OPTIMA HEALTH COMMUNITY CARE
AND
OPTIMA FAMILY CARE
(MEDICAID)

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. **If the information is not complete, correct, or legible, the authorization can be delayed.**

Drug Requested: **Galafold™** (migalastat)

DRUG INFORMATION: Complete information below or authorization will be delayed

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. **ALL** documentation including labs or chart notes (if required) **must** be submitted or request will be denied.

Initial Authorization Approval – Six (6) months

1. Patient has a documented diagnosis of Fabry disease with biochemical/genetic confirmation by **one** of the following: ❑ Yes ❑ No
   - Males only: a-galactosidase A (*a*-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells; OR
   - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3); OR
   - Detection of pathogenic mutations in the GALA/GLA gene by molecular genetic testing;

   AND
2. Is the patient 18 years old or older? ❑ Yes ❑ No

   AND
3. Patient has an amenable GLA mutation (as defined in the migalastat labeling) determined by or in consult with a clinical genetics professional as causing Fabry disease (pathogenic); ❑ Yes ❑ No

   AND
4. If taking an angiotensin-converting enzyme inhibitors (ACE-I) or angiotensin II receptor blocker (ARB), patient must be stable on therapy for at least 4 weeks;

   AND
5. Baseline echocardiogram, estimate glomerular filtration rate (eGFR), 24-hour urine protein, urine GL-3 and/or GL-3 inclusions, and alpha-galactosidase (*a*-Gal, male patients only) must be performed prior to initiation; ❑ Yes ❑ No

   AND

(continued on next page)

6. Patient has not undergone or scheduled to undergo kidney transplantation or currently on dialysis; ❑ Yes ❑ No

AND

7. Will **NOT** be used in combination with agalsidase beta. ❑ Yes ❑ No

Renewal Authorization Approval – Six (6) months. **ALL** criteria **must** be met for approval. **ALL** documentation including labs or chart notes (if required) **must** be submitted or request will be denied.

8. Patient continues to meet initial criteria; ❑ Yes ❑ No

AND

9. Disease response with treatment as defined by a reduction in urine GL03 and/or GL03 inclusions compared to pre-treatment baseline; ❑ Yes ❑ No

AND

10. Absence of unacceptable toxicity (e.g., kidney infections) and absence of progression into renal impairment or end-stage renal disease (e.g., eGFR < 30mL/min/1.73m^2). ❑ Yes ❑ No

Medication being provided by a 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 #: _____

***REVISED/UPDATED: 2/25/2019**