OPTIMA HEALTH COMMUNITY 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 1-844-348-3720**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is NOT complete, correct, or legible, authorization will be delayed.**

Drug Requested: Fabrazyme® (agalsidase beta) **(IV INFUSION ONLY) (J0180) (Medical)**

❑ **URGENT REVIEW. In checking this box, prescriber attests to the fact that by applying the standard review timeframe may seriously jeopardize the member's life, health, or ability to regain maximum function.**

❑ **STANDARD REVIEW**. In checking this box, the timeframe does **NOT** jeopardize the life or health of the member or the member's ability to regain maximum function and would **NOT** subject the member to severe pain.

DRUG INFORMATION: Complete **all** information below or authorization will be delayed.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code:** _____

CLINICAL CRITERIA: Check below **ALL** that apply. **ALL** criteria **must** be met for approval. To support **ALL** documentation, including lab results, diagnostics, and/or chart notes, **must** be provided or request will be denied.

Initial Approval - 6 months. MAXIMUM approved dose will be 1mg/kg infused every 2 weeks.

- ❑ Member is ≥ 8 years of age
- ❑ **Provider is** a specialist in genetics **OR** metabolic disorders, a cardiologist **OR** a nephrologist
- ❑ Member has a diagnosis of Fabry disease (also referred to as Anderson-Fabry disease)
- ❑ Diagnosis of Fabry disease has been confirmed by **one** of the following:
  - ❑ **For males**: α-GAL A enzyme activity <1.5nmol/hr/mL in plasma or <4nmol/hr/mL in isolated leukocytes **AND** documentation of disease-causing mutation in GLA gene located on Xq22.1 (labs must be submitted)
  - ❑ **For females**: documentation of disease-causing mutation in GLA gene located on Xq22.1 (lab must be submitted) **AND** documentation of clinically significant organ involvement (ie. symptomatic cardiac disease, renal impairment, TIA or stroke history) must be submitted; symptoms must not be attributable to any other causes
- ❑ Baseline plasma globotriaosylceramide (GL-3) level **must** be submitted
- ❑ Baseline plasma or urinary sediment lyso-Gb3 level **must** be submitted

(Continued on next page)

- ❑ Member must be taking appropriate prophylaxis/treatment medications for the following:

  Chart notes and labs for all criteria below listed MUST be submitted to document member's renal, cardiac, cerebrovascular, pulmonary function and pain levels at baseline.

  - ❑ **RENAL**:
    - ❑ Current pharmacy claims for ACE inhibitor or angiotensin receptor blocker (ARB) therapy **MUST** be noted for members with proteinuria
  - ❑ **NEUROLOGICAL**:
    - ❑ Members with history of TIA or thrombotic stroke **MUST** have current pharmacy claims for antiplatelet therapy (i.e. clopidogrel, aspirin, prasugrel; etc.)
  - ❑ **CARDIAC:**
    - ❑ Pharmacy claims for ACE-I, calcium channel blocker, ARB, or antiplatelet therapy **MUST** be noted if member has documented valvular insufficiency, shortened PR interval, diastolic dysfunction, resting bradycardia or <EF
    - ❑ Current pharmacy claims for statin or other hyperlipidemia therapy **MUST** be noted for treatment of elevated lipids
  - ❑ **PULMONARY:**
    - ❑ Pharmacy claims for bronchodilator therapy **MUST** be noted for Members with pulmonary symptoms
  - ❑ **ACROPARESTHESIA Monitoring:**
    - ❑ Pharmacy claims for gabapentin, carbamazepine, topiramate, oxcarbazepine, phenytoin or other anticonvulsant therapy **MUST** be noted for acroparesthesia treatment

Exclusion criteria: Well characterized benign GLS polymorphisms; absence of demonstrable Fabry disease-related tissue pathology or clinical symptoms; development of ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV); current hemodialysis therapy; history of renal transplantation; persistent life-threatening or severe infusion reactions that do not respond to prophylaxis **(e.g., anaphylaxis)**; end-stage Fabry disease or other comorbidities with a life expectancy of <1 year

Continuation of Therapy Approval - 6 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 will be denied. **MAXIMUM** approved dose will be 1mg/kg infused every 2 weeks.

- ❑ Provider is a specialist in genetics or metabolic disorders, a cardiologist or a nephrologist
- ❑ Current plasma globotriaosylceramide (GL-3) level must be submitted and **MUST** have decreased from baseline level

(Continued on next page)

- ❑ Current plasma or urinary sediment lyso-Gb3 level must be submitted and **MUST** have decreased from baseline level
- ❑ Current IgG anti-agalsidase antibody titer must be submitted
- ❑ Chart notes and labs for all criteria listed **MUST** be submitted to document clinical improvement or stabilization in member's renal, cardiac, cerebrovascular, pulmonary function and pain levels from baseline
- ❑ Member **must** be taking appropriate prophylaxis/treatment medications for member's renal, cardiac, cerebrovascular, pulmonary function and pain levels if applicable from baseline

Exclusion criteria: Well characterized benign GLS polymorphisms; absence of demonstrable Fabry disease-related tissue pathology or clinical symptoms; development of ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV); current hemodialysis therapy; history of renal transplantation; persistent life-threatening or severe infusion reactions that do not respond to prophylaxis **(e.g., anaphylaxis**); end-stage Fabry disease or other comorbidities with a life expectancy of <1 year.

Medication being provided by (check below that applies) - Limited Distribution Drug

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR
- ❑ **Specialty Pharmacy – PropriumRx**

  OR
- ❑ **Specialty Pharmacy**: _____

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.*

Member 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:** 4/3/2019;
REVISED/UPDATED: ~~6/6/2019;~~ **(Reformatted) 7/22/2019**;