

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	X

*FHK- Florida Healthy Kids

Galafold (migalastat)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Galafold (migalastat)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Galafold (migalastat) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Fabry disease as confirmed with either of the following (ACMG, NSGC):
 - A. Documentation of complete deficiency or less than 5% of mean normal alpha-galactosidase A (α -Gal A) enzyme activity in leukocytes, dried blood spots, or serum (plasma) analysis; **OR**
 - B. Documented galactosidase alpha (*GLA*) gene mutation by gene sequencing;

AND

- II. Individual has an amendable *GLA* gene variant based on the human embryonic kidney-293 (HEK-293) assay;

AND

- III. Individual has one or more symptoms or physical findings attributable to Fabry disease (ACMG), such as but not limited to:
 - A. Burning pain in the extremities (acroparesthesias); **or**
 - B. Cutaneous vascular lesions (angiokeratomas); **or**
 - C. Corneal verticillata (whorls); **or**
 - D. Decreased sweating (anhidrosis or hypohidrosis); **or**
 - E. Personal or family history of exercise, heat, or cold intolerance; **or**
 - F. Personal or family history of kidney failure.

Requests for Galafold (migalastat) may **not** be approved for the following:

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New Program Date 08/28/2018

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	X

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- I. Individual has severe renal impairment or end-stage renal disease.

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

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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