Corporate Medical Policy: Prademagene zamikeracel (Zevaskyn®)

Restricted Product(s):

- prademagene zamikeracel (Zevaskyn®) gene-modified cellular sheets for topical administration by a healthcare professional

FDA Approved Use:

- For the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient is 6 years of age or older; **AND**
2. The patient has a diagnosis of **recessive dystrophic epidermolysis bullosa (RDEB) [medical record documentation required]**; **AND**
3. The diagnosis has been confirmed by molecular genetic testing detecting presence of biallelic mutation(s) in the *collagen type VII alpha 1 chain* (*COL7A1*) gene with recessive inheritance patterns **[medical record documentation required]**; **OR**
    a. Confirmation that BOTH parents do NOT have any evidence of dominant disease **[medical record documentation required]**; **AND**
4. The patient has cutaneous wound(s) associated with RDEB which are adequate for treatment with the requested agent (i.e., stage 2 [partial-thickness] wounds with a surface area of at least 20 cm^2) and have been present for at least 6 months **[medical record documentation required]**; **AND**
5. The patient does NOT have current evidence or history of squamous cell carcinoma in the area undergoing treatment **[medical record documentation required]**; **AND**
6. The patient does NOT have evidence of systemic infection or active infection in the area undergoing treatment **[medical record documentation required]**; **AND**
7. The patient will NOT be using the requested agent in combination with Filsuvez (birch triterpenes), Vyjuvek (beremagene geperpavec-svdt), or another gene therapy on the same treatment area for the requested indication **[medical record documentation required]**; **AND**
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
9. The requested agent will be applied to an area that has NOT been previously treated with the requested agent **[medical record documentation required]**; **AND**
10. The requested agent will be administered at a qualified treatment center (QTC) **[medical record documentation required]**; **AND**
11. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**.

Duration of Approval: 180 days (6 months), one-time application per treatment area(s)

Please note, for certain identified gene and cellular therapies such as prademagene zamikeracel (Zevaskyn®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. **Please contact Blue Cross NC to coordinate this therapy.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
prademagene zamikeracel (Zevaskyn®) gene-modified cellular sheets for topical use	Treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)	For autologous topical application on wounds only. Recommended dose is based on the surface area of the wound(s). One sheet covers an area of 41.25 cm^2. Up to 12 sheets may be manufactured from the patient biopsies and supplied for potential use. Applied surgically by a qualified healthcare provider. Supplied as a single-dose of up to 12 cellular sheets each measuring 41.25 cm^2 (5.5 cm x 7.5 cm) and consisting of patient's own, viable, gene-modified cells that contain functional copies of the *COL7A1* gene, which express collagen 7 (C7) protein.	J3389	**1 application per affected area(s)** (up to 12 cellular sheets per surgical session)

***Maximum units allowed for duration of approval**

Other revenue codes that may be applicable to this policy: 0891, 0892

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Fine JD, Bruckner-Tuderman L, Eady RA, et al. Inherited epidermolysis bullosa: updated recommendations on diagnosis and classification. *J Am Acad Dermatol*. 2014 Jun;70(6):1103-26.

2. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. *Br J Dermatol*. 2020 Mar;182(3):574-592.
3. 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.
4. Tang JY, Marinkovich MP, Wiss K, 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). J Invest Dermatol. May 2023;143(5):S138.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). **Policy notification given 2/1/2026 for effective date 4/1/2026**.
January 2026: Coding change: Added HCPCS code J3389 (1 unit per treatment) to dosing reference table effective 1/1/2026; deleted C9399, J3490, and J3590 termed 12/31/2025.
July 2025: Original medical policy criteria issued.