

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Zevaskyn under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Zevaskyn is indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)..

Applicable Drug List:

Zevaskyn

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Medical records documenting clinical manifestations of disease.
- Genetic test results confirming biallelic pathogenic mutations in the COL7A1 gene.
- Test results documenting positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin.

Exclusions

Coverage will not be provided for members with evidence of immune response to C7 by indirect immunofluorescence (IIF).

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or wound care specialist

Criteria for Initial Approval:

Recessive Dystrophic Epidermolysis Bullosa (RDEB)

Authorization of three months for one dose total may be granted for treatment of wounds in members with recessive dystrophic epidermolysis bullosa (RDEB) when ALL the following criteria are met:

- Member is 6 years of age or older.
- Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
- Member has genetic test results confirming biallelic pathogenic mutations in the COL7A1 gene.



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Coverage Policy/Guideline

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Effective Date: 7/14/2025			Last Review Date:	6/16/2025
Applies to:	⊠Illinois ⊠Maryland	⊠Virginia ⊠Florida Kids	⊠New Jersey ⊠Pennsylvania Kid	S

- Member has positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin.
- Member has at least one stage 2 chronic wound that will be treated (open for 6 months or more).
- Member does not have a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.
- Member does not have an active infection.
- The requested medication will not be administered to wound(s) that are currently healed.
- Member will not use Vyjuvek (beremagene geperpavec-svdt) or Filsuvez (birch triterpenes) on wounds that have been previously treated with Zevaskyn.
- The requested medication will not be administered to wound(s) that have been previously treated with Zevaskyn.

Approval Duration and Quantity Restrictions:

Approval: 3 months

Quantity Level Limit: One dose total for lifetime

References:

- 1. Zevaskyn [package insert]. Cleveland, OH: Abeona Therapeutics, Inc.; April 2025.
- 2. ClinicalTrials.gov. NCT04227106. Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB). Accessed May 12, 2025.