STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGALASTAT HCL	GALAFOLD	44433		GPI-10 (3090365010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease and meet **ALL** of the following criteria?
   - The patient is 18 years or older
   - Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
   - The patient has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data as interpreted by clinical genetics professional as pathogenic or likely pathogenic (i.e., patient does not have a benign amenable GLA variant)
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   - The patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female patient who meets the following criterion?
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, continue to #3.

3. Is the request for a male patient who meets **ONE** of the following criteria?
   - The patient has an alpha galactosidase A (a-Gal -A) deficiency as indicated by an enzyme assay
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIGALASTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:

A. You have Fabry disease (a rare genetic disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
D. You have an amenable (responsive) galactosidase alpha (GLA: a type of gene) gene variant based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by clinical genetics professional as the cause of disease (pathogenic or likely pathogenic)
E. You will NOT use Galafold concurrently (taking at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
F. You are symptomatic OR have evidence of injury from globotriaosylceramide (GL-3: a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings. Evidence of injury includes decreased GFR (measurement of how well your kidneys are working) for age, persistent albuminuria (buildup of a type of protein), cerebral white matter lesions on brain MRI (magnetic resonance imaging: a type of imaging lab), cardiac fibrosis (scarring of the heart) on contrast cardiac MRI
G. **If you are a female, approval also requires:**
    1. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing
H. **If you are a male patient, approval also requires ONE of the following:**
    1. You do not have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
    2. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease **AND** meet the following criterion?
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy?
   - Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
   - Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
   - Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:
   A. You have Fabry disease (rare genetic disease)
   B. You will NOT use Galafold concurrently (taking at the same time) with another Fabry disease therapy (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   C. You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
      1. Symptoms such as pain, hypohidrosis/anhidrosis (little to no sweat), exercise intolerance, gastrointestinal (GI) symptoms, angiokeratomas (dark red/purple raised spots), abnormal cornea, tinnitus (ringing in the ears), or hearing loss
      2. Imaging such as brain/cardiac MRI (magnetic resonance imaging: a type of imaging lab), DEXA (test to measure bone density), or renal (kidney) ultrasound
      3. Laboratory or histological (viewed by microscope) testing such as globotriaosylceramide (GL-3: a type of fat) in plasma/urine, renal biopsy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGALASTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Galafold.

REFERENCES

- Galafold [Prescribing Information]. Cranbury, NJ: Amicus Therapeutics; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 11/18
Client Approval: 08/23
P&T Approval: 07/23