Clinical Policy Title:	elosulfase alfa
Policy Number:	RxA.551
Drug(s) Applied:	Vimizim®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Mucopolysaccharidosis IVA: Morquio A Syndrome (must meet all):

1. Diagnosis of Morquio A syndrome (MPS IVA) confirmed by one of the following:
   a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase activity;
   b. DNA testing;
2. Age ≥ 5 years;
3. Dose does not exceed 2 mg per kg per week.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Mucopolysaccharidosis IVA: Morquio A Syndrome (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by improvement in the individual member's MPS IVA disease manifestation profile;
3. If request is for a dose increase, new dose does not exceed 2 mg per kg per week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. Muenzer J. The mucopolysaccharidoses: a heterogeneous group of disorders with variable pediatric presentations. J Pediatr. 2004; 144(5 Suppl): S27-S34. Available at: https://www.researchgate.net/publication/8578562_The_mucopolysaccharidoses_a_heterogeneous_group_of_disorders_with_variable_pediatric_presentations_J_Pediatr_1445_SupplS27-S34. Accessed July 26, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed	09/21/2020	12/07/2020

1. Clinical policy title updated 2. Line of business policy applies to was updated to 'All lines of business' 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Reference reviewed and updated.		
Policy was reviewed 1. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	09/23/2021	12/07/2021
Policy was reviewed: 1. Continued Therapy Approval II.A: Updated approval duration for commercial from 6 months to 12 months. 2. References were reviewed and updated.	07/26/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023