

FILSUEZ
(birch triterpenes topical gel)**RATIONALE FOR INCLUSION IN PA PROGRAM****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).

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; January 2024.