Pharmacy Medical Necessity Guidelines: Fabrazyme® (agalsidase beta)

Effective: April 11, 2017 (All plans except Tufts Health RITogether)
Effective: June 1, 2017 (Tufts Health RITogether)

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<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
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<td>Pharmacy (RX) or Medical (MED) Benefit</td>
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<td>PRECERT/MM</td>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
- All plans except Tufts Health Public Plans: Precert: 617.972.9409
- Tufts Health Public Plans only: MM: 888.415.9055

**Note:** For Tufts Health Plan Medicare Preferred Members, refer to the Tufts Health Plan Medicare Preferred prior authorization criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FDA-APPROVED INDICATIONS**

Fabrazyme (agalsidase beta) is indicated for use in patients with Fabry disease. Fabrazyme reduces globotriaosylceramide (GL-3) deposition in capillary endothelium of the kidney and certain other cell types.

Fabry disease (also referred to as Anderson-Fabry disease) is a rare genetic lysosomal disorder caused by the body’s inability to produce a specific enzyme responsible for the degradation of glycosphingolipids. In affected individuals, the missing enzyme prevents the normal breakdown and recycling of cells resulting in the storage of these cell deposits in cells of the kidney, heart, skin, eyes, gastrointestinal system, and central and peripheral nervous system. As a result of the storage, cells do not perform properly and may cause progressive damage throughout the body. The signs and symptoms of this condition develop with age as more cells become damaged by the accumulation of cell deposits. The incidence of Fabry disease is reported to be 1 in 40,000 to 60,000 and is most typically seen in males.

Fabrazyme is intended to provide an exogenous source of the enzyme, deficient in patients with Fabry disease, responsible for breaking down glycosphingolipids including GL-3.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Fabrazyme (agalsidase beta) for Members when the ALL of the following criteria are met:

1. The Member must have the definitive diagnosis of Fabry disease
   AND
2. The prescribing physician must be a nephrologist, cardiologist, or from a physician specializing in metabolic disorders or genetics.

**LIMITATIONS**

None

**CODES**

The following HCPCS/CPT code(s) are:

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J0180</td>
<td>Injection, agalsidase beta, 1 mg</td>
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REFERENCES


APPROVAL HISTORY

January 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 11, 2005: No changes
- January 10, 2006: No changes
- December 12, 2006: No changes
- November 13, 2007: No changes
- November 11, 2008: No changes
- November 10, 2009: No changes
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- September 14, 2010: No changes
- July 12, 2011: No changes
- June 12, 2012: No changes
- May 14, 2013: No changes
- May 13, 2014: No changes
- May 12, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- April 12, 2016: No changes
**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, refer to Tufts Health Plan Medicare Preferred prior authorization criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.