Applicable Drugs: Filsuvez (birch triterpenes)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/30/2024

Date Last Reviewed / Revised: 5/21/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria Vare met)

I. Diagnosis of dystrophic epidermolysis bullosa (DEB) and the following criteria A through E are met:

   A. Documentation of pathogenic mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene

   B. Documentation of clinical manifestations of disease (eg, extensive skin blistering, skin erosions, scarring)

   C. Documentation of baseline number and size of wounds

   D. Documentation that standard wound care management has not adequately healed wounds (eg, increased wound dressings, pain, infections)

   E. Documentation of target recurrent or chronic open wound(s) to receive treatment that meet all of the following criteria i though iv:

      i. Wound size is 10 cm^2 to 50 cm^2

      ii. Wound is partial thickness (ie, affecting the epidermis and may extend into the dermis).

      iii. Wound has been present for at least 21 days but less than 9 months

      iv. No evidence of active wound infection

      v. No evidence of squamous cell or basal cell carcinoma

II. Minimum age requirement: 6 months old

III. Treatment must be prescribed by or in consultation with a dermatologist with expertise in the treatment of epidermolysis bullosa.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

Exclusion Criteria

- Treatment of wounds with squamous cell or basal cell carcinoma
- Treatment of full-thickness wounds (ie, extending through the dermis and into adipose tissue)
- History or concurrent use of gene therapies for the treatment of EB
- Treatment of EB simplex or junctional epidermolysis bullosa (JEB)
- Concurrent immunotherapy, chemotherapy, or investigational products
- Pregnancy

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- 30 tubes per 30 days

Approval Length

- **Authorization:** 45 days
- **Re-Authorization:** 3 months, with an updated letter of medical necessity or progress notes documenting treatment response for the target wound(s) including, but not limited to:
  1) Decrease in target wound size from baseline
  2) The target wound remains open
  3) Decrease in number of target wounds
  4) Filsuvez is not applied to any target wounds that have completely closed
  Note: Treatment of new wounds (not previously treated with Filsuvez) or a reopened previously treated wound must meet initial criteria.

Appendix

- N/A

References

1. Filsuvez. Prescribing information. Chiesi USA, Inc; 2024. Accessed May 21, 2026.. https://resources.chiesiusa.com/Filsuvez/FILSUVEZ_PI.pdf
2. IPD Analytics. New Drug Review. Filsuvez (birch triterpenes) topical gel. Payer & Provider Insights. www.IPDAnalytics.com. March 2024. Accessed May 21, 2026.
3. Popenhagen MP, Genovese P, Blishen M, et al. Consensus-based guidelines for the provision of palliative and end-of-life care for people living with epidermolysis bullosa. *Orphanet J Rare Dis*. 2023;18(1):268. doi:10.1186/s13023-023-02870-8

4. Has C, El Hachem M, Bučková H, et al. Practical management of epidermolysis bullosa: consensus clinical position statement from the European Reference Network for Rare Skin Diseases. *J Eur Acad Dermatol Venereol*. 2021;35(12):2349-2360. doi:10.1111/jdv.17629
5. Kern JS, Sprecher E, Fernandez MF, et al. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. *Br J Dermatol*. 2023;188(1):12-21. doi:10.1093/bjd/ljac001
6. Murrell DF, Bodemer C, Bruckner AL,et al. Long-term safety and efficacy of Oleogel-S10 (birch bark extract) in epidermolysis bullosa: 24-month results from the phase III EASE study. *Br J Dermatol.* 2025;192(6):1007-1017. doi: 10.1093/bjd/ljaf022
7. Bruckner AL,Murrell, D, Lee LW, et al. Reduction in dressing change burden in patients with epidermolysis bullosa-impact of Oleogel-S10. *J Dermatol.* 2025;52(9):1447-1451. doi: 10.1111/1346-8138.17884
8. El Hachem M, Diociaiuti A, Bonamonte D, et al. Delphi Study Group. Taking care of patients with recessive dystrophic epidermolysis bullosa from birth to adulthood: a multidisciplinary Italian Delphi consensus. *Orphanet J Rare Dis.* 2025;20(1):128. doi: 10.1186/s13023-025-03635-1
9. Alheggi A, Alhashem A, Alshihry HMH, et al. The Saudi national policy and protocol for epidermolysis bullosa. *Risk Manag Healthc Policy*. 2025;18:3521-3538. doi: 10.2147/RMHP.S532321

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.