Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 19, 2024

Filsuvez® (birch triterpenes)

LENGTH OF AUTHORIZATION: Initial: 4 months
Continuation of Therapy: 1 year

REVIEW CRITERIA:

- Patient must be ≥ 6 months of age; **AND**
- Patient must have a diagnosis of dystrophic or junctional epidermolysis bullosa (EB) (medical records required):
- The patient does NOT have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment; **AND**
- The patient does NOT have an active infection in the area that will undergo treatment; **AND**
- 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.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of positive clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., local or systemic hypersensitivity); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as topic gel of 10% birch triterpenes w/w supplied in 25 mL sterile tubes.