WELL SENSE HEALTH PLAN

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Pharmacy Policy

Homozygous Familial Hypercholesterolemia

Policy Number: 9.603
Revision Number: R1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☒ New Hampshire Medicaid ☐ _____	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options ☐ _____

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Juxtapid (lomitapide)**
- **Kynamro (mipomersen)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Concurrent use with PCSK9 inhibitors
Required Medical Information	Documentation of all the following: 1. Diagnosis of homozygous familial hypercholesterolemia; ***AND*** 2. **<u>One</u>** of the following: a. Inadequate LDL reduction while adherent to a minimum of 90 day continuous use of atorvastatin 80mg or rosuvastatin 40mg in combination with ezetimibe evidenced by: i. Current LDL-C greater than or equal to 100mg/dL; ***AND***

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	ii. Less than a 50 percent reduction in LDL-C from baseline; ***OR*** b. Inability to tolerate a high intensity statin (atorvastatin 80mg or rosuvastatin 40mg); ***AND*** Inadequate response while adherent to a minimum of 90 day continuous use of a maximum tolerated dose of a non-high intensity statin and ezetimibe evidenced by: i. Current LDL-C greater than or equal to 100mg/dL; ***AND*** 3. An inadequate response to Repatha while adherent to a minimum of 90 day continuous use as evidenced by: a. Current LDL-C greater than or equal to 100 mg/dL; ***OR*** b. An adverse effect or contraindication to Repatha; ***AND*** 4. **For Juxtapid**- an inadequate response, adverse effect or contraindication to Kynamro; **OR** Member is concurrently receiving lipid apheresis.
Age Restriction	None
Prescriber Restriction	None
Coverage Duration	1 year
Other criteria	Re-authorization: Documentation of the following: 1. Clinical response to therapy as defined by a decrease in LDL-C levels from baseline; ***AND*** 2. Liver function test including AST and ALT are being monitored every 3 months and drug will be discontinued if liver function tests are 3 times the ULN.

Clinical Background Information and References

1. Rosenson R, de Ferranti S, Durrington P. Treatment of drug resistant hypercholesterolemia. UptoDate. Last updated January 30, 2013, Accessed April 2014. Available from http://www.uptodate.com.
2. Rosenson R, de Ferranti S, Durrington P. Inherited disorders of LDL-cholesterol metabolism. UptoDate. Last updated February 12, 2014, Accessed April 2014. Available from http://www.uptodate.com.
3. Ito M, McGowan M, Moriarty P. Management of familial hypercholesterolemias in adult patients: recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. Journal of Clinical Lipidology. 2011;5: S38-S45.
4. Juxtapid™ [package insert]. Cambridge (MA): Aegerion Pharmaceuticals; March 2016.
5. Kynamro™ [package insert]. Cambridge (MA): Genzyme Corporation; March 2015.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Discontinued Policy 9.039 and created separate policy for NH. No other changes made.	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.