

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

*FHK- Florida Healthy Kids

Vimizim (elosulfase alfa)

CG-DRUG-55

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Vimizim (elosulfase alfa)	N/A

APPROVAL CRITERIA

- I. Enzyme replacement therapy with Vimizim (elosulfase alfa) is considered **medically necessary** for the treatment of mucopolysaccharidosis IVA (Morquio A syndrome) in individuals who meet **all** the following criteria:
 - A. Confirmed diagnosis of Morquio A syndrome by documented reduced fibroblast or leukocyte N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity or by genetic testing; **AND**
 - B. Documented clinical signs and symptoms of Morquio A syndrome (for example, knee deformity, corneal opacity or pectus carinatum).

Note: Vimizim (elosulfase alfa) has a black box warning for the risk of anaphylaxis. Life-threatening anaphylactic reactions, presenting as cough, erythema, throat tightness, urticaria, flushing, cyanosis, hypotension, rash, dyspnea, chest discomfort, and gastrointestinal symptoms have occurred in some individuals during infusions, regardless of duration of the course of treatment. Individuals should be closely observed during and after administration with preparations available to manage anaphylaxis. Inform individuals of the signs and symptoms of anaphylaxis and have them seek immediate medical care should symptoms occur. Individuals with compromised respiratory function or acute respiratory disease may be at risk of serious acute exacerbation of their respiratory compromise due to hypersensitivity reactions, 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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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. American Thoracic Society (ATS). 2002. ATS Statement: Guidelines for the six-minute walk test. Available at: <https://www.thoracic.org/statements/resources/pfet/sixminute.pdf>. Accessed on September 07, 2016.
2. Elosulfase alfa In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated March 03, 2016. Available at: <http://www.micromedexsolutions.com>. Accessed on September 07, 2016.
3. 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.
4. Vimizim [Product Information]. BioMarin Inc., Novato, CA.; February 14, 2014. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125460s000lbl.pdf. Accessed on September 07, 2016.

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