MEDICAL MUTUAL®

Drug Policy

Policy:	Filsuvez (birch triterpenes topical gel)	Annual Review Date: 3/20/2025 Last Revised Date: 03/20/2025

OVERVIEW

Filsuvez is indicated for the treatment of wounds associated with **dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB) in patients ≥ 6 months of age**.[1]

Filsuvez is a sterile botanical drug product for topical use and contains birch triterpenes in an oil base. Birch triterpenes is a botanical drug substance composed of a mixture of pentacyclic triterpenes. Filsuvez should be applied to cleansed wounds with wound dressing changes until the wound is healed. If a Filsuvez-treated wound becomes infected, treatment should be discontinued until the infection has resolved.

POLICY STATEMENT

This policy involves the use of Filsuvez. Prior authorization is recommended for pharmacy benefit coverage of Filsuvez. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Filsuvez as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Filsuvez be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Filsuvez is recommended in those who meet the following criteria:

1. **Dystrophic Epidermolysis Bullosa.** Approve for the duration outlined below if the patient meets ONE of the following (A or B):
   Note: For new wound(s) the patient is directed to Initial Therapy criteria. If the patient is continuing to treat the same wound(s) the patient is directed to criteria for Patient Currently Receiving Filsuvez on Previously Treated Wound(s).
   A) Initial Therapy: Approve for 3 months if the patient meets the following (i, ii, and iii):

i. Patient is ≥ 6 months of age; AND
ii. Patient meets ALL of the following (a, b, and c):
  a) Patient has at least one clinical feature of dystrophic epidermolysis bullosa **[documentation required]**; AND
  Note: Examples of clinical features of dystrophic epidermolysis bullosa include but are not limited to blistering, wounds, and scarring.
  b) Patient has one or more open wound(s) that will be treated (i.e., "target wound[s]); AND
  c) Target wound(s) meet the following, according to the prescriber [(1), (2), (3), and (4)]:
    (1) Target wound(s) is clean in appearance and does not appear to be infected; AND
    (2) Target wound(s) is 10 cm^2 to 50 cm^2; AND
    (3) Target wound(s) is ≥ 21 days and < 9 months old; AND
    (4) Squamous cell and/or basal cell carcinoma has been ruled out for the target wound(s).
iii. The medication is prescribed by or in consultation with a dermatologist or wound care specialist.

B) Patient is Currently Receiving Filsuvez on **Previously Treated Wound(s)**: Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
Note: If the patient is treating a new wound(s) not previously treated with Filsuvez or a reopened recurrent wound(s), then refer to Initial Therapy criteria above.
i. According to the prescriber, the target wound(s) remains open; AND
ii. According to the prescriber, the target wound(s) has decreased in size from baseline; AND
iii. The medication is prescribed by or in consultation with a dermatologist or wound care specialist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months
B) *Extended Approval:* 3 months

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Filsuvez has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Combination use with Vyjuvek (beremagene geperpavec-svdt topical gel).** Combination use of Vyjuvek and Filsuvez have not been studied. Patients who had undergone gene therapy for the treatment of inherited EB were excluded from the pivotal EASE trial with Filsuvez.[2]

2. **Junctional Epidermolysis Bullosa (JEB).** Efficacy has not proven to be better than placebo. In the pivotal EASE trial, patients with JEB comprised 11% of the total population (n = 26).[2] At Day 45 (± 7 days) complete

wound closure In patients with JEB was greater in patients who received placebo vs. Filsuvez (26.7% vs. 18.6%).

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Filsuvez® topical gel [prescribing information]. Wahlstedt, Germany: Lichtenheldt GmbH/Chiesi; December 2023.
2. Kern JS, Sprecher E, Fernandez MF, et al. Efficacy and safety of Olegel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. *Br J Dermatol*. 2023;188:12-21.
3. Kern JS, Schwieger-Briel A, Lowe S, et al. Olegel-S10 phase 3 study "EASE" for epidermolysis bullosa: Study design and rationale. *Trials*. 2019;20:350.
4. Has C, Bauer JW, Bolling MC et al. Consensus and reclassification of inherited epidermolysis bullosa and other disorders with skin fragility. *Br J Dermatol*. 2020;183:614-627.
5. Has C, El Hachem M, Buckova H, et al. Practical management of epidermolysis bullosa: consensus clinical position statement from the European Reference Network for Rare Skin Diseases. *J Eur Acad Derm Venereol*. 2021;35:2349-2360.
6. Denyer J, Pillay E, Clapham J. Best practice guidelines for skin and wound care in epidermolysis bullosa. An International Consensus. *Wounds International*. 2017. Available at: https://af13d689-15eb-4199-8733-e91a7bb8ae3f.usrfiles.com/ugd/af13d6_01ed147ab87e49c584c20a917c47f19f.pdf. Accessed on January 22, 2024.