| Reference number(s) |
| --- |
| 6964-A |

# Specialty Guideline Management Zevaskyn

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Zevaskyn | prademagene zamikeracel |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications

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

## 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.

# Coverage Criteria

## 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 of 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.
- 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.

# 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.