Fabry's Disease

Elfabrio (pegunigalsidase alfa-iwxj) J1413, Fabrazyme (agalsidase beta) J0180, Galafold (migalastat) J8499

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Elfabrio (J1413)**

- ☐ Documentation is provided that individual has a diagnosis of Fabry disease as defined with EITTHER of the following (ACMG, NSGC):
  - ☐ Documentation of complete deficiency or < 5% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity in leukocytes, dried blood spots, or serum (plasma) analysis; OR
  - ☐ Documented galactosidase alpha gene mutation by gene sequencing;
- ☐ The individual to be treated has ONE or more symptoms, or physical findings attributable to Fabry disease (ACMG), including, but not limited to:
  - ☐ 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 intolerance; OR
  - ☐ Personal or family history of kidney failure.

☐ **Fabrazyme (J0180)**

- ☐ Adult and pediatric patients 2 years of age and older;
- ☐ Patient must have the definitive diagnosis of Fabry disease confirmed by one of the following:
  - ☐ α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells;
  - ☐ 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;
- ☐ The prescribing physician must be a nephrologist, cardiologist, or from a physician specializing in metabolic or genetic disorders;
- ☐ Documentation of baseline status by one of the following:
  - ☐ Mainz Severity Score Index (MSSI);
  - ☐ FOS Mainz Severity Score Index; or
  - ☐ Objective/subjective clinical information, including signs/symptoms, with sufficient clinical manifestations to justify treatment and supported by at least one of the following:
  - ☐ Pain in the extremities;
  - ☐ Hypohidrosis;
  - ☐ Corneal opacities;
  - ☐ Kidney dysfunction;
  - ☐ Cardiac dysfunction; or
  - ☐ Cerebrovascular disorders OR baseline plasma globotriaosylceramide (GL3 or Gb3) level;

☐ **Galafold (J8499)**

- ☐ Diagnosis of Fabry disease AND
- ☐ Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data AND
- ☐ Patient is NOT receiving Galafold in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj)

☐ **Continuation Requests: (Clinical documentation required for all requests)**

- ☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Fabry's Disease PA

Drug Name(s):

ELFABRIO	**PEGUNIGALSIDASE ALFA-IWXJ**
FABRAZYME	**AGALSIDASE BETA**
GALAFOLD	**MIGALASTAT**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

- **Nephrologist, Cardiologist, or Physician specializing in metabolic or genetic disorders**

Coverage Duration:

Initial Approval for up to 6 months.
Continuation requests may be approved for up to 1 year.

FDA Indications:

Elfabrio, Fabrazyme

- Fabry's disease

Galafold

- Fabry's disease - in patients with a confirmed diagnosis and an amenable galactosidase alpha gene (GLA) variant per in vitro assay data

Off-Label Uses:

N/A

Age Restrictions:

Fabrazyme – 2 years old or older
Elfabrio, Galafold - Safety and effectiveness not established in pediatric patients

Other Clinical Consideration:

Elfabrio - Black Box Warning:

- Patients treated with pegunigalsidase alfa-iwxj have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during pegunigalsidase alfa-iwxj administration. If a severe hypersensitivity reaction (eg, anaphylaxis) occurs, discontinue pegunigalsidase alfa-iwxj immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to pegunigalsidase may be considered

Resources:

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