# Enzymes & Enzymatic:

## Aldurazyme (laronidase) J1931, Vimizim (elosulfase alfa) J1322, Cerezyme (imiglucerase) J1786, Elelyso (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.*

| ☐ | **NEW START - Start Date:**______________ | ☐ | **Continuation** (within 365 days)**:**<br>Date of last treatment _______________ |
|---|---|---|---|
| ☐ | 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 ☐ Self-administered | Dose (Wt: _____ kg Ht:______ ) | Frequency | End Date if known |
|---|---|---|---|---|
| | | | | |

☐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 <u>adequate response</u> or <u>significant improvement</u> 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, ALDURAZYME, 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

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**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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