UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Dermatology – Gene Therapy – Zevaskyn Utilization Management Medical Policy
- Zevaskyn™ (prademagene zamikeracel gene-modified cellular sheets – Abeona)

REVIEW DATE: 06/03/2026; Selected revision 07/01/2026

OVERVIEW

Zevaskyn, an autologous cell sheet-based gene therapy, is indicated for the treatment of wounds with **recessive dystrophic epidermolysis bullosa** (RDEB) in adult and pediatric patients.[1]

Zevaskyn is composed of autologous cells isolated from skin punch biopsies of patients with mutation in the collagen type VII alpha 1 chain (COL7A1) gene.[1] The cells have been transduced ex vivo with a replication-incompetent retroviral vector (RRV) containing the full length COL7A1 gene. The cell sheets express function collagen VII protein. Up to twelve, 41.25 cm^2 sheets may be manufactured from the patients biopsy and surgically applied.

Disease Overview

Dystrophic epidermolysis bullosa (DEB) can be inherited in a dominant or recessive pattern.[2,3] All subtypes of DEB are caused by mutations in the gene coding for COL7A1 leading to extreme skin fragility. The hallmark of DEB is scarring of blisters, both on the skin and on other mucosal surfaces. The estimated incidence and prevalence of DEB vary. The prevalence of all types of DEB in the US has been estimated as approximately 6 per 1 million individuals. The incidence of RDEB in the US has been reported as 3.05 per 1 million live births.

Clinical Efficacy

VIITAL, a Phase III, multicenter, randomized, intrapatient-controlled, pivotal study, assigned patients with RDEB to treat two matched, large wounds; one with Zevaskyn and one with standard of care wound dressings (N = 11 [86 wounds]).[1] Eligible patients were required to be ≥ 6 years of age, have at least 1 pair of matched, large (≥ 20 cm^2), and chronic wounds (open for ≥ 6 months) associated with RDEB. Patients with current or a history of squamous-cell carcinoma at the treatment site or systemic infection were excluded. A total of 86 wounds were treated with Zevaskyn or standard of care. At Month 6, significantly more Zevaskyn- vs. standard of care-treated wounds were healed (35 wounds [81%] vs. 7 wounds [16%], respectively; $P < 0.0001$) and more patients treated with Zevaskyn reported pain reduction (-3.07 vs. -0.90, respectively; $P = 0.0002$)[co-primary endpoint]. Secondary endpoints of complete wound healing at Months 3 and 6 were not found to be statistically significant; however, Zevaskyn was favored over placebo. At Month 3, 6 wounds (14%) showed complete healing for Zevaskyn vs. 0 wounds for standard of care; similar results were seen at Month 6 (7 wounds [16%] vs 0 wounds, respectively).

Dosing Information

The recommended dose is based on the surface area of the wound(s).[1] Up to twelve 41.23 cm^2 sheets of Zevaskyn may be manufactured from the patient biopsies and supplied for use. To administer Zevaskyn, the wound(s) need to be prepared with debridement. Full sheets of Zevaskyn are applied onto the wound bed with resorbable sutures. All sheets must be applied in one sterile surgical procedure and the application sites must be covered with non-adhesive dressing. Patients should leave the treated area undisturbed for 5 to 10 days and it should be kept dry until the gauze backing falls off (within 2 to 3 weeks).

Guidelines

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Zevaskyn is not addressed in available guidelines. According to a position statement by the **European Reference Network for Rare Skin Diseases** (2021), wound care is the cornerstone of treatment for patients with DEB.[2] Careful and complete skin and wound assessment should be undertaken regularly, at least every 6 months. The healing rate of chronic wounds should be closely monitored, by checking wound edges.

The diagnosis of DEB is based on a combination of clinical features, family history, and laboratory findings.[2] Laboratory techniques include immunofluorescence mapping, transmission electron microscopy, and molecular genetic testing. Whenever possible, laboratory diagnosis should be performed in a specialized DEB center. Genetic testing is the gold standard for the diagnosis of DEB, since it provides a definitive diagnosis and classification of the major DEB type and in many cases the subtype.

An **international consensus best practice guideline** on skin and wound care in epidermolysis bullosa (EB) [2017] notes that EB is a lifelong disease that requires specialist intervention and consideration to minimize complications and improve quality of life.[3] Management should take place in a specialized center by a multi-disciplinary team, ideally. Definitive diagnosis is most commonly made from analysis of a skin biopsy using positive immunofluorescence, antigenic mapping, and transmission electron microscopy. These key diagnostic tools help confirm diagnosis and indicate the particular subtype of EB. Due to the rarity of expertise and facilities, diagnosis is generally made using immunofluorescence and antigen mapping. Some laboratories are moving towards molecular diagnosis from exome sequencing of a panel of known skin fragility genes. Experienced clinicians can often make a provisional diagnosis on clinical observations, but a definitive diagnosis will always be required.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Zevaskyn. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for one single application. The approval duration is 6 months to allow for an adequate timeframe to administer Zevaskyn. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zevaskyn as well as the monitoring required for adverse events and long-term efficacy, approval requires Zevaskyn to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required for use of Zevaskyn as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zevaskyn is recommended in those who meet the following criteria:

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FDA-Approved Indication

1. **Dystrophic Epidermolysis Bullosa; Recessive.** Approve a single application (up to 12 sheets) if the patient meets ALL of the following (A, B, and C):
   - **A)** The diagnosis is confirmed by genetic testing showing a pathogenic variant in both alleles in the collagen type VII alpha 1 chain (COL7A1) gene **[documentation required]**; AND
   - **B)** Patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient has at least one clinical feature of recessive dystrophic epidermolysis bullosa **[documentation required]**; AND
       Note: Examples of clinical features of recessive dystrophic epidermolysis bullosa include but are not limited to blistering, wounds, and scarring.
     - **ii.** Patient has one or more open wound(s) that will be treated (i.e., "target wound[s]); AND
     - **iii.** Target wound(s) meets ALL of the following, according to the prescriber (a, b, c, d and e):
       - **a)** Target wound(s) is clean in appearance and does not appear to be infected; AND
       - **b)** Target wound(s) has adequate granulation tissue and vascularization; AND
       - **c)** Target wound(s) is chronic wound(s) (present ≥ 6 months); AND
       - **d)** The prescriber attests that there is no evidence or clinical suspicion of squamous cell carcinoma identified at the target wound(s); AND
       - **e)** The prescriber attests that the medication has NOT been previously applied to the target wound(s); AND
   - **C)** The medication is prescribed by or in consultation with a dermatologist or wound care specialist.

   Dosing. Approve one application of up to 12 gene-modified cellular sheets.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zevaskyn is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zevaskyn™ gene-modified cellular sheets [prescribing information]. Cleveland, OH: Abeona Therapeutics; July 2025.
2. Has C, El Hachem M, Buckova H, et al. Practical management of epidermolysis bullosa: consensus clinical position statement from the European Reference Network for Rare Skin Diseases. *J Eur Acad Derm Venereol.* 2021;35:2349-2360.
3. Denyer J, Pillay E, Clapham J. Best practice guidelines for skin and wound care in epidermolysis bullosa. An International Consensus. *Wounds International.* 2017. Available at: https://af13d689-15eb-4199-8733-e91a7bb8ae3f.usrfiles.com/ugd/af13d6_01ed147ab87e49c584c20a917c47f19f.pdf. Accessed on: May 28, 2026.

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HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/18/2025
Selected Revision	**Dystrophic Epidermolysis Bullosa; Recessive:** The requirement the prescriber attests that the medication has not been previously applied to the target wound(s) was added. The requirement "squamous cell carcinoma has been considered for the target wound(s)" was modified to "the prescriber attests that there is no evidence or clinical suspicion of squamous cell carcinoma at the target wound(s)".	08/27/2025
Annual Revision	No criteria changes	06/03/2026
Selected Revision	The Policy Statement was updated to clarify that "All approvals are provided for one single application. The approval duration is 6 months to allow for an adequate timeframe to administer Zevaskyn."	07/01/2026

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