Pharmacy Drug Policy & Procedure

Policy Name:	Vimizim (elosulfase alfa)	Policy #:	2482P

Purpose of the Policy

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

Statement of the Policy

Health Alliance Medical Plans will approve the use of Vimizim (elosulfase alfa) under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for the Treatment of Mucopolysaccharidosis Type IVA (Morquio A Syndrome)

1.1 Diagnosis of Morquio A syndrome
- Evidence of gene mutation (GALNS) required to support diagnosis of MPS IVA

1.2 Prescribed by a geneticist (gene specialist)

1.3 5 years of age and older

2. Approval Period

2.1 Initial: 12 months

2.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

HCPCS Codes

J1322	Injection, elosulfase alfa, 1mg

References

1. Vimizim (elosulfase alfa) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; December 2019.
2. Akyol MU, Alden TD, Amartino H, et al. Recommendations for the management of MPS IVA: systematic evidence- and consensus-based guidance. Orphanet J Rare Dis. 2019 June;14:137.
3. Hendriksz C, Santra S, Jones SA, et al. Safety, immunogenicity, and clinical outcomes in patients with Morquio A syndrome participating in 2 sequential open-label studies of elosulfase alfa enzyme replacement therapy. Mol Genet Metab. 2018 Apr;123(4):479-487.
4. Hendriksz CJ, Burton B, Fleming TR, et al. Efficacy and safety of enzyme replacement therapy with BMN 110 (elosulfase alfa) for Morquio A syndrome (mucopolysaccharidosis IVA): a phase 3 randomised placebo-controlled study. J Inherit Metab Dis 2014; 37:979.

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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 intendedvi 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.