Generic Name: Birch triterpenes

Therapeutic Class or Brand Name: Filsuvez

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/30/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria IV are 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.

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) 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; 2024. Accessed September 7, 2024. https://resources.chiesiusa.com/Filsuvez/FILSUVEZ_PI.pdf
2. Dermatology: Epidermolysis Bullosa. Payer & Provider Insights. www.IPDAnalytics.com. Accessed September 7, 2024.
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 Filsuvez (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