

prademagene zamikeracel (Zevaskyn)

Medical Benefit Drug Policy

Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: Autologous cell sheet-based gene therapy

HCPCS:

J3389:Topical administration, prademagene zamikeracel, per treatment

How Supplied:

Single-dose of up to twelve cellular sheets each measuring 41.25 cm² (5.5 cm x 7.5 cm) and consisting of patient's own, viable, gene-modified cells that contain functional copies of the COL7A1 gene, which express collagen 7 (C7) protein

Condition(s) listed in policy *(see coverage criteria for details)*

- Recessive Dystrophic Epidermolysis Bullosa (RDEB)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Recessive Dystrophic Epidermolysis Bullosa (RDEB)

Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a dermatologist, and
2. Presence of mutations in both collagen type VII alpha-1 chain (COL7A1) genes
3. Patient is not being treated for areas that have been previously treated with Zevaskyn

4. Not being used in combination with another drug therapy for RDEB (e.g., Vyjuvek, Filsuvez)

Covered Doses:

- The recommended dose is based on the surface area of the wound(s). One sheet covers an area of 41.25 cm².
- Up to twelve sheets (~500 cm²) may be manufactured from the patient biopsies and supplied for potential use.

Coverage Period:

One-time application per treatment area

ICD-10:

Q81.2

References

1. Zevaskyn (prademagene zamikeracel) Prescribing Information. Abeona Therapeutics Inc., Cleveland, OH: 4/2025.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- HCPCS: Added J3389, effective 1/1/2026.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*