

Endari Prior Authorization 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
Endari	glutamine (sickle cell) powd pack	5 GM	M ; N ; O ; Y	O ; Y		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Endari	glutamine (sickle cell) powd pack	5 GM	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>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> The patient has a diagnosis of sickle cell disease AND The patient is using the requested agent to reduce the acute complications of sickle cell disease AND If the patient has an FDA approved indication, then ONE of the following: <ol style="list-style-type: none"> The patient’s age is within FDA labeling for the requested indication for the requested agent OR

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	<p>B. There is support for using the requested agent for the patient's age for the requested indication AND</p> <p>4. ONE of the following</p> <p>A. The patient has tried and had an inadequate response after at least 6 months duration of therapy with maximally tolerated hydroxyurea [medical records including chart notes are required] OR</p> <p>B. The patient has an intolerance or hypersensitivity to hydroxyurea OR</p> <p>C. The patient has an FDA labeled contraindication to hydroxyurea AND</p> <p>5. ONE of the following:</p> <p>A. The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR</p> <p>B. There is support for use of the requested agent in combination with Adakveo (crizanlizumab-tmca) AND</p> <p>6. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:</p> <table border="1" data-bbox="235 653 950 730"> <thead> <tr> <th data-bbox="235 653 592 688">Brand</th> <th data-bbox="592 653 950 688">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 688 592 730">ENDARI</td> <td data-bbox="592 688 950 730">L-glutamine</td> </tr> </tbody> </table> <p>A. The request is for a BCBS IL Fully Insured, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>C. The patient has tried and had an inadequate response to the generic equivalent [chart notes required] OR</p> <p>D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>E. The patient has an intolerance or hypersensitivity to the generic equivalent that is NOT expected to occur with the brand agent [chart notes required] OR</p> <p>F. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the brand agent [chart notes required] OR</p> <p>G. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>H. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>8. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <p>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <p>A. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p>	Brand	Generic Equivalent	ENDARI	L-glutamine
Brand	Generic Equivalent				
ENDARI	L-glutamine				

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	<p>B. The requested indication is a rare disease AND</p> <p>C. ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR <p>2. ALL of the following:</p> <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. 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] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: 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>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 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] AND 2. The patient has had clinical benefit with the requested agent (e.g., reduction in acute complications of sickle cell disease since initiating therapy with the requested agent) AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR B. There is support for use of the requested agent in combination with Adakevo (crizanlizumab-tmca) AND 4. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: <table border="1" data-bbox="235 1885 950 1959"> <thead> <tr> <th data-bbox="235 1885 592 1921">Brand</th> <th data-bbox="592 1885 950 1921">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1921 592 1959">ENDARI</td> <td data-bbox="592 1921 950 1959">L-glutamine</td> </tr> </tbody> </table>	Brand	Generic Equivalent	ENDARI	L-glutamine
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