Effective Date: 11/01/2024
Reviewed: 08/2024
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

FILSUVEZ (birch triterpenes)

POLICY

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

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

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a wound care specialist who specializes in the treatment of EB.

III. CRITERIA FOR INITIAL APPROVAL

Epidermolysis Bullosa (EB)
Authorization of 3 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:

A. Member is 6 months of age or older.
B. Documentation that member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
C. Documentation that member has laboratory test results confirming diagnosis (i.e., genetic testing, immunofluorescence mapping [IFM], or transmission electron microscopy [TEM] confirming a genetic mutation associated with DEB or JEB [e.g., COL7A1, LAMA3, LAMB3, LAMC2, COL17A1, ITGA6, ITGB4, ITGA3]).
D. Filsuvez will be applied at dressing changes at least once every four days, up to once daily.
E. Filsuvez will not be administered to wound(s) that are currently healed.
F. Filsuvez will not be administered in combination with other topical skin products including Vyjuvek (beremagene geperpavec), or in wounds previously treated with Vyjuvek (beremagene geperpavec).
G. Target wound(s) meet all the following criteria:
    a. Are partial thickness
    b. Are 10-50 cm^2 in size
    c. Have been present for a minimum of 3 weeks
    d. Have no evidence of active infection
    e. Have no history of basal or squamous cell carcinoma (SCC)

IV. CONTINUATION OF THERAPY

Epidermolysis Bullosa (EB)
Authorization of 6 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:

A. Documentation of positive clinical response to therapy evidenced by one or more of the following:
    a. Complete wound closure
    b. Reduction in wound size
    c. Decreased procedural pain
    d. Decreased frequency of dressing changes
    e. Decreased total body wound burden
B. Member continues to meet all initial criteria

V. QUANTITY LIMIT

- One 23.4 gm tube per day

VI. COVERAGE DURATION

- Initial: 3 months
- Renewal: 6 months

VII. 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.