Updated: 09/2018
PARP Approved: 10/2018

Prior Authorization Criteria

Fabry Disease Medications

All requests for Fabry Disease Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Fabrazyme (agalsidase beta) all of the following criteria must be met:
Coverage may be provided with a diagnosis of Fabry Disease and the following criteria is met:

- Diagnosis has been confirmed by biochemical/genetic confirmation by ONE of the following:
  - α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells.
  - Plasma or urinary globotriaosylceramide(Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3).
  - Detection of pathogenic mutations in the alpha-galactosidase A (alpha-Gal A; galactosidase alpha [GLA]) gene by molecular genetic testing.
- Medication must be prescribed by or in association with a metabolic specialist, dermatologist, neurologist, nephrologist, rheumatologist, or cardiologist.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria**
  - Chart documentation demonstrating clinical benefit and tolerance to Fabrazyme
- **Reauthorization Duration of approval:** 12 months

For all requests for Galafold (migalastat) all of the following criteria must be met:

Coverage may be provided with a diagnosis of a confirmed diagnosis of Fabry disease and the following criteria is met:

- Member must be 18 years or older
- Member must have amenable GLA variant that is interpreted by a clinical genetics professional as causing Fabry disease (pathogenic, likely pathogenic) in the clinical context of the patient. (see attachment 1)
- Prescriber must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to Fabrazyme (agalsidase beta).
- Baseline number of GL-3 inclusions per kidney interstitial capillary must be provided.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Exclusion criteria
  - Member must not have severe renal impairment (eGFR <30 mL/minute/1.73 m^2)
  - Member must not have end-stage renal disease requiring dialysis
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**

  - There must be ≥ 50% reduction from baseline in the number of GL-3 inclusions per kidney interstitial capillary OR chart documentation demonstrating clinical benefit of Galafold.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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Fabrazyme (agalsidase beta)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:_____ ICD-10 Code: _____

1. Is member age 8 years of age or older?
   ☐ Yes ☐ No

2. Has member's diagnosis been confirmed by biochemical/genetic confirmation by ONE of the following:
   a. α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells.
      ☐ Yes ☐ No
   b. Plasma or urinary globotriaosylceramide(Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3).
      ☐ Yes ☐ No
   c. Detection of pathogenic mutations in the GALA/GLA gene by molecular genetic testing.
      ☐ Yes ☐ No

3. Is the medication been prescribed by or in association with a dermatologist, neurologist, nephrologist, rheumatologist, or cardiologist?
   ☐ Yes ☐ No

4. Does the member have medical history of at least ONE of the following:
   ☐ Yes ☐ No
   a. Intermittent episodes of burning pain in the extremities (acroparesthesias)
   b. Cutaneous vascular lesions (angiokeratomas)
   c. Diminished perspiration (hypo- or anhidrosis)
   d. Characteristic corneal and lenticular opacities
   e. Abdominal pain, nausea, and/or diarrhea of unknown etiology in young adulthood
   f. Left ventricular hypertrophy (LVH) or hypertrophic cardiomyopathy of unknown etiology, particularly in young adults
   g. Arrhythmias of unknown etiology, particularly in young adults
   h. Stroke of unknown etiology at any age
   i. Chronic kidney disease (CKD) and/or proteinuria of unknown etiology
   j. Multiple renal sinus cysts discovered incidentally
   k. Family history suggestive of the disorder (ie, history of unexplained gastrointestinal symptoms, extremity pain, and/or kidney disease, ischemic stroke, or cardiac disease in one or more family members)

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Please provide baseline values for plasma GL-3 and/or GL-3 inclusions. (Please provide documentation):

Please provide improved values for plasma GL-3 and/or GL-3 inclusions defined by a reduction in plasma GL-3 and/or GL-3 inclusion compared to pre-treatment baseline. (Please provide documentation):

_____

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

Gateway Health

Updated: 09/2018
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GALAFOLD (MIGALASTAT)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:_____ ICD-10 Code: _____

1) Is member 18 years of age or older?
   ☐ Yes ☐ No

2) Does the member have amenable GLA variant that has been interpreted by a clinical genetics professional as causing Fabry disease (pathogenic, likely pathogenic) in the clinical context of the patient?
   ☐ Yes ☐ No
   Please provide variant:

3) Has member tried and failed or had an intolerance or contraindication to Fabrazyme (agalsidase beta)?

☐ Yes ☐ No

4) What is the baseline number of GL-3 inclusions per kidney interstitial capillary?

_____

5) Does the member have severe renal impairment (eGFR <30 mL/minute/1.73 m^2)?
☐ Yes ☐ No

6) Does the member have end-stage renal disease requiring dialysis?
☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION

Please provide number of GL-3 inclusions per kidney interstitial capillary :

_____

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date