

## Pharmacy Policy

# Fabrazyme

**Policy Number:** 9.341

**Revision Number:** 1

**Version Effective Date:** 9/1/2021

Product Applicability <input type="checkbox"/> <b>All Plan<sup>+</sup> Products</b>	
<b>Well Sense Health Plan</b> <input type="checkbox"/> New Hampshire Medicaid <input type="checkbox"/> _____	<b>Boston Medical Center HealthNet Plan</b> <input checked="" type="checkbox"/> MassHealth - MCO <input checked="" type="checkbox"/> MassHealth - ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options <input type="checkbox"/> _____

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

## Prior Authorization Policy

### Products Affected:

- Fabrazyme (agalsidase beta)

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

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	Excluded with concurrent use of Galafold (migalastat)
<b>Required</b>	1. Documented diagnosis of Fabry disease confirmed by one of the following:

<sup>\*</sup> 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.

<b>Medical Information</b>	<ul style="list-style-type: none"> <li>a. Enzyme assay demonstrating a deficiency of alpha-galactosidase activity; OR</li> <li>b. DNA testing showing detection of pathogenic mutations galactosidase alpha (GLA) gene</li> </ul> <ul style="list-style-type: none"> <li>2. Requested dose is appropriate for member's BSA</li> <li>3. Dose does not exceed 1mg/kg every 2 weeks</li> </ul>
<b>Age Restriction</b>	2 years of age or older
<b>Prescriber Restriction</b>	Prescribed by or in consultation with a nephrologist, cardiologist, metabolic disorder specialist, or genetic specialist
<b>Coverage Duration</b>	Initial: 6 months Reauthorization: 12 months
<b>Other criteria</b>	Reauthorization: <ul style="list-style-type: none"> <li>1. Member has responded positively to therapy</li> <li>2. Requested dose is appropriate for member's BSA</li> <li>3. Dose does not exceed 1mg/kg every 2 weeks</li> <li>4. Medication is not being used in combination with Galafold (migalastat)</li> </ul>

#### Applicable Coding:

Code	Medication
J0180	Injection, agalsidase beta, 1mg

#### Clinical Background Information and References

1. Fabrazyme (agalsidase beta) [prescribing information]. Cambridge, Massachusetts: Genzyme Corporation; March 2021.
2. Fabry Disease. UptoDate Website. <http://www.uptodate.com>. Accessed April 25, 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	New policy created	9/1/2021	P&T Committee

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## Next Review Date

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5/2022

## Other Applicable Policies

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## Reference to Applicable Laws and Regulations, If Any

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### 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.

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