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

Blue Shield of California Promise Health Plan is an independent licensee of the Blue Shield Association

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: 3Q2026
Changes from previous policy version:

- No change to policy following routine annual review

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