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# 5.90.070

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	June 28, 2024
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**Last Review Date:** March 6, 2026

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## Filsuvez

### Description

#### Filsuvez (birch triterpenes) topical gel

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#### 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).

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#### Related policies

Regranex, Santyl, Vyjuvek

### Policy

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*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)

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## 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)

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## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 6 months

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### 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
March 2026	Annual review

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**