Medical Policy

Mepsevii (vestronidase alfa-vjbk)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-055
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Mepsevii (vestronidase alfa-vjbk) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Mepsevii will be provided for 12 months

1. Patient has a diagnosis of Mucopolysaccharidosis Type VII (Sly Syndrome) established by one of the following:
    a. Patient has a laboratory test demonstrating deficient beta-glucuronidase activity in leukocytes, fibroblasts, or serum; **OR**
    b. Patient has a molecular genetic test demonstrating glucuronidase gene mutation; **AND**

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2. Mepsevii is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Mepsevii is lysosomal beta glucuronidase (GUS) produced in a Chinese hamster ovary cell line via recombinant DNA technology. It has the same amino acid sequence as human GUS and catabolizes accumulated glycosaminoglycans in lysosomes in affected tissues. Mepsevii is indicated in pediatric and adult patients for the treatment of Mucopolysaccharidosis type VII ([MPS VII], Sly syndrome).

DEFINITIONS

1. MEPSEVII (vestronidase alfa-vjbk) injection, for intravenous use. Initial U.S. Approval: 2017
    a. MEPSEVII (vestronidase alfa-vjbk) injection is a colorless to slightly yellow liquid supplied as a carton containing one 10 mg/5 mL (2 mg/mL) single-dose vial

CODING

Applicable NDC Codes	
69794-0001-XX	Mepsevii 10 mg/5 mL single-dose vial

Applicable Procedure Code	
J3397	Injection, vestronidase alfa-vjbk, 1mg

Applicable ICD-10 Codes	
E76.29	Other mucopolysaccharidoses

EVIDENCE BASED REFERENCES

1. Mepsevii injection [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical; December 2019.
2. Montano AM, Lock-Hock N, Steiner RD, et al. Clinical course of sly syndrome (mucopolysaccharidosis type VII). *J Med Genet*. 2016;53:403-418.
3. Tomatsu S, Montano AM, Dung VC, et al. Mutations and polymorphisms in GUSB gene in mucopolysaccharidosis VII (Sly syndrome). *Hum Mutat*. 2009;30:511-519.

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POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. February 22, 2022: Annual review – no changes made. February 28, 2023 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 2/28/2023

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