

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Vimizim (elosulfase alfa)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Vimizim (elosulfase alfa)

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 (Hendriksz 2015; 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. 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. Individuals with acute respiratory illness may be at risk of serious acute exacerbation of their respiratory disease and require additional monitoring.

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.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 22, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Hendriksz CJ, Berger KI, Giugliani R, et 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.; 2018; Updated periodically.
7. Wood TC, Harvey K, Beck M, et al. Diagnosing mucopolysaccharidosis IVA. *J Inherit Metab Dis*. 2013;36:293–307.

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