

vestronidase alfa-vjbk (Mepsevii)**Medical Benefit Drug Policy****Place of Service**

Office Administration

Outpatient Facility Infusion Administration

Infusion Center Administration

Home Infusion Administration

Drug Details**USP Category:** GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT**Mechanism of Action:** Recombinant human lysosomal beta glucuronidase**HCPCS:**

J3397:Injection, vestronidase alfa-vjbk, 1 mg

How Supplied:

10 mg/5 mL (2 mg/mL) single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Mucopolysaccharidosis VII (MPS VII, Sly Syndrome)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria**The following condition(s) require Prior Authorization/Preservice.****Mucopolysaccharidosis VII (MPS VII, Sly Syndrome)****Meets medical necessity if all the following are met:**

1. Either of the following (a or b):
 - a. Documented reduced enzyme activity in beta-glucuronidase
 - b. Genetic testing confirming diagnosis of MPS VII

Covered Doses:

Up to 4 mg/kg given intravenously every two weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

E76.29

References

1. AHFS®. Available by subscription at <http://www.lexi.com>
2. DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Mepsevii (vestronidase alfa) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc; December 2020.
4. Wang RY, Bodamer OA, Watson MS, Wilcox WR. American College of Medical Genetics (ACMG) Work Group on Diagnostic Confirmation of Lysosomal Storage Diseases. Lysosomal storage diseases: diagnostic confirmation and management of presymptomatic individuals. *Genet Med*. 2011; 13(5):457-484.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*