

Policy Name:	Mepsevii (vestronidase alfa)	Policy #:	2651P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Mepsevii (vestronidase alfa).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Mepsevii (vestronidase alfa) under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Documented Diagnosis of Sly Syndrome (mucopolysaccharidosis type VII)
 - Diagnosis confirmed by presence of soft tissue storage and skeletal disease without brain disease AND genetic mutation beta-glucuronidase (GUSB), located on chromosome 7q21.11
- 1.2 Prescribed by a geneticist (gene specialist)

2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

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HCPCS Codes

J3397	Injection, vestronidase alfa, 1 mg
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References

1. Mepsevii (vestronidase alfa-vjvk) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc; December 2020.
2. Cadaoas J, Boyle G, Jungles S, et al. Vestronidase alfa: Recombinant human β -glucuronidase as an enzyme replacement therapy for MPS VII. *Mol Genet Metab*, 2020 May;130(1):65-76.
3. Wang RY, da Silva Franco JF, Lopez-Valdez J, et al. The long-term safety and efficacy of vestronidase alfa, rhGUS enzyme replacement therapy, in subjects with mucopolysaccharidosis VII. *Mol Genet Metab*. 2020 Mar;129(3):219-227

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.