



# Galafold Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Galafold	migalastat hcl cap	123 MG	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Galafold	Migalastat HCl Cap 123 MG (Base Equivalent)	123 MG	14	Capsules	28	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Galafold	migalastat hcl cap	123 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Galafold	Migalastat HCl Cap 123 MG (Base Equivalent)	123 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>The patient has a diagnosis of Fabry disease AND BOTH of the following: <ol style="list-style-type: none"> <li>The diagnosis was confirmed by mutation in the galactosidase alpha (<i>GLA</i>) gene <b>AND</b></li> <li>The patient has a confirmed amenable <i>GLA</i> variant based on in vitro assay data (a complete list of amenable variants is available in the Galafold prescribing information, or a specific variant can be verified as amenable at <a href="http://www.galafoldamenabilitytable.com/hcp">http://www.galafoldamenabilitytable.com/hcp</a>) <b>AND</b></li> </ol> </li> <li>If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li>The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></li> </ol> </li> <li>The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>The patient will NOT be using the requested agent in combination with enzyme replacement therapy (ERT) (e.g., Elfabrio, Fabrazyme) for the requested indication <b>AND</b></li> <li>The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months  BCBSIL and BCBSMT: 12 months  ALL other plans: 6 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

Module	Clinical Criteria for Approval
	<p><b>The requested agent will also be approved when the following are met:</b></p> <ol style="list-style-type: none"> <li>1. The member resides in Ohio <b>AND</b></li> <li>2. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></li> <li>3. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>4. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>B. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</li> </ol> </li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>4. The patient will NOT be using the requested agent in combination with enzyme replacement therapy (ERT) (e.g., Elfabrio, Fabrazyme) for the requested indication <b>AND</b></li> <li>5. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"><li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li><li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:<ol style="list-style-type: none"><li>A. BOTH of the following:<ol style="list-style-type: none"><li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li><li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li></ol></li><li>B. BOTH of the following:<ol style="list-style-type: none"><li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li><li>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit</li></ol></li></ol></li></ol> <p><b>Length of Approval:</b></p> <p>BCBSIL: 12 months All other plans: Initial 6 months; Renewal 12 months</p>