Fabrazyme® (agalsidase beta)

Effective: 10/1/15

Clinical documentation and prior authorization required ✓ Type of review – case management

Not covered Type of review – clinical review ✓

Pharmacy (RX) or medical (MED) benefit MED Department to review MM

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.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of Fabrazyme (agalsidase beta) for members when all of the following criteria for a particular regimen are met and limitations do not apply:

- The Member must have the definitive diagnosis of Fabry disease AND
- 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:

<table>
<thead>
<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**

- May 12, 2015: Reviewed by the Pharmacy and Therapeutics Committee

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable *Member Handbook* and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable *Member Handbook*. Check the applicable *Preferred Drug List* (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For *Tufts Health Unify* (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the *Tufts Health Unify Prior Authorization Medical Necessity Guidelines*.

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.