



MEDICAL COVERAGE POLICY

SERVICE: Prademagene zamikeracel (Zevaskyn®)

Policy Number: 321

Effective Date: 10/01/2026

Last Review: 09/24/2026

Next Review: 09/24/2027

Important note: Unless otherwise indicated, medical policies will apply to all lines of business.

Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

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PRIOR AUTHORIZATION: Required.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

Baylor Scott & White Health Plan (BSWHP) may consider prademagene zamikeracel (Zevaskyn®) medically necessary when documentation is submitted showing ALL of the following criteria are met:

Universal Criteria Applied To All Requests

1. Member has a diagnosis of confirmed **recessive dystrophic epidermolysis bullosa (RDEB)** with **all** the following:
 - a. Skin biopsy for immunohistochemistry (IHC) with fluorescence-labelled secondary antibodies (immunofluorescence mapping, IFM), confirming positive expression of the non-collagenous region 1 of the CVII protein (NC1+) in the skin; **AND**
 - b. Confirmation of COL7A1 (*collagen type VII alpha 1*) gene mutation and Collagen VII (CVII) deficiency or absence with a recessive inheritance pattern by genetic testing
- AND**
2. Member has appropriate clinical presentation, such as skin blistering, erosions, slow healing chronic wounds, scarring, milia, and itchy painful skin; **AND**
3. Provider has ruled out other related skin disorders with similar clinical presentation; **AND**
4. Member is ≥ 6 years or older; **AND**
5. Prademagene zamikeracel (Zevaskyn®) application is prescribed by or in consultation with a dermatologist with experience in treating patients with RDEB; **AND**
6. Member has at least one wound with **ALL** the following characteristics:
 - a. Have a surface area size of $\geq 20 \text{ cm}^2$



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- b. Stage 2 chronic wound is defined as an open skin wound with partial thickness loss of dermis that has not extended through the dermis into subcutaneous tissue
- c. Present for ≥ 6 months

AND

- 7. Prademagene zamikeracel (Zevaskyn®) will be applied according to FDA approved labeling;

AND

- 8. Provider attests member will use an [authorized treatment center](#); **AND**
- 9. Member does not have any of the following:
 - c. Anti-type VII collagen (C7) antibodies.
 - d. No evidence of active systemic infections, such as hepatitis B or C, and human immunodeficiency virus (HIV), **AND** infection at candidate wound sites.
 - e. Cardiac abnormalities that can complicate anesthesia use, such as left ventricular dysfunction, congestive heart failure, and dilated cardiomyopathy.
 - f. Squamous cell carcinoma lesions at or near candidate wounds.
 - g. Vancomycin and amikacin hypersensitivity.
 - h. The patient will not apply beremagene geperpavec (Vyjuvek®), birch bark gel (Filsuvez®), ®), investigational gene or cell therapies onto candidate wounds leading up to and after prademagene zamikeracel (Zevaskyn®) application.

Renewal requests:

- 1. Member meets all universal criteria; **AND**
- 2. The request is for new candidate wounds that were not previously treated with prademagene zamikeracel; **AND**
- 3. Member has manageable or no side effects from previous treatment; **AND**
- 4. Member's previously prademagene zamikeracel-treated wounds show positive clinical response (e.g., reduction in wound area size, etc.) within 6 months of application; **AND**
- 5. Member did not experience graft rejection from the previous application

Authorization duration – 1 year for one dose (12 cellular sheets)

BSWHP considers only **TWO** treatments per lifetime are medically necessary as further administration of prademagene zamikeracel (Zevaskyn®) is experimental and investigational because the effectiveness of this strategy has not been established.

BSWHP considers prademagene zamikeracel (Zevaskyn®) for the treatment of all other indications to be experimental and investigational because the effectiveness of this strategy has not been established.

All requests will be reviewed by a clinical pharmacist and medical director.



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BACKGROUND:

Epidermolysis Bullosa (EB) is a rare, progressive group of genetic disorders characterized by skin fragility, blistering, and chronic wounds, affecting approximately 200 newborns annually in the United States. Recessive dystrophic epidermolysis bullosa (RDEB), one of the most severe forms, is caused by mutations in the *COL7A1* gene, resulting in absent or deficient Collagen VII, a protein essential for anchoring the epidermis to the dermis. Without Collagen VII (C7), even minor trauma causes skin separation and chronic non-healing wounds. Beyond the skin, RDEB can lead to fusion of the fingers and toes (pseudosyndactyly), involvement of the esophagus and teeth, leading to malnutrition and anemia. Patients are at significantly increased risk of developing aggressive cutaneous squamous cell carcinomas, the leading cause of death in this population.

Prademagene zamikeracel (Zevaskyn®) is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with RDEB. Prademagene zamikeracel utilizes autologous keratinocytes from a patient's skin biopsy and are modified through a retrovirus replicating vector (RRV) to express a non-mutant *COL7A1* gene. These RRV-modified cells are formed into cellular sheets that are then surgically topically applied onto the patient's wounds. As the wound heals, the non-mutant *COL7A1* gene is introduced into the patient's skin cells to produce CVII and anchoring filaments to heal.

Prademagene zamikeracel (Zevaskyn®)'s safety and efficacy were studied in the VIITAL study, which is a randomized, open-label, multicenter, intrapatient-controlled, phase 3 trial. Patients included in the trial had a maximum of six chronic wounds (>20 cm²), that were matched in pairs by size, chronicity, and anatomical region underwent computer randomization to treatment with prademagene zamikeracel or control (1:1), which was standard wound care. Patients were not masked in this trial. Patients with a current or previous history of cutaneous squamous cell carcinoma and medical complications such as systemic infections, HIV, hepatitis B or C, and cardiac abnormalities were excluded.

The co-primary endpoints included the proportion of wounds with at least 50% healing and pain reduction from baseline at week 24. A total of 86 wounds underwent randomization and treatment, and at week 24, 35 of 43 (81%) Zevaskyn®-treated wounds showed at least 50% of wound healing compared to 7 (16%) of 43 control wounds (mean difference 67% [95% CI 50 to 89]; $p < 0.0001$), and reported pain reduction -3.07 for Zevaskyn®-treated wounds vs. -0.90 for control wounds, (mean pairwise difference -2.23 [95% CI -3.45 to -0.66], $P = 0.0002$).⁴ For secondary endpoints of complete wound healing at months 3 and 6 were not statistically significant, but favored Zevaskyn® (3 months = 6 wounds [14%]; 6 months = 7 wounds [16%]) over placebo (3 months and 6 months = 0 wounds). No serious treatment-related adverse events were observed.

CODES:



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Important note: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
HCPCS Codes:	J3389, Topical administration, prademagene zamikeracel, per treatment
ICD10 codes:	
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	09/24/2026	New policy

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

- Has C, Liu L, Bolling MC, Charlesworth AV, El Hachem M, Escámez MJ, Fuentes I, Büchel S, Hiremagalore R, Pohla-Gubo G, van den Akker PC, Wertheim-Tysarowska K, Zambruno G. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. *Br J Dermatol*. 2020 Mar;182(3):574-592. doi: 10.1111/bjd.18128. Epub 2019 Aug 9. PMID: 31090061; PMCID: PMC7064925.
- Mayo Clinic Staff. Epidermolysis bullosa: symptoms and causes. Mayo Clinic. Updated June 12, 2024. Accessed June 5, 2026. <https://www.mayoclinic.org/diseases-conditions/epidermolysis-bullosa/symptoms-causes/syc-20361062>
- Abeona Therapeutics Inc. ZEVASKYN (prademagene zamikeracel) prescribing information. March 2026. Accessed June 5, 2026. <https://www.abeonatherapeutics.com/wp-content/uploads/2026/06/Mar-2026-US-REG-ZEV-240001.pdf>
- Tang JY, Marinkovich MP, Wiss K, et al. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomised, open-label, inpatient-controlled phase 3 trial. *Lancet*. 2025;406(10499):163-173. doi:10.1016/S0140-6736(25)00778-0
- Eichstadt S, Barriga M, Ponakala A, et al. Phase 1/2a clinical trial of gene-corrected autologous cell therapy for recessive dystrophic epidermolysis bullosa. *JCI Insight*. 2019;4(19):e130554. doi:10.1172/jci.insight.130554
- Siprashvili Z, Nguyen NT, Gorell ES, et al. Safety and Wound Outcomes Following Genetically Corrected Autologous Epidermal Grafts in Patients With Recessive Dystrophic Epidermolysis Bullosa. *JAMA*. 2016;316(17):1808–1817. doi:10.1001/jama.2016.15588



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8. DEBRA of America. Understanding epidermolysis bullosa (EB). DEBRA of America. Accessed June 9, 2026. <https://www.debra.org/about-eb/understanding-epidermolysis-bullosa-eb>
9. Lesiak A, Marinkovich MP. An evaluation of prademagene zamikeracel for the treatment of recessive dystrophic epidermolysis bullosa. Expert Opin Biol Ther. 2026 Mar;26(3):225-230. doi: 10.1080/14712598.2026.2639393. Epub 2026 Mar 18. PMID: 41764660.
10. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel, and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Haesler E, ed. EPUAP/NPIAP/PPPIA; 2019. Accessed June 24, 2026. Available at: <https://static1.squarespace.com/static/6479484083027f25a6246fcb/t/6a223475823a8975f5a4765b/1780626549904/EPUAP-NPIAP-PPPIA+CLASSIFICATION+2019.pdf>

Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.