

Dojolvi Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

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
Dojolvi	triheptanoin oral liquid	100 %	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Dojolvi	triheptanoin oral liquid	100 %	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 HMO Performance Quarterly ; 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"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of long-chain fatty acid oxidation disorder (LCFAOD) AND ALL of the following: <ol style="list-style-type: none"> 1. The diagnosis has been confirmed by TWO of the following: <ol style="list-style-type: none"> A. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma B. Enzyme activity assay (in cultured fibroblasts or lymphocytes) demonstrating deficiency of an enzyme associated with LCFAODs

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	<p style="text-align: center;">C. Genetic testing demonstrating pathogenic mutation in a gene associated with LCFAODs AND</p> <ol style="list-style-type: none"> 2. The patient had symptomatic LCFAOD prior to therapy with the requested agent AND 3. The patient will NOT be using the requested agent in combination with another medium chain triglyceride product for the requested indication AND 4. The patient will NOT be using the requested agent for more than 35% of the patient's total prescribed daily caloric intake OR <p>B. The patient has another FDA labeled indication for the requested agent and route of administration OR</p> <p>C. The patient has an indication that is supported in compendia for the requested agent and route of administration AND</p> <ol style="list-style-type: none"> 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Compendia Allowed: AHFS, or DrugDex 1, 2a, or 2b level of evidence</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> <ol style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. 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 2. ALL of the following: <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>

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	<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 AND 3. If the patient has a diagnosis of LCFAOD, then BOTH of the following: <ol style="list-style-type: none"> A. The patient will NOT be using the requested agent in combination with another medium chain triglyceride product for the requested indication AND B. The patient will NOT be using the requested agent for more than 35% of the patient's total prescribed daily caloric intake AND 4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p>