Elfabrio® (pegunigalsidase alfa-iwxj) Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021 (TTY: 711)
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Please indicate: ☐ Start of treatment, start date: ___/___/___ ☐ Continuation of therapy, date of last treatment: ___/___/___

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:	DOB:	
Address:	City:	State:	ZIP:
Home Phone: / Work Phone:	Cell Phone:	E-mail:	
Current Weight: ____ lbs or ____ kgs Height: ____ inches or ____ cms	Allergies:		

B. INSURANCE INFORMATION

Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #: **Medicaid:** ☐ Yes ☐ No If yes, provide ID #:

C. PRESCRIBER INFORMATION

First Name:	Last Name: *(Check one):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.				
Address:	City:	State:	ZIP:		
Phone: / Fax:	St Lic #:	NPI #:	DEA #:	UPIN:	
Provider E-mail:	Office Contact Name:	Phone:			

Specialty *(Check one):* ☐ **Ophthalmologist** ☐ **Nephrologist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *(Patient selected choice)*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ FAX: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for: Fabrazyme (agalsidase beta) Dose: _____ **Directions for Use:** _____

F. DIAGNOSIS INFORMATION - Please indicate primary ICD code and specify any other any other where applicable (*).

Primary ICD Code: _____ **Other ICD Code**: _____

G. CLINICAL INFORMATION - Required clinical information must be completed for ALL precertification requests.

For All Requests (clinical documentation required for all requests):

☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?

→ ☐ Yes ☐ No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?

☐ Yes ☐ No Has the patient developed laboratory confirmed anti-pegunigalsidase alfa-iwxj IgG or IgE antibodies which increases the risk for infusion related reactions?

☐ Yes ☐ No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?

☐ Yes ☐ No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?

→ Please provide a description of the behavioral issue or impairment: _____

☐ Yes ☐ No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?

→ Please provide a description of the condition: ☐ Cardiopulmonary: _____
☐ Respiratory: _____
☐ Renal: _____
☐ Other: _____

☐ Yes ☐ No Does the patient have a diagnosis of Fabry disease?

Continued on next page

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

For Initiation Requests (clinical documentation required for all requests):

☐ Yes ☐ No Was the diagnosis confirmed by enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity OR by genetic testing?

☐ Yes ☐ No Is the patient a symptomatic obligate carrier?

☐ Yes ☐ No Will the requested medication be used concomitantly with Galafold (migalastat)?

For Continuation Requests (clinical documentation required for all requests):

☐ Yes ☐ No Is the patient responding to therapy (e.g., reduction in plasma globotriaosylceramide [GL-3, Gb3] or GL-3/Gb3 inclusions, improvement and/or stabilization in renal function, pain reduction)?

H. ACKNOWLEDGEMENT

Request Completed 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.

The plan may request additional information or clarification, if needed, to evaluate requests.