BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.90.070

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	June 28, 2024
Subject:	Filsuvez	**Page:**	1 of 3

Last Review Date: March 7, 2025

Filsuvez

Description

Filsuvez (birch triterpenes) topical gel

Background
The mechanism of action of Filsuvez in the treatment of wounds associated with epidermolysis bullosa is unknown (1).

Regulatory Status
FDA-approved indication: Filsuvez topical gel is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adult and pediatric patients 6 months of age and older (1).

Filsuvez should be applied to cleansed wounds with wound dressing changes until the wound is healed. Each tube of Filsuvez is for one-time use only. Avoid contact with eyes and mucous membranes (1).

Safety and effectiveness of Filsuvez in pediatric patients less than 6 months of age have not been established (1).

Related policies
Regranex, Santyl, Vyjuvek

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Filsuvez may be considered **medically necessary** if the conditions indicated below are met.

Filsuvez may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 months of age or older

Diagnosis

Patient must have the following:

Wounds associated with dystrophic and junctional epidermolysis bullosa (EB)

AND ALL of the following:

1. Prescribed by or in consultation with a dermatologist or a provider who specializes in EB
2. **NO** active infection, active squamous cell carcinoma, or history of squamous cell carcinoma in the targeted wound(s)

Prior – Approval *Renewal* Requirements

Age 6 months of age or older

Diagnosis

Patient must have the following:

Wounds associated with dystrophic and junctional epidermolysis bullosa (EB)

AND the following:

1. Patient has had clinical improvement while on Filsuvez (e.g., partial or complete wound closure)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Filsuvez is indicated for the treatment of wounds in patients 6 months of age and older with dystrophic and junctional epidermolysis bullosa (EB). Safety and effectiveness of Filsuvez in patients under the age of 6 months have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Filsuvez while maintaining optimal therapeutic outcomes.

References

1. Filsuvez [package insert]. Wahlstedt, Germany: Lichtenheldt GmbH; May 2024.

Policy History

Date	Action
June 2024	Addition to PA
September 2024	Annual review
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.