Neighborhood Health Plan OF RHODE ISLAND™
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Zevaskyn™ (prademagene zamikeracel) (Topical)

Effective Date: 11/01/2025
Dates Reviewed: 08/20/2025
Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Coverage will be provided for six (6) months and may be renewed.

II. Dosing Limits

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

- Up to twelve (12) C7-expressing cellular sheets for each surgical session (supplied as 3 containers containing up to 4 sheets each)

III. Summary of Evidence

Zevaskyn (prademagene zamikeracel) is indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). The approval of Zevaskyn was based on the outcome of the VIITAL multi-center, randomized, intrapatient-controlled study which compared Zevaskyn to standard of care treatment. A total of 86 chronic (existing ≥6 months) RDEB wounds in 11 patients were enrolled. Similar wounds on the same individual were randomized 1:1 to receive up to 6 sheets of Zevaksyn or control treatment. The co-primary efficacy measures were proportion of randomized wound pairs with at least 50% healing at month 6 with confirmation of wound healing two weeks later as assessed using baseline digital photography by the Investigator, and pain reduction as assessed by the mean differences in patient-reported pain scores using the Wong-Baker FACES scale between randomized wound pairs at month 6. Zevaskyn statistically significantly met both efficacy endpoints with 81% of wounds achieving at least 50% healing at month 6 versus 16% in the control group, and a mean pain reduction of -3.07 versus -0.90 respectively.

IV. 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:

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

Universal Criteria [1]

- Member 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 (Filsuvez), beremagene geperpavecetc (Vyjuvek)) *(**NOTE:** this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.)*; **AND**
- Member does not show current evidence or have a history of squamous cell carcinoma (SCC) in the area to be treated; **AND**
- Zevaskyn is prescribed by or in consultation with a qualified dermatologist specializing in EB at an enrolled QTC; **AND**
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements; **AND**

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

- Member 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.)
- Member 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

V. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Member 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**
- Member 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**
- Member 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.)*

VI. 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 member 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 members 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.	

VII. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics

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

VIII. 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

Policy Rationale:
Zevskyn was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Zevaskyn according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.