

# Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to:  Commercial (Traditional)  Commercial (Individual/Optimized)

Medicaid

This request is:  Urgent (life threatening)  Non-Urgent (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

## Fabrazyme<sup>®</sup> (agalsidase beta)

### Member

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_

ID #: \_\_\_\_\_ DOB: \_\_\_\_\_ Gender: \_\_\_\_\_

Primary Care Physician: \_\_\_\_\_

Requesting Physician: \_\_\_\_\_ Phys. Phone: \_\_\_\_\_ Phys. Fax: \_\_\_\_\_

Physician Address: \_\_\_\_\_

Physician NPI: \_\_\_\_\_ Contact Name: \_\_\_\_\_

Provider Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Product and Billing Information

New Request  Continuation Request

Drug product:  Fabrazyme 5 mg injection  Fabrazyme 35 mg injection

Dose: \_\_\_\_\_ Dose Frequency: \_\_\_\_\_

Start date (or date of next dose): \_\_\_\_\_

Date of last dose (if applicable): \_\_\_\_\_

Date of next dose: \_\_\_\_\_

Place of administration:  Physician's office  Outpatient infusion  
 Facility: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

Home infusion  
 Agency: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

Billing:  Physician to buy and bill  Facility to buy and bill  Specialty Pharmacy  
 Pharmacy: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

ICD-10 Diagnosis code(s): \_\_\_\_\_

### Precertification Requirements

Before this drug is covered, the patient must meet all of the following criteria:

1. Diagnosis of Fabry disease
  - a. Provide supporting documentation to confirm diagnosis (e.g. alpha-Gal A activity in leukocytes or plasma, mutation analysis of the alpha-Gal A gene)
2. Patient is either:
  - a. Classically affected male (i.e. male with very low or undetectable levels of alpha-galactosidase A [alpha-Gal A]), OR
  - b. Female carrier or male with atypical presentations (i.e. with marginal levels of alpha-Gal A) with clinical manifestations of Fabry disease (e.g. renal, neurologic, cardiovascular) present
3. Prescribing physician must be a nephrologist, cardiologist, specialist in metabolic disorders or genetics
4. The patient will receive antipyretics before the infusion

If authorized, up to 12 months may be approved.

**For continuation of therapy, the patient must meet all of the following criteria:**

1. Continued response to treatment (e.g. reduction in plasma glycosphingolipid GL-3 levels compared to baseline)
2. Compliance with >50 percent of treatments
3. Regularly attends follow-up visits
4. Has not experienced persistent life-threatening or severe infusion reactions that do not respond to prophylaxis (eg, anaphylaxis)
5. Has not developed ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV)
6. Does not have end-stage Fabry disease or other comorbidities with a life expectancy of <1 year
7. Has not experienced severe cognitive decline

**Note:** Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

**New Request**

**Priority Health Precertification Documentation**

**A. Is the patient new to this medication, or will this be a continuation in therapy?**

- Request for new start  
 Request for continuation, patient has received \_\_\_\_\_ number of doses to date

**B. What condition is this drug being requested for (please provide documentation to support)?**

- Fabry disease  
 Other – the patient's condition is: \_\_\_\_\_  
 Rationale for use: \_\_\_\_\_

**C. Will the patient receive antipyretics before the Fabrazyme infusion?**

- Yes  No

**Continuation Request**

**Priority Health Recertification Documentation**

- A. Has the patient continued to respond to treatment? (please provide documentation)  
 Yes  No
- B. Has the patient been compliant with therapy and attended follow-up visits?  
 Yes  No
- C. Has the patient experienced persistent life-threatening or severe infusion reactions that do not respond to prophylaxis (eg, anaphylaxis)?  
 Yes  No
- D. Has the patient developed ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV)?  
 Yes  No
- E. Does the patient have end-stage Fabry disease or other comorbidities with a life expectancy of <1 year?  
 Yes  No
- F. Has the patient experienced severe cognitive decline?  
 Yes  No

**Additional Information**

**NOTE:** Medicaid members will be required to receive the medication by home infusion after the first 6 doses.