

Filsuvez Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin
01-22-2024

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Filsuvez	birch triterpenes gel	10 %	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Filsuvez	birch triterpenes gel	10 %	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
PA	<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. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of dystrophic or junctional epidermolysis bullosa confirmed by genetic testing (medical records required) OR B. The patient has another FDA labeled indication for the requested agent AND 2. If the patient has an FDA approved indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient’s age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient’s age for the requested indication AND

Module	Clinical Criteria for Approval
	<p>3. The patient does NOT have current evidence or a history of squamous cell carcinoma on the area to be treated AND</p> <p>4. The patient does NOT have an active infection on the area to be treated AND</p> <p>5. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., dermatologist, geneticist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>6. The patient will NOT be using the requested agent in combination with a gene therapy agent on the area to be treated AND</p> <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans: 4 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> <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>

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	<p data-bbox="232 180 483 210">BCBSOK: 36 months</p> <p data-bbox="232 249 570 279">ALL other plans: 12 months</p> <p data-bbox="232 380 498 409">Renewal Evaluation</p> <p data-bbox="232 447 1081 476">Target Agent(s) will be approved when ALL of the following are met:</p> <ol data-bbox="280 514 1393 888" style="list-style-type: none"> <li data-bbox="280 514 1393 596">1. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria (Note: patients not previously approved for the requested agent will require initial evaluation review) AND <li data-bbox="280 600 1127 630">2. The patient has had clinical benefit with the requested agent AND <li data-bbox="280 634 1393 682">3. The patient does NOT have current evidence or a history of squamous cell carcinoma on the area to be treated AND <li data-bbox="280 686 1263 716">4. The patient does NOT have an active infection on the area to be treated AND <li data-bbox="280 720 1393 802">5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND <li data-bbox="280 806 1393 854">6. The patient will NOT be using the requested agent in combination with a gene therapy agent on the area to be treated AND <li data-bbox="280 858 1357 888">7. The patient does NOT have any FDA labeled contraindications to the requested agent <p data-bbox="232 926 498 955">Length of Approval:</p> <p data-bbox="232 993 483 1022">BCBSOK: 36 months</p> <p data-bbox="232 1060 570 1089">ALL other plans: 12 months</p>