BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Vyndaqel, Vyndamax

Policy Number: 9.323
Version Number: 2.0
Version Effective Date: 9/1/2021

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:

- **Vyndaqel (tafamidis)**
- **Vyndamax (tafamidis)**

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	NHYA functional class III or IV heart failure CrCl <25 mg/dl/1.73m2 Prior liver or heart transplant Presence of implanted cardiac mechanical assist device
Required Medical	1. Member has diagnosis of wild type or hereditary transthyretin amyloid cardiomyopathy confirmed by one of the following (documentation required) : a. Presence of amyloid deposits in biopsy tissue and presence of a variant transthyretin (TTR)

[+] *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.

Information	genotype b. Presence of TTR precursor protein identification by immunohistochemistry, scintigraphy or mass spectrometry c. Genetic testing showing TTR mutation; **AND** 2. Member does not have primary (light chain) amyloidosis: **AND** 3. Patient has a confirmed diagnosis of New York Heart Association (NYHA) class I, II heart failure
Age Restriction	18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a Cardiologist, Amyloid Specialist, Pulmonologist, or Hematologist/Oncologist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Initial criteria is met; **AND** 2. Member had improvement or stabilization in one of the following tests: • Total distance walked during 6 minute walk test (6MWT); • Kansas City Cardiomyopathy Questionnaire overall Score (KCCQ-OS) • Decrease in cardiovascular related hospitalizations

Applicable Coding:

None

Clinical Background Information and References

1. Vyndaqel & Vybdamax (tafamidis) [prescribing information]. Pfizer 2019
2. McKenna WJ. Treatment of amyloid cardiomyopathy. Last updated: **May 10, 2019.**

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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**

Policy Revisions History			
12/1/2020	9.992 Vyndaqel, Vyndamax Policy retired, new policy created. Added documentation requirement, removed diagnoses	1/1/2021	P&T Committee
5/13/2021	P&T Annual Review: updated initial criteria to specify diagnostic tests; updated reauthorization criteria to require improvement/stabilization information; Updated exclusion criteria	9/1/2021	P&T Committee

Next Review Date

5/2022

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.