AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Galafold® (migalastat)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member must be 18 years of age or older
- ❑ Provider has submitted member's current eGFR: _____
- ❑ Provider is a specialist in genetics or metabolic disorders, a cardiologist, or a nephrologist
- ❑ Member has a diagnosis of Fabry disease confirmed by at least **ONE** of the following:
  - ❑ Documentation of complete deficiency or less than 5% of mean normal alpha-galactosidase A (a-Gal A) enzyme activity in leukocytes, dried blood spots, or serum (plasma) analysis
  - ❑ Documented galactosidase alpha (GLA) gene mutation by gene sequencing
- ❑ Member has an amenable GLA gene variant based on the Good Laboratory Practice (GLP)-validated HEK assay **(test result confirmation must be submitted for documentation)**

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- ❑ Member has at least **ONE** of the following symptoms or physical findings attributable to Fabry disease (**chart notes must be submitted for documentation)**:
  - ❑ Burning pain in the extremities (acroparesthesias)
  - ❑ Cutaneous vascular lesions (angiokeratomas)
  - ❑ Corneal verticillata (whorls)
  - ❑ Decreased sweating (anhidrosis or hypohidrosis)
  - ❑ Personal or family history of exercise, heat, or cold intolerance
  - ❑ Personal or family history of kidney failure
- ❑ Urinary GL3 level is ≥ 4 times the upper limit of normal **(lab documentation must be submitted)**
- ❑ Requests for Galafold™ may **NOT** be approved for any of the following:
  - ❑ Member has severe renal impairment (eGFR<30mL/min), is currently on dialysis or has end-stage renal disease
  - ❑ Member has received or is scheduled to receive a kidney transplant
  - ❑ Member is currently using Fabrazyme or other enzyme replacement therapy (ERT) for treatment of Fabry disease **(Galafold™ will NOT be approved for concurrent use with ERT)**

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider has submitted member's current eGFR: _____
- ❑ Urinary GL3 level has decreased from baseline and is stabilized below baseline level **(lab documentation must be submitted)**
- ❑ Requests for Galafold™ may **NOT** be approved for any of the following:
  - ❑ Member has severe renal impairment (eGFR<30mL/min), is currently on dialysis or has end-stage renal disease
  - ❑ Member has received or is scheduled to receive a kidney transplant
  - ❑ Member is currently using Fabrazyme or other enzyme replacement therapy (ERT) for treatment of Fabry disease **(Galafold™ will NOT be approved for concurrent use with ERT)**

Medication being provided by Specialty Pharmacy - PropriumRx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~1/1/2019; 10/17/2019; 7~~/21/2022;
REVISED/UPDATED: ~~3/27/2019; 6/7/2022;8/7/2022;~~ **10/27/2023**