorization: Juxtapid (lomitapide)

Products Affected: Juxtapid (lomitapide) oral capsule

Medication Description: Juxtapid is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, to reduce LDL cholesterol, total cholesterol, apolipoprotein B (apo B), and non–high-density lipoprotein cholesterol (non–HDL-C) in patients with homozygous familial hypercholesterolemia.

Covered Uses: Homozygous familial hypercholesterolemia

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed
3. LDL labs or genetic confirmation test results

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Must be prescribed by a cardiologist, lipidologist, or endocrinologist

Coverage Duration:
Initial: 8 weeks
Continuation: 12 months

Other Criteria: ConnectiCare will consider Juxtapid to be medically necessary in patients who meet all of the following criteria:

- Medication is being prescribed by a cardiologist, lipidologist, or endocrinologist
- Member must be 18 years of age or older
- Member must have a diagnosis of definite homozygous familial hypercholesterolemia as defined by at least one of the following:
    - Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus

    OR

    - An untreated LDL-C > 500 mg/dL or treated LDL-C > 300 mg/dL, or treated non-HDL cholesterol > 330 mg/dL

    With at least one of the following:

- Cutaneous or tendonous xanthoma before age 10 years

OR

- Elevated LDL cholesterol levels before lipid lowering therapy consistent with heterozygous familial hypercholesterolemia in both parents (untreated total cholesterol > 290 mg/dL (7.5 mmol/L) or untreated LDL-C > 190 mg/dL

AND

- Member must have had 90 days of consecutive therapy in the past 12 months, intolerance or contraindication to a high intensity HMG CoA reductase inhibitor (statin) at the maximum approved or tolerated dose per the package insert (high intensity statins include atorvastatin 80 mg and Crestor 40 mg) and Zetia

AND

- Member has had an inadequate response or contraindication to Repatha

References:

1. Identification and management of familial hypercholesterolaemia. National Institute for Health and Clinical Excellence (NICE), Royal College of General Practitioners. Available at: http://www.nice.org.uk/cg71. Accessed July 2013
2. Juxtapid [package insert]. Cambridge, MA: Aegerion Pharmaceuticals Inc.; December 2012.
3. Raal FJ and Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. Atherosclerosis 2012;223:262-268.
4. Vergopoulos, Knoblauch, Schuster. DNA testing for familial hypercholesterolemia: improving disease recognition and patient care. Am J Pharmacogenomics, 2002; 2 (4); 253-62
5. Robinson. Management of Familial Hypercholesterolemia: A Review of the Recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Manag Care Pharm. 2013; 19 (2): 139-49
6. Facts & Comparisons, Online

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	2/2013

2	Policy Update	CCI to adopt EH Policy Template, CCI P&T Review History: 2/13, 10/13, 10/14, 11/15, 8/16, 8/17, 7/18 CCI Revision History: 8/16	All	7/2/2019