UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2337-2
Program	Prior Authorization/Medical Necessity
Medication	Filsuvez® (birch triterpenes) topical gel
P&T Approval Date	4/2024, 4/2024
Effective Date	7/1/2025

1. Background:

Filsuvez (birch triterpenes) topical gel is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Filsuvez** will be approved based on **all** of the following criteria:

   a. Patient is at least 6 months of age and older

   -AND-

   b. **One** of the following diagnoses:

      (1) Dystrophic epidermolysis bullosa (DEB)

      -OR-

      (2) Junctional epidermolysis bullosa (JEB)

      -AND-

   c. Submission of medical records (e.g., chart notes, laboratory values) confirming a genetic mutation associated with DEB or JEB (i.e., *COL7A1, LAMA3, LAMB3, LAMC2, COL17A1, ITGA6, ITGB4, ITGA3*)

   -AND-

   d. Patient has at least one partial thickness wound that meets **all** of the following criteria:

      (1) 10-50 cm^2 in size

      -AND-

      (2) Present for at least 3 weeks

-AND-

(3) Adequate granulation tissue

-AND-

(4) Excellent vascularization

-AND-

(5) No evidence of active wound infection

-AND-

(6) No evidence or history of basal or squamous cell carcinomas (SCC)

-AND-

e. Prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)

-AND-

f. Patient is **not** receiving Filsuvez in combination with Vyjuvek (beremagene geperpavec-svdt) on the same wound(s)

Authorization will be issued for 12 months

B. Reauthorization

1. **Filsuvez** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response to Filsuvez therapy (e.g., complete wound closure, reduction in wound size, decrease in procedural pain, less frequent dressing changes, decreased total body wound burden)

-AND-

b. Wound (s) being treated meet all of the following criteria:

(1) Adequate granulation tissue

-AND-

(2) Excellent vascularization

-AND-

(3) No evidence of active wound infection

-AND-

(4) No evidence or history of basal or squamous cell carcinomas (SCC)

-AND-

c. Filsuvez is prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)

-AND-

d. Patient is **not** receiving Filsuvez in combination with Vyjuvek (beremagene geperpavec-svdt) on the same wound(s)

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Filsuvez [package insert]. Boston, MA: Chiesi Global Rare Diseases; May 2024.
2. 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.
3. Varki R, Sadowski S, Pfendner E, Uitto J. Epidermolysis bullosa. I. Molecular genetics of the junctional and hemidesmosomal variants. J Med Genet. 2006;43(8):641-652.

Program	Prior Authorization/Medical Necessity - Filsuvez (birch triterpenes)
Change Control	
4/2024	New program
4/2025	Annual review with no changes to criteria. Updated references.