

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: Treatment of Fabry Disease Policy

Drug(s): FABRAZYME (agalsidase beta)

Covered Uses: Treatment of Fabry disease. All criteria in "other criteria" section must be met for coverage for all drugs.

Required Medical Information: Chart note identifying symptoms and Mainz Severity Score Index (MSSI) or FOS Mainz Severity Score Index and/or globotriaosylceramide level.

Age Restrictions: Restricted to members who are greater than 18 years old

Prescriber Restrictions: N/A

Other Criteria: Treatment with Fabrazyme will be considered medically necessary when the following criteria are met:

- The diagnosis of α -galactosidase deficiency has been confirmed which is supported by at least one of the following:
 1. pain in the extremities
 2. hypohidrosis
 3. corneal opacities
 4. kidney dysfunction
 5. cardiac dysfunction
 6. cerebrovascular disorders.

For continued therapy after the initial approval, the case must be reviewed for appropriate dosages and response to drug therapy (e.g. absence of disease progression).

Exclusion Criteria: The use of Fabrazyme will not be considered medically necessary in the following situations:

- members who are carriers of the disease,
- doses or frequency exceeding FDA approved dosing regimen.

Coverage Duration: 12 months