Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: July 14, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Filsuvez (birch triterpenes) topical gel when **ALL** 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 cm^2 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).
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Filsuvez [package insert]. Lichtenheldt GmbH Pharmazeutische Fabrik. May 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 And Revision History

July 9, 2024: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 8, 2025: No changes.
- July 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

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.