SENTARA HEALTH PLAN

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 1-844-668-1550**. 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 can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Elfabrio® (pegunigalsidase alfa-iwxj) **IV Infusion J2508 (Medical)**

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

Member Name: _____

Member Sentara #: _____ **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:** _____

Weight: _____ **Date:** _____

❑ 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.

Recommended Dose: 1 mg/kg every 2 weeks

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.

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- ❑ Member is 18 years of age or older
- ❑ Provider is a cardiologist, nephrologist or specialist in genetics or metabolic disorders
- ❑ Member has a diagnosis of Fabry disease confirmed by at least **ONE** of the following:
  - ❑ Biological males: plasma and/or leucocyte alpha galactosidase activity (by activity assay) less than lower limit of normal **(submit labs; LLN in plasma = 3.2 nmol/hr/mL, LLN in leucocytes = 32 nmol/hr/mg/protein)**
  - ❑ Biological females: pathogenic variant in one of the Fabry disease GLA genes **(submit documentation)**
- ❑ 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 history of exercise, heat, or cold intolerance
  - ❑ Personal or family history of kidney failure
- ❑ Member's baseline urinary globotriaosylceramide (GL-3) concentration is > 1.5 times the upper limit of normal **(submit labs)**
- ❑ Provider has submitted member's current plasma globotriaosylsphingosine (lyso-Gb-3) level
- ❑ Member has had trial and intolerable life-endangering adverse event with Fabrazyme® **(must submit completed MedWatch form and chart notes to document adverse event with Fabrazyme®)**
- ❑ Medication will **NOT** be used in combination with Galafold® (migalastat) or Fabrazyme® (agalsidase beta)
- ❑ Member does **NOT** have any of the following contraindications to therapy:
  - Absence of demonstrable Fabry disease-related tissue pathology or clinical symptoms
  - Chronic kidney disease stages 3 to 5
  - History of renal dialysis
  - History of renal transplantation
  - Severe myocardial fibrosis defined as ≥ 2 late-enhancement positive ventricular segments
  - End-stage Fabry disease or other comorbidities with a life expectancy of < 1 year

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.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., anaphylaxis and severe hypersensitivity reactions, severe infusion-associated reaction or glomerulonephritis)

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- ❑ Member has experienced a positive clinical response to treatment as defined by a reduction or stabilization in at least **ONE** of the following as compared to pre-treatment baseline **(check all that apply; submit labs)**:
  - ❑ Plasma or urinary globotriaosylceramide (GL-3)
  - ❑ Plasma globotriaosylsphingosine (lyso-Gb3)
  - ❑ GL-3 inclusions per kidney biopsy

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.*