



Enzymes & Enzymatic:

Aldurazyme (Iaronidase) J1931, Vimizim (elosulfase alfa) J1322, Cerezyme (imiglucerase) J1786, Eleyso (taliglucerase alfa) J3060, VPRIV (velaglucerase) J3385, Elitek (rasburicase) J2783, Fabrazyme (agalsidase) J0180, Glassia (alpha 1 proteinase inhibitor) J0257, Lumizyme / Myozyme (alglucosidase alfa) J0221, Naglazyme (galsulfase) J1458, Xiaflex (collagenase, clostridium histolyticum) J0775
 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.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	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)
 Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.
 If not, please provide clinical rationale for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)
 Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.
 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 – Enzymes and Enzymatic PA

Drug Name(s):

CEREZYME	ELELYSO	VPRIV	ALDURAZYM	VIMIZIM	ELITEK,
FABRAZYME	GLASSIA	LUMIZYME	MYOZYME	NAGLAZYME	XIAFLEX

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
3. 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.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Aldurazyme, Cerezyme, Glassia: 6 months
Remaining drug approvals will be for 12 months

FDA Indications:

Aldurazyme

- Mucopolysaccharidosis, Type I (Hurler and Hurler-Scheie forms) and Scheie form with moderate to severe symptoms

Vimizim

- Mucopolysaccharidosis, MPS-IV-A

Elelyso

- Gaucher's disease, Type 1

VPRIV

- Non-neuropathic Gaucher's disease, chronic

Elitek

- Uric acid level management, Initial management in patients with leukemia, lymphoma, and solid tumor malignancies receiving anti-cancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid

Fabrazyme

- Fabry's disease

Glassia

- Alpha-1-antitrypsin deficiency

Lumizyme, Myozyme

- Glycogen storage disease due to acid maltase deficiency

Naglazyme

- Maroteaux-Lamy syndrome

Xiaflex

- Dupuytren's contracture, with a palpable cord
- Peyronie's disease

Off-Label Uses:

Xiaflex

- Nipple tenderness

Age Restrictions:

N/A

Other Clinical Considerations:

Elitek

- CI: Hemolytic reactions or methemoglobinemia with rasburicase
- CI: Glucose-6-phosphate dehydrogenase deficiency

Xiaflex

- Peyronie plaques involving the penile urethra

Resources:

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Part B Prior Authorization Guidelines

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