



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** agalsidase beta

**Brand Name:** Fabrazyme

**FDA Approved Uses:** long-term enzyme replacement therapy of patients with confirmed Fabry disease ( $\alpha$ -galactosidase A deficiency).

**Medication Class:** Enzyme replacement; Metabolic storage disease

**Usual Dose:** 1 mg/kg as an intravenous infusion every 2 weeks.

**Duration of Therapy:** Indefinite

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

(initial approval for 3 months, may be renewed for up to one year)

- Must have clinically documented Fabry disease.
  - Alpha-galactosidase levels of less than 1.5 nmol/hr/ml on plasma or less than 4nmol/hr/mg in leukocytes.
- Physician must provide goals of therapy.
- Physician must provide patient's baseline disease status and documentation of the patients signs and symptoms of the disease including objective and subjective clinical information (including, but not limited to, labs, progress notes, specialty consult notes)
  - Labs- globotriaosylceramide (GL-3) concentrations in plasma of 5 ng/mcL or greater.
  - Serum creatinine less than 2.5 mg/dL and no history of renal dialysis or transplantation.

**Criteria for Continuation of Therapy:**

- Must meet goals of therapy:
  - Decreased GL-3 levels.
  - Decreased pain
  - Decreased fatigue

**Contraindications:** None identified.

**Not approved if:**

- Patient does not meet the above stated criteria.



**Special considerations:**

- Patient will be referred to high-risk case management.
- Some patients developed IgE or skin test reactivity specific to agalsidase beta. **Testing for IgE antibodies should be considered for patients developing suspected allergic reactions.** The risk and benefits of continued therapy must be considered in patients developing IgE antibodies to agalsidase beta. Most patients developed IgG antibodies within the first 3 months but this was not associated with inhibition of enzyme activity or efficacy of treatment.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_