OPTIMA HEALTH PLAN

PHARMACY/MEDICAL 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 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **Incomplete form will delay authorization process.**

Drug Requested: Galafold™ (migalastat)

DRUG INFORMATION: Information below **must** be completed to ensure authorization will **NOT** be delayed.

Drug Name/Form: _____ **Strength/Month:** _____

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

Diagnosis: _____ **ICD Code:** _____

CLINICAL CRITERIA: Check applicable box(es) below. The criteria **MUST** be met to qualify. If **not** checked, authorization process will be delayed.

Initial Criteria for 6 months Approval. **All** of the criteria below **MUST** be met. **(Chart notes and lab results MUST be submitted for documentation.)**

- ❑ Patient must be 18 years of age or older and current eGFR must be noted: _____

AND

- ❑ Provider is a specialist in genetics **OR** mebaolic disorders, a cardiologist or a nephrologist **AND**
- ❑ Patient must have a diagnosis of Fabry disease as confirmed with either 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 **OR**
  - ❑ Documented galactosidase alpha (GLA) gene mutation by gene sequencing

AND

- ❑ Individual has an amendable GLA gene variant based on the Good Laboratory Practice (GLP)-validated HEK assay **(test result confirmation must be submitted for documentation)** **AND**
- ❑ Individual has one or more of the following symptoms or physical findings attributable to Fabry disease **(chart notes must be submitted for documentation)**
  - ❑ Burning pain in the extremities (acroparesthesias) **OR**
  - ❑ Cutaneous vascular lesions (angiokeratomas) **OR**
  - ❑ Corneal verticillata (whorls) **OR**
  - ❑ Decreased sweating (anhidrosis or hypohidrosis) **OR**
  - ❑ Personal or family history of exercise, heat, or cold intolerarance **OR**
  - ❑ Personal or family history of kidney failure

AND

- ❑ Number of globotriaosylceramide (GL3) inclusions per kidney interstitial capillary at baseline must be documented (histological scoring of kidney biopsy must be submiited for documentation) **AND**

(continued on next page)

- ❑ Urinary GL3 level is ≥ 4 times the upper limit of normal **(lab documentation must be submitted)**

AND

- ❑ Requests for Galafold™ (migalastat) may **NOT** be approved for the following:
  - ❑ Patient has severe renal impairment (eGFR < 30mL/min), is currently on dialysis or has end stage renal disease
  - ❑ Patient has received or is scheduled to receive a kidney transplant
  - ❑ Patient 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 Criteria for 12 Months Approval – All of the following criteria MUST be met:

- ❑ Patient's current eGFR **MUST** be noted: _____
- ❑ Number of globotriaosylceramide (GL3) inclusions per kidney interstitial capillary **MUST** have decreased by at least 50% from baseline **(current histological scoring of kidney biopsy must be submitted for documentation)**

AND

- ❑ Urinary GL3 level has decreased from baseling and is stablized below baseline level **(lab documentation must be submitted)** **AND**
- ❑ Requests for Galafold™ (migalastat) may **NOT** be approved for the following:
  - ❑ Patient has severe renal impairment (eGFR<30mL/min), is currently on dialysis or has end-stage renal disease
  - ❑ Patient has received or is scheduled to receive a kidney transplant
  - ❑ Patient 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.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 11/15/2018
REVISED/UPDATED: 12/31/2018