

# New Hampshire Medicaid Fee-for-Service Program Epidermolysis Bullosa Criteria

Approval Date: November 21, 2024

## Medications

Brand Names	Generic Names	Indication
Filsuvez®	birch triterpenes	Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adult and pediatric patients ≥ 6 months of age
Vyjuvek®	beremagene geperpavec-svdt	Treatment of wounds in adult and pediatric patients ≥ 6 months of age with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

## Criteria for Approval

### All Drugs

1. Patient is 6 months of age or older; **AND**
2. Prescribed by or in consultation with a dermatologist or geneticist; **AND**

### Filsuvez® only

1. The patient has a diagnosis of dystrophic or junctional epidermolysis bullosa (EB) confirmed by **one** of the following:
  - Immunofluorescence mapping (IFM)
  - Transmission electron microscopy (TEM)
  - Genetic testing; **AND**
2. The patient does not have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment; **AND**
3. The patient does not have an active infection in the area that will undergo treatment.

### Vyjuvek® only

1. The patient has not received a skin graft within the past 3 months; **AND**
2. The patient has a genetically confirmed diagnosis of dystrophic epidermolysis bullosa with mutation in the COL7A1 gene; **AND**
3. The patient has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected.

**Initial approval period:** 6 months

## Criteria for Renewal

1. Patient must continue to meet the above criteria; **AND**
2. Patient must demonstrate clinical benefit with use; **AND**
3. Patient has not experienced any treatment-restricting adverse effects (e.g., local or systemic hypersensitivity; severe medication reactions).

**Renewal period:** 6 months

## Criteria for Denial

1. Failure to meet approval criteria.

## References

Available upon request.

## Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	10/15/2024
Commissioner designee	Approval	11/21/2024