



Mucopolysaccharidosis
Mepsevii (vestronidase alfa-vjkb) J3397
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)

- Patient has a diagnosis of Mucopolysaccharidosis type VII (Sly syndrome); AND
- Documentation is provided that diagnosis is based on leukocyte or fibroblast glucuronidase enzyme assay OR genetic testing AND
- Documentation is provided that elevated urine glycosaminoglycans excretion is at a minimum of 3-fold over the mean normal for age at screening.

Continuation Requests: (Clinical documentation required for all requests)

- Documentation is provided to show clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in urinary GAG excretion, reduction in hepatosplenomegaly, improvement in pulmonary function, improvement in walking distance and/or improvement in fine or gross motor function) compared to the predicted natural history trajectory of disease

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 – Mucopolysaccharidosis, MPS-VII Drug PA

Drug Name(s):

MEPSEVII

VESTRONIDASE ALFA-VJBK

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:

Approval will be approved for 12 months

FDA Indications:

Mepsevii

- Mucopolysaccharidosis, MPS-VII

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Consideration:

Black Box Warning:

Anaphylaxis has occurred with vestronidase alfa-vjbk administration, as early as the first dose, therefore appropriate medical support should be readily available when vestronidase alfa-vjbk is administered. Closely observe patients during and for 60 minutes after vestronidase alfa-vjbk infusion. Immediately discontinue the vestronidase alfa-vjbk infusion if the patient experiences anaphylaxis

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/FAD3DF/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/64C3DF/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932377&contentSetId=100&title=Vestronidase+Alfa-vjbk&servicesTitle=Vestronidase+Alfa-vjbk&brandName=Mepsevii&UserMdxSearchTerm=Mepsevii&=null#