CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Filsuvez (birch triterpenes)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Filsuvez topical gel was approved by the FDA in 2023. It is a botanical drug product indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.
Epidermolysis Bullosa (EB) is a rare genetic disease with skin fragility and mechanically induced blistering that can lead to infections, scarring, and disfigurement. Dystrophic EB (DEB) is one of four EB subtypes. It is caused by mutations in COL7A1, the gene that codes collagen type VII (C7), the major component of anchoring fibrils in part of the skin. DEB can be autosomal dominant (DDEB) or recessive (RDEB). RDEB is more severe. Junctional EB (JEB) is usually caused by mutations in the laminin-332 genes.
In the EASE phase III study, the primary endpoint was met for first complete closure of target wound within 45 days.

Filsuvez (birch triterpenes) will be considered for coverage when the following criteria are met:

Epidermolysis Bullosa (EB)

For **initial** authorization:
1. Member is at least 6 months of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of dystrophic or junctional EB confirmed by genetic testing results; AND
4. Member has at least 1 partial-thickness wound to be treated, that has been present for at least 21 days and does not appear infected; AND
5. Member will continue standard wound care.
6. **Dosage allowed/Quantity limit:** Apply a 1 mm layer of gel to the affected wound surface and cover with wound dressing or apply directly to dressing so that the topical gel is in direct contact with the wound. Apply at wound dressing changes until the wound is healed.
   QL: 30 tubes/30 days

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Documentation of complete closure of EB wound treated with Filsuvez; AND
2. Member has other remaining EB wound(s) to be treated that meet initial criteria.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Filsuvez (birch triterpenes) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/30/2024	New policy for Filsuvez created.
05/19/2025	Annual review; no updates.

References:

1. Filsuvez [prescribing information]. Lichtenheldt GmbH; 2024.
2. Kern JS, Sprecher E, Fernandez MF, et al. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. *Br J Dermatol.* 2023;188(1):12-21. doi:10.1093/bjd/ljac001
3. Torres Pradilla M, Álvarez E, Novoa M, Lozano I, Trujillo M. Oleogel-S10 in Dystrophic Epidermolysis Bullosa: A Case Series Evaluating the Impact on Wound Burden Over Two Years. *Adv Ther*. 2024;41(2):867-877. doi:10.1007/s12325-023-02749-x
4. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. *Br J Dermatol*. 2020;182(3):574-592. doi:10.1111/bjd.18128 4
5. Has C, Bauer JW, Bodemer C, et al. Consensus reclassification of inherited epidermoly sis bullosa and other disorders with skin fragility. *Br J Dermatol*. 2020;183(4):614-627. doi:10.1111/bjd.18921

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