Zevaskyn (prademagene zamikeracel)

Humana

Medicaid Medical Coverage Policy

Original Effective Date: 09/02/2025
Effective Date: xx/xx/xxxx
Review Date: 09/02/2025
Policy Number: HUM-2630-000
Line of Business: Medicaid
State(s): LA

Table of Contents

Description

Epidermolysis bullosa (EB) refers to a group of rare, inherited skin disorders marked by exceptionally fragile skin that blisters and tears easily, often in response to minor friction or trauma. Common skin-related features include blistering, chronic wounds, erosions and scarring. In more severe forms, blistering can also occur internally. Symptoms typically present at birth or during early infancy ranging from mild to profoundly disabling and some cases of EB are life-threatening.[4] There are four main types of EB, classified by the layer of skin where blistering occurs: epidermolysis bullosa simplex, junctional EB, dystrophic EB and Kindler EB. The severity of EB varies widely and depends on both the depth of skin separation and the specific genetic mutation involved.[8]

Dystrophic epidermolysis bullosa (DEB) is caused by mutations in the *COL7A1* gene, which impair or eliminate the production of type VII collagen (C7), a critical protein essential for maintaining skin integrity.
C7 is a key part of the fibers that help hold the top layer of skin to the layer underneath, without functional C7, the skin becomes extremely fragile and prone to separation from even minor trauma. DEB can be inherited in a dominant or recessive pattern, with symptoms depending on the type. The recessive form (RDEB) is the most severe, resulting from mutations in both copies of the *COL7A1* gene.[4]

Standard care for EB is supportive and includes infection control, maintaining proper nutrition, monitoring for squamous cell carcinoma (SCC), occupational/physical therapy, pain management,

protective bandaging and wound care. Zevaskyn (prademagene zamikeracel) is an autologous cell sheet-based gene therapy developed to address the urgent need for treatments that improve outcomes in individuals with EB, particularly those with dystrophic forms of the disease.[4] This gene therapy was approved by the US FDA in April 2025 for the treatment of wounds in both adult and pediatric individuals with RDEB.[8]

Zevaskyn (prademagene zamikeracel) is made from the individual's own skin cells, collected through a small biopsy from individuals with *COL7A1* mutations. These cells are genetically modified ex vivo (outside the body) using a replication-incompetent retroviral vector encoding the full-length *COL7A1* gene, enabling expression of functional type C7. The modified cells are expanded and formed into thin sheets and surgically applied directly to wounds to help rebuild the skin's structure. This is manufactured using both human and animal derived materials and is supplied as a single-dose treatment consisting of up to twelve cellular sheets, each measuring 41.25 cm^2 (5.5 cm × 7.5 cm).[10]

Requests for Zevaskyn (prademagene zamikeracel) *require review by a medical director*.

Coverage Determination

Refer all requests or questions regarding Zevaskyn to the Corporate Transplant Department.

Phone	Fax	Email
1-866-421-5663	502-508-9300	transplant@humana.com

Humana members may be eligible under the Plan for Zevaskyn (prademagene zamikeracel) for the treatment of wounds in an individual with RDEB for the following indications [10]:

- **Absence of limitations; AND**
- **Individual is 6 to 65 years of age; AND**
- **Clinical diagnosis or genetic testing confirmation of recessive dystrophic epidermolysis bullosa; AND**
- **Presence of wounds characteristic of RDEB (eg, blistering, chronic wounds, erosions or scarring)**

Coverage Limitations

Humana members may NOT be eligible under the Plan for Zevaskyn (prademagene zamikeracel) for any indications other than those listed above including, but may not be limited to[10]:

- **Individual has desire to become pregnant/reproduce OR unwilling to use effective contraception; OR**
- **Individual is pregnant or breastfeeding**

A review of the current medical literature shows that there is no evidence to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
15040	Harvest of skin for tissue cultured skin autograft, 100 sq cm or less	-
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
J3590	Unclassified biologics	-
ICD-10-PCS Code(s)	**Description**	**Comments**
XHR0XGA	Replacement of Head and Neck Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-
XHR1XGA	Replacement of Chest Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-
XHR2XGA	Replacement of Abdomen Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-
XHR3XGA	Replacement of Back Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-
XHR4XGA	Replacement of Right Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-

XHR5XGA	Replacement of Left Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-
XHR6XGA	Replacement of Right Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-
XHR7XGA	Replacement of Left Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10	-

References

1. ClinicalKey. Drug Monograph. Prademagene zamikeracel. https://clinicalkey.com. Updated July 16, 2025.

2. ClinicalKey. Moon M, Guerrero AM, Xiaoxiao, L, et al. Clinical assessment of dry eye disease: tear film and ocular surface health. In Galor A. *Dry Eye Disease*. Elsevier; 2023:15-23. https://clinicalkey.com.

3. 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.

4. Hayes, Inc. Emerging Technology Report. Prademagene zamikeracel (Zevaskyn; Abeona Therapeutics Inc.) for recessive dystrophic epidermolysis bullosa. https://evidence.hayesinc.com. Published May 1, 2025.

5. National Center for Biotechnology Information (NCBI). Lucky AW, Pope E, Crawford S. Dystrophic epidermolysis bullosa. In: Adam MP, Feldman J, Mirzaa GM, Pagon RA, Wallace SE, Amemiya A. *GeneReviews.* Seattle (WA): University of Washington, Seattle*; 2006:1993-2025.* https://ncbi.nlm.nih.gov.

6. 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.

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;17(1):377.

8. UpToDate, Inc. Overview of the management of epidermolysis bullosa. https://uptodate.com. Updated June 10, 2025.

9. **UpToDate, Inc. Prademagene zamikeracel: drug information. https://uptodate.com. Updated April 2025.**

10. **US Food & Drug Administration (FDA). Full prescribing information: Zevaskyn (prademagene zamikeracel). https://fda.gov. Published April 28, 2025.**

Change Summary

09/02/2025 New Policy.