Mannosidosis
Lamzede (velmanase alfa-tycv) J0217
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)**

- ☐ Individual has a diagnosis of alpha-mannosidosis; AND
- ☐ Documentation is provided that diagnosis is demonstrated by one of the following:
  - ☐ Deficiency in alpha-mannosidase enzyme activity as measured in fibroblasts or leukocytes; OR
  - ☐ MAN2B1 gene mutation;
- ☐ Individual is using for the treatment of non-central nervous system disease manifestations.

☐ **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 – Lamzede PA

Drug Name(s):
LAMZEDE **VELMANASE ALFA-TYCV**

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:
N/A

Coverage Duration:
Initial Approval for 3 months
Continuation to be determined based on therapeutic need.

FDA Indications:
Lamzede

- Mannosidosis, Non-central nervous system manifestations

Off-Label Uses:
N/A

Age Restrictions:
N/A

Other Clinical Consideration:
Black Box Warning:

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

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/F151F0/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/D960ED/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933966&contentSetId=100&title=Velmanase+Alfa-tycv&servicesTitle=Velmanase+Alfa-tycv&brandName=Lamzede&UserMdxSearchTerm=Lamzede&=null#