Pharmacy Medical Necessity Guidelines:
Filsuvez (birch triterpenes) topical gel

Effective: July 14, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Filsuvez (birch triterpenes) topical gel is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of **Filsuvez (birch triterpenes)** topical gel for Members when **ALL** of the following criteria are met:

Initial Authorization

1. Documented diagnosis of one of the following as confirmed by genetic testing:
    a. Dystrophic epidermolysis bullosa (DEB) (pathogenic variant of COL7A1 gene), or
    b. Junctional epidermolysis bullosa (JEB) (pathogenic variant of LAMA3, LAMB3, LAMC2, COL17A, ITGA6, ITGB4, or ITGA3)

AND

2. Age 6 months or older

AND

3. Previous trial and failure or contraindication to standard wound therapy

AND

4. Member has at least one recurrent or chronic partial-thickness wound and ALL of the following:
    a. 10 – 50 cm2 in surface area, and
    b. Present for at least 3 weeks, and
    c. Adequate granulation tissue and excellent vascularization, and
    d. Wound has no evidence of active wound infection

AND

5. Member does not have history or current evidence of squamous cell carcinoma in the area that will undergo treatment

AND

6. Prescribed by or in consultation with a dermatologist with expertise in the treatment of DEB or JEB

Reauthorization Criteria

1. Clinical documentation must be provided to confirm that Filsuvez is providing clinical benefit (e.g., decrease in wound size, increase in granulation tissue, decrease in pain severity)

AND

2. Prescribed by or in consultation with a dermatologist with expertise in the treatment of DEB or JEB

AND

3. Documentation of wound to be treated is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected

AND

4. Member does not have current evidence of squamous cell carcinoma in the area that will undergo treatment

LIMITATIONS

1. Initial coverage of Filsuvez will be authorized for 6 months. Reauthorization of Filsuvez will be

provided for 6-month intervals.

2. Combination use with Filsuvez (birch triterpenes topical gel) and Vyjuvek (beremagene geperpavec-svdt topical gel) has not been studied. Approval of Filsuvez for initial coverage and reauthorization will not be authorized in members who are currently on Vyjuvek (beremagene geperpavec-svdt topical gel).

CODES

None

REFERENCES

1. Filsuvez [package insert]. Lichtenheldt GmbH Pharmazeutische Fabrik. February 2024.
2. Has C, Liu L, Bolling MC, Charlesworth AV, El Hachem M, Escámez MJ, Fuentes I, Büchel S, Hiremagalore R, Pohla-Gubo G, van den Akker PC, Wertheim-Tysarowska K, Zambruno G. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. Br J Dermatol. 2020 Mar;182(3):574-592. doi: 10.1111/bjd.18128. Epub 2019 Aug 9. PMID: 31090061; PMCID: PMC7064925.

APPROVAL HISTORY

July 9, 2024: Reviewed by the Pharmacy & Therapeutics Committee.
July 8, 2025: No Changes
July 14, 2026: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.