BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Givlaari

Policy Number: 9.321
Version Number: 1
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:

- Givlaari (givosiran)

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	None
Required Medical Information	1. Diagnosis of an acute hepatic porphyria (i.e. acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, ALA dehydratase deficient porphyria) as

[+] *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.

	evidenced by one of the following: a. Elevated urine or plasma porphobilinogen (PBG) and/or aminolevulinic acid (ALA) ***OR*** b. Genetic confirmation of mutation ***AND*** 2. Member has active disease which is documented by one of the following: a. At least two (2) acute porphyria attacks requiring medical treatment and/or administration of hemin in the previous 6 months ***AND*** 3. Member has not had a liver transplant ***AND*** 4. Member will not concurrently receive prophylactic hemin therapy while on Givlaari ***AND*** 5. Dose does not exceed 2.5 mg/kg (body weight) once monthly
Age Restriction	18 year of age and older
Prescriber Restriction	Prescribed by or in consultation with a hematologist, gastroenterologist or a specialist with expertise in the diagnosis and management of AHPs
Coverage Duration	Initial : 6 months Reauthorization: 12 months
Other criteria	Reauthorization: 1. A positive clinical response as evidenced by a reduction of acute porphyria attacks requiring hemin administration or medical intervention ***AND*** 2. Member has not had a liver transplant ***AND*** 3. Dose does not exceed 2.5mg/kg (body weight) once monthly

Applicable Coding:

Code	Medication
J3490	Unclassified drugs
To be determined	Injection, givosiran, 0.5mg

Clinical Background Information and References

1. Givlaari (givosiran) [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2019.
2. Sood GK, Anderson KE. Acute intermittent porphyria: Management. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020.
3. Wang B, Rudnick S, Cengia B, et al. Acute hepatic porphyria's: review and recent progress. Hepatology Communications. 2019;3:193-206.
4. Manisha Balwani Bruce Wang Karl E. Anderson Joseph R. Bloomer, et al. Hepatology. Acute hepatic porphyria's: Recommendations for evaluation and long-term management. 2017; 66:1314-1322

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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.202 Givlaari Policy retired, new policy created.	1/1/2021	P&T Committee

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.