Draft New Policy: Do Not Implement

Prademagene Zamikeracel (Zevaskyn™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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 SPECIALITIES

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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE

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