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

Approval Date: November 17, 2025

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
Zevaskyn	**prademagene zamikeracel**	Treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)

Criteria for Approval

All drugs

1. Prescribed by or in consultation with a dermatologist or geneticist

Filsuvez only

1. The patient is 6 months of age or older; **AND**
2. 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**
3. The patient does not have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment; **AND**
4. 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

Zevaskyn only

1. The patient is ≥ 6 years of age; **AND**
2. The patient has a diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) as established by detection of biallelic mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing (note: if unable to confirm biallelic mutation, confirmation that BOTH parents do not have any evidence of dominant disease is acceptable); **AND**
3. The patient has cutaneous wound(s) which are adequate for treatment (e.g., stage 2 wounds that have an area of ≥ 20 cm^2) and have been present for ≥ 6 months; **AND**
4. The patient does not have severe hypersensitivity (e.g., anaphylaxis) to vancomycin or amikacin; **AND**
5. The patient does not show current evidence or have a history of squamous cell carcinoma (SCC) in the area to be treated: **AND**
6. Zevaskyn will not be used concurrently, in the same wound, with another disease-modifying therapeutic agent indicated for dystrophic epidermolysis bullosa (e.g., birch triterpenes [Filsuvez], beramegene geperpavec-svdt [Vyjuvek]); **AND**
7. Females of childbearing potential should use an effective method of contraception to prevent pregnancy at the time of treatment with Zevaskyn**.**

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. The patient requires continued treatment due to new expansion of pre-existing, or development of new (de novo), open wounds (Note: Zevaskyn is intended as a one-time treatment per area; re-

treatment of wounds that were previously grafted would be considered investigational, at this time, and may not be renewed); **AND**

4. 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
DUR Board	Update	09/23/2025
Commissioner designee	Approval	11/17/2025