

Vimizim® (elosulfase alfa) (IV Formulation)

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I. Length of Authorization

Coverage will be for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Vimizim 5mg/5ml: 184 vials every 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 230 billable units (230 mg) every 7 days

III. Initial Approval Criteria

Mucopolysaccharidosis IVA (MPS IVA, Morquio A Syndrome)

- Patient is 5 years of age or older; **AND**
- Documented diagnosis of Mucopolysaccharidosis IVA with biochemical/genetic confirmation by one of the following:
 - Absence or marked reduction in N-acetylgalactosamine 6-sulfatase (GALNS) enzyme activity; **OR**
 - Sequence analysis and/or deletion/duplication analysis of the *GALNS* gene for biallelic mutation; **AND**
- Documented baseline six minute walk test (6-MWT), a current (within 30 days) test will be needed for renewal

IV. Renewal Criteria

- Disease response with treatment as defined by an improvement in 6 MWT from baseline;
AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity reactions.

V. Dosage/Administration

Indication	Dose
Mucopolysaccharidosis IVA	2 mg per kg body weight administered once every week as an intravenous infusion over a minimum of 3.5 to 4.5 hours, based on infusion volume

VI. Billing Code/Availability Information

Jcode:

- J1322 – Vimizim (Biomarin Pharmaceutical) 5 mg injection: 1 billable unit = 1 mg

NDC:

- Vimizim 5mg/5ml injection: 68135-0100-xx (Biomarin Pharmaceutical)

VII. References

1. Vimizim [package insert]. Novato, CA; Biomarin Pharmaceutical Inc.; February 2014. Accessed December 2016.
2. Regier DS, Oetgen M, Tanpaiboon P. Mucopolysaccharidosis Type IVA. In: Pagon RA, Adam MP, Bird TD, Dolan CR, Fong CT, Smith RJH, Stephens K, editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2014. 2013 Jul 11 [updated 2014 Mar 13].

Appendix 1 – Covered Diagnosis Codes

ICD-10	Description
E76.210	Morquio A mucopolysaccharidoses

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC