Vestronidase alfa-vjbk (Mepsevii®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration Home Infusion Administration HCPCS: **J3397** per 1 mg

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

- Mucopolysaccharidosis VII

AHFS therapeutic class: Enzymes

Mechanism of action: Recombinant human lysosomal beta glucuronidase

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for vestronidase alfa-vjbk (Mepsevii®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Mucopolysaccharidosis VII (MPS VII, Sly syndrome)

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

Covered Dose
Up to 4 mg/kg IV every two weeks

Coverage Period
Indefinite

ICD-10:
E76.29

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for vestronidase alfa-vjbk (Mepsevii®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:
10 mg/5 mL (2 mg/mL) in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Mepsevii® (vestronidase alfa-vjbk) [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; 12/2020.
- 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.

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee