Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the Blue Cross Blue Shield Association

Title: Zevaskyn™ (prademagene zamikeracel) (Topical)

Professional / Institutional
Original Effective Date: June 24, 2025
Latest Review Date: July 24, 2025
Current Effective Date: July 24, 2025

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

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.	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

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. 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); ǂ 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.)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS Code:

J3590 – Unclassified biologics

NDC:

Zevaskyn sheets of 41.25 cm² (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

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.

REVISIONS	
Posted 06-24-2025; Effective 07-24-2025	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.