

Title: Zevaskyn (prademagene zamikeracel)	Division: Medical Management Department: Utilization Management
Approval Date: 9/29/2026	LOB: Medicaid, SNP, HARP, CHP, QHP, EP, Gold, Goldcare, Medicare, Ultracare
Effective Date: 9/26/2026	Policy Number: UM-MP359
Review Date: 9/29/2027	Cross Reference Number:
Retired Date:	

1. POLICY DESCRIPTION:

Gene Therapy – Zevaskyn (prademagene zamikeracel)

2. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

3. DEFINITIONS:

Zevaskyn is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

4. POLICY:

Zevaskyn will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:**1. Recessive Dystrophic Epidermolysis Bullosa (RDEB)**

A. Member must be ≥ 6 years of age and ≤ 40 years of age;

AND

B. Member must have diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) confirmed by genetic testing defined as ONE of the following:

a. Two confirmed RDEB C7 mutations with recessive inheritance patterns;

OR

b. Confirmation that parents don't have any evidence of dominant disease;

AND

C. Member must have confirmed positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin;

AND

D. Prescribed by or in consultation with board-certified dermatologist or wound care specialist with expertise in RDEB;

AND

- E. Member is receiving and will remain adherent to standard of care wound therapy (i.e., dressings, bandages, debridement of the wound);

AND

- F. Target wound must meet ALL of the following criteria:

- a. Adequate granulation tissue;

AND

- b. Excellent vascularization;

AND

- c. Wound location must be suitable for Zevaskyn application by prescribing physician (e.g. wound location is in non-flexion areas);

AND

- d. Wound size must be at least 20 cm² or greater and total target wound area must be greater than or equal to 120 cm²;

AND

- e. Wound must have been present for at least 6 months;

AND

- f. Wound is classified as stage 2 (e.g. partial thickness loss of dermis presenting as a shallow open wound with a red-pink wound bed; abrasion or serum filled blister that is intact or open/ruptured, presents as shiny or dry shallow ulcer without slough or bruising);

AND

- G. Member does not have ANY of the following:

- a. Current evidence of history of squamous cell carcinoma in the area that will undergo treatment;

AND

- b. Active infection with human immunodeficiency virus (HIV), hepatitis B, or hepatitis C;

AND

- c. Current systemic infection or active wound infection;

AND

- d. Evidence of immune response to C7 by indirect immunofluorescence on skin biopsy;

AND

- e. Hypersensitivity to vancomycin or amikacin;

AND

- f. Active drug or alcohol addiction;

AND

- H. Member is not receiving concurrent therapy with beremagene geperpavec-svdt (Vyjuvek) or birch triterpenes (Filsuvez);

AND

- I. Member must be on a stable pain medication regimen at least 30 days prior to therapy;

AND

- J. Members who are of childbearing age must have ALL of the following:

- a. Negative pregnancy test;

AND

- b. Reliable method of birth control throughout the duration of treatment and 6 months post treatment;

AND

- c. Member must not be breastfeeding;

AND

- K. Member is not a candidate for any clinical trials;

AND

- L. Authorization is for one-time treatment for affected wound area.

RENEWAL REQUEST:

1. Recessive Dystrophic Epidermolysis Bullosa (RDEB)

- A. Retreatment with Zevaskyn on opened or recurrent wounds are not allowed;

AND

- B. If treatment is for a new wound not previously treated with Zevaskyn, all initial conditions of coverage must be met.

5. LIMITATIONS/ EXCLUSIONS:

Zevaskyn will be considered experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy.

Treatment of Zevaskyn for opened or recurrent wounds is considered experimental and investigational and will not be covered under this policy.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
J3389	Topical administration, prademagene zamikeracel, per treatment

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
Q81.2	Epidermolysis Bullosa Dystrophica

8. REFERENCES:

1. Zevaskyn [package insert]. Cleveland, OH: Abeona Therapeutics, Inc.; October 2024. Accessed August 17, 2026.
2. ClinicalTrials.gov. NCT04227106. Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB). Accessed August 17, 2026. <http://clinicaltrials.gov>.
3. Micromedex DrugDex Compendium®. 2025. Prademagene zamikeracel.
4. IPD Analytics. ICD-10-CM CODES.

9. REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	JL	9/29/2026
Annual Review		

Sanjiv Shah
MD

Digitally signed by Sanjiv
Shah MD
Date: 2026.10.21
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Approved:
Sanjiv Shah, MD
Chief Medical Officer

Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.