

Specialty Guideline Management

Filsuvez

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Filsuvez	birch triterpenes

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adults and pediatric patients 6 months of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Medical records documenting clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
- Laboratory test results supporting diagnosis (i.e., genetic testing, immunofluorescence mapping [IFM], transmission electron microscopy [TEM]).

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or wound care specialist.

Coverage Criteria

Epidermolysis Bullosa (EB)^{1,2}

Authorization of 12 months may be granted for treatment of wounds in members with dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB) when all of the following criteria are met:

- Member is 6 months of age or older.
- Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
- Member has laboratory test results confirming diagnosis (i.e., genetic testing, immunofluorescence mapping [IFM], transmission electron microscopy [TEM]).
- Filsuvez will not be administered to wound(s) that are currently healed.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

References

1. Filsuvez [package insert]. Wahlstedt, Germany: Lichtenheldt GmbH; December 2023.
2. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. Br J Dermatol. 2020; 182: 574-592.