Epidermolysis Bullosa

Goal(s):

- Approve wound treatments in people with epidermolysis bullosa when supported by the evidence.
- Incorporate 2-step review process for drugs on the high-cost drug carve-out list.

Length of Authorization:

- Up to 12 months

Requires PA: pharmacy or provider administered claims

- Birch triterpenes (Filsuvez)
- Beremagene geperpavec (Vyjuvek)
- Prademagene zamikeracel (Zevaskyn)

Covered Populations: FFS and CCO patients beginning 1/1/26

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. FDA-approved indications and dose

Drug	Maximum dose	Indication	Pathogenic gene mutation
Birch triterpenes (Filsuvez)	1 tube (25 mL) per day	Junctional or dystrophic epidermolysis bullosa	Junctional: LAMA3, LAMB3, LAMC2, ITGB4, ITGA6, COL17A1, ITGA3 Dystrophic: COL7A1
Beremagene geperpavec (Vyjuvek)	1 mL weekly for ages < 3 years 2 mL weekly for ages ≥ 3 years	Dystrophic epidermolysis bullosa	At least one pathogenic mutation in COL7A1
Prademagene zamikeracel (Zevaskyn)	12 sheets per dose	Recessive dystrophic epidermolysis bullosa	2 pathogenic mutations in the COL7A1 gene with recessive inheritance pattern (biallelic)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for a patient with a prior FFS approval for the requested drug?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3
3. Is this an FDA approved indication (Table 1)?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is there documentation of genetic testing to support the diagnosis?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the request prescribed by, or in consultation with, a dermatologist or provider with experience in epidermolysis bullosa management or wound care?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
6. Is the request for birch triterpenes in a patient with junctional epidermolysis bullosa? Note: In junctional epidermolysis bullosa, people treated with standard of care had better wound healing compared to people who used birch triterpenes.	**Yes:** Pass to RPh. Deny; Refer request to medical director for manual review, assessment of clinical severity, and goals of therapy.	**No:** Go to #7
7. Is there documentation of current open chronic wounds including baseline wound size and estimated duration?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the request for re-treatment of a wound or location previously treated with prademagene zamikeracel?	**Yes:** Pass to RPh. Deny; Refer request to medical director for manual review, assessment of clinical severity, and goals of therapy.	**No:** Go to #9
9. Is the request for an FDA-approved quantity (Table 1)?	**Yes:** Pass to RPh. Pend; Refer to DMAP for secondary review. Approval durations: Filsuvez for 3 months. Vyjuvek for 3 months. Zevaskyn for up to 12 months. Notify DMAP of approved Zevaskyn requests for care coordination.	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the request for an FDA-approved quantity (Table 1)?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; medical appropriateness.
2. Is the request for re-treatment of a wound or location previously treated with prademagene zamikeracel?	**Yes:** Pass to RPh. Deny; Refer request to medical director for manual review of prior therapy, assessment of clinical severity, and goals of therapy.	**No**: Go to #3

Renewal Criteria		
3. Is there documentation that treated wound(s) have improved (e.g., decrease in size, closed, or healed)?	**Yes:** Pass to RPh. Refer to DMAP for secondary review. Approval duration: 12 months.	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 12/2025
Implementation: 1/1/26