Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Vimizim (elosulfase alfa)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Dosing Limit
Vimizim (elosulfase alfa) 5 mg vial	2 mg/kg once per week

APPROVAL CRITERIA

Requests for Vimizim (elosulfase alfa) may be approved if the following criteria are met:

I. Individual has a diagnosis of mucopolysaccharidosis IVA (Morquio A syndrome); **AND**
II. Confirmed diagnosis by (Akyol 2019; Wood 2013):
    A. Documented reduced fibroblast or leukocyte N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity combined with normal enzyme activity level of another sulfatase; **OR**
    B. Documented genetic testing;

AND

III. Documented clinical signs and symptoms of Morquio A syndrome (for example, knee deformity, corneal opacity or pectus carinatum) (Hendriksz 2015; Wood 2013)**.**

Requests for Vimizim (elosulfase alfa) may not be approved for the following:

I. All other indications not included above; **OR**
II. Individual is using to treat mucopolysaccharidosis IVB (Morquio B syndrome).

Note:
Vimizim (elosulfase alfa) has a black box warning for anaphylaxis. Life-threatening anaphylactic reactions have occurred during Vimizim infusions so appropriate medical support should be available during Vimizim administration. Individuals should be educated on the signs and symptoms of anaphylaxis and to seek immediate medical care should they occur.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Individuals with acute respiratory illness may be at risk of serious acute exacerbation of their respiratory disease and require additional monitoring.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. 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;14(1):137. doi: 10.1186/s13023-019-1074-9
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 31, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Hendriksz CJ, Berger KI, Giugliani R, at al. International guidelines for the management and treatment of Morquio A syndrome. Am J Med Genet A. 2015; 167A(1):11-25.
5. Lehman TJ, Miller N, Norquist B, et al. Diagnosis of the mucopolysaccharidoses. Rheumatology. 2011; 50:V41-V46.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. Wood TC, Harvey K, Beck M, et al. Diagnosing mucopolysaccharidosis IVA. J Inherit Metab Dis. 2013;36:293–307.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.