Zevaskyn™ (prademagene zamikeracel)
(Topical)

Document Number: EOCCO-0796

Last Review Date: 06/05/2025
Date of Origin: 06/05/2025
Dates Reviewed: 06/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 treatment of up to twelve [12] C7-expressing cellular sheets for each surgical session [supplied as 3 containers containing up to 4 sheets each])

III. Initial Approval Criteria [1]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. **Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.**

Coverage is provided in the following conditions:

- Patient is at least 6 years of age; **AND**

Universal Criteria [1]

- Patient does not have severe hypersensitivity (i.e., anaphylaxis) to vancomycin or amikacin; **AND**
- Will not be used concurrently, in the same wound, with another disease-modifying therapeutic agent indicated for DEB (e.g., birch triterpenes, beremagene geperpavecetc.) *(**NOTE:** this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.)*; **AND**
- Patient does not show current evidence or have a history of squamous cell carcinoma (SCC) in the area to be treated; **AND**

Recessive Dystrophic Epidermolysis Bullosa (RDEB) † Φ [1,2]

- Patient has a diagnosis of recessive dystrophic epidermolysis bullosa as established by detection of biallelic mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene on molecular genetic testing; **AND**

  (Note: If unable to confirm a biallelic mutation, confirmation that BOTH parents do not have any evidence of dominant disease is also acceptable.)
- Patient has cutaneous wound(s) which are adequate for treatment (e.g., stage 2 wounds that have an area ≥20 cm^2) and have been present for at least 6 months

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, development of new malignancies, contracting a serious infectious disease or agent, etc.; **AND**
- Patient shows disease response to treatment as defined by improvement (healing) of treated wound sites, and/or reduction in skin infections, etc., as attested by his/her physician; **AND**
- Patient requires continued* treatment due to new expansion of pre-existing, or development of new (de novo), open wounds

  (Note: Zevaskyn is intended as a one-time treatment per area. Re-treatment of wounds that were previously grafted would be considered investigational, at this time, and may not be renewed.)

V. Dosage/Administration [1]

Indication	Dose
Wound treatment of Dystrophic Epidermolysis Bullosa (DEB)	The recommended dose of Zevaskyn is based on the surface area of the wound(s). One sheet of Zevaskyn covers an area of 41.25 cm^2. Up to twelve sheets may be manufactured from patient biopsies and supplied for potential use.
• For autologous topical application on wounds only. • Zevaskyn is shipped directly to the qualified treatment center sealed in transport packaging. • Apply all selected sheets in a single surgical session. Do not trim sheets and do not overlap sheets on wounds. • Instruct patients to leave the treated area undisturbed for 5-10 days at the discretion of the physician based on individual needs for immobilization of treated areas and post-surgical recovery.	

VI. Billing Code/Availability Information

HCPCS Code:

- J3389 – Topical administration, prademagene zamikeracel, per treatment; 1 billable unit = 1 treatment *(Effective 01/01/2026)*
- J3590 – Unclassified biologics *(Discontinue use on 01/01/2026)*

NDC:

- Zevaskyn sheets of 41.25 cm^2 (5.5 cm × 7.5 cm) with up to four sheets provided in a single transport container, and with up to three containers per manufactured lot, for a total of up to twelve sheets. All available sheets per manufactured lot are supplied under the same NDC: 84103-0007-xx

VII. References

1. Zevaskyn™ [package insert]. Cleveland, OH; Abeona Therapeutics, Inc.; October 2024. Accessed April 2025.
2. Tang, J.Y. et al. 806 Results from VIITAL: A phase 3, randomized, intrapatient-controlled trial of an investigational collagen type VII gene–corrected autologous cell therapy, EB-101, for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). Journal of Investigative Dermatology, Volume 143, Issue 5, S138.
3. Lucky AW, Pope E, Crawford S. Dystrophic Epidermolysis Bullosa. GeneReviews. https://www.ncbi.nlm.nih.gov/books/NBK1304/. Initial Posting: August 21, 2006; Last Update: March 27, 2025. Accessed on April 29, 2025.
4. Has, C., Liu, L., Bolling, M.C., et al. (2020), Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa†. Br J Dermatol, 182: 574-592. https://doi-org.ezproxy.med.nyu.edu/10.1111/bjd.18128
5. Has, C., Bauer, J.W., Bodemer, C., Bolling, M.C., Bruckner-Tuderman, L., Diem, A., Fine, J.-.-D., Heagerty, A., Hovnanian, A., Marinkovich, M.P., Martinez, A.E., McGrath, J.A., Moss, C., Murrell, D.F., Palisson, F., Schwieger-Briel, A., Sprecher, E., Tamai, K., Uitto, J., Woodley, D.T., Zambruno, G. and Mellerio, J.E. (2020), Consensus reclassification of inherited epidermolysis bullosa and other disorders with skin fragility†. Br. J. Dermatol., 183: 614-627. https://doi-org.ezproxy.med.nyu.edu/10.1111/bjd.18921
6. Fine JD, Bruckner-Tuderman L, Eady RA, et al. Inherited epidermolysis bullosa: updated recommendations on diagnosis and classification. *J Am Acad Dermatol* 2014; 70:1103.
7. So JY, Nazaroff J, Iwummadu CV, et al. Long-term safety and efficacy of gene-corrected autologous keratinocyte grafts for recessive dystrophic epidermolysis bullosa. Orphanet *J Rare Dis.* 2022 Oct 17;17(1):377. doi: 10.1186/s13023-022-02546-9. PMID: 36253825; PMCID: PMC9574807.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
Q81.2	Epidermolysis Bullosa Dystrophic

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC