Commercial PA Criteria

Effective: March 28, 2024

Prior Authorization: Filsuvez (birch triterpenes)

Products Affected: Filsuvez (birch triterpenes) topical gel

Medication Description: 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. The mechanism of action of Filsuvez in the treatment of wounds associated with epidermolysis bullosa (EB) is unknown. Filsuvez has been approved in Europe since June 2022 for the same indication.

Covered Uses: indicated for the treatment of wounds associated with dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB) in patients ≥ 6 months of age.

Exclusion Criteria:

1. Combination use with Vyjuvek (beremagene geperpavec-svdt topical gel)
2. Junctional Epidermolysis Bullosa (JEB).

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Medication must be prescribed by or in consultation with a dermatologist or wound care specialist.

Age Restriction: ≥ 6 months of age and older

Coverage Duration: Initial and Continuation: 3 months

Other Criteria:

Initial Approval Criteria

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

Renewal Criteria

1. Patient is Currently Receiving Filsuvez on **Previously Treated Wound(s)**: Approve if the patient meets ALL of the following
   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.
   A. According to the prescriber, the target wound(s) remains open; **AND**
   B. According to the prescriber, the target wound(s) has decreased in size from baseline; **AND**

References:

1. Filsuvez® topical gel [prescribing information]. Wahlstedt, Germany: Lichtenheldt GmbH/Chiesi; December 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	3/28/2024