CVS/caremark™

POLICY Document for Fabrazyme

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Administration of Intravenous Fabrazyme

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Fabrazyme in an outpatient hospital setting for up to 8 doses when a member is new to therapy.

This policy provides coverage for administration of Fabrazyme in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member has developed fabrazyme IgE antibodies which increases the risk for infusion related reactions.
C. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
D. The member has severe venous access issues that require the use of a special intervention.
E. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
F. Alternative infusion sites are not available.
G. The member is less than 21 years of age or 65 years of age or older.

For situations where administration of Fabrazyme does not meet the criteria for outpatient hospital infusion, coverage for Fabrazyme is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion

B. Medical records supporting the member has developed fabrazyme IgE antibodies
C. Medical records supporting the member is medically unstable
D. Medical records supporting the member has severe venous access issues
E. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
F. Records supporting alternative infusion sites are not available

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

FABRAZYME (agalsidase beta)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Fabrazyme 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.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Fabry disease
Indefinite authorization may be granted for treatment of Fabry disease when the diagnosis of Fabry disease was confirmed by enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, or the member is a symptomatic obligate carrier.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

REFERENCES:

SECTION 1

1. Fabrazyme [package insert]. Cambridge, MA: Genzyme Corporation.; December 2012.
2. Cousins A, Lee P, Rorman D, et al. Home-based infusion therapy for patients with Fabry disease. *Br J Nurs.* 2008;17(10):653-657.
3. Wilcox WR, Banikazemi M, Guffon N, et al. Long-term safety and efficacy of enzyme replacement therapy for Fabry disease. *Am J Hum Genet.* 2004;75(1):65-74.
4. Banikazemi M, Bultas J, Waldek S, et al. Agalsidase-beta therapy for advanced Fabry disease: a randomized trial. *Ann Intern Med.* 2007;146(2):77-86.

SECTION 2

1. Fabrazyme [package insert]. Cambridge, MA: Genzyme Corporation; May 2010.
2. Desnick RJ, Brady RO. Fabry disease in childhood. *J Pediatr.* 2004;144(5 Suppl):S20-S26.
3. Biegstraaten M, Arngrimsson R, Barbey F, et al. Recommendations for initiation and cessation of enzyme replacement therapy in patients with Fabry disease: the European Fabry Working Group consensus document. *Orphanet J Rare Dis.* 2015; 1036.
4. Desnick RJ, Brady R, Barranger J, et al. Fabry disease, an under-recognized multisystemic disorder: expert recommendations for for diagnosis, and enzyme repalacement therapy. *Ann Intern Med.* 2003; 138(4):338.
5. Sirrs, S, Bichet DG, Iwanochko RM, et al. Canadian Fabry disease treatment guidelines 2016.