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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	September 5, 2025
Subject:	Zevaskyn	**Page:**	1 of 4

Last Review Date: September 19, 2025

Zevaskyn

Description

Zevaskyn (prademagene zamikeracel)

Background
In patients with recessive dystrophic epidermolysis bullosa (RDEB), both copies of the COL7A1 gene are mutated, resulting in the absence or low levels of biologically active C7 protein which form anchoring fibrils (AFs). The lack of AFs disrupts the connection between the epidermis and the dermis and causes skin fragility and other signs and symptoms of RDEB. Zevaskyn consists of a patient's own cells that have been gene-modified through retroviral vector (RVV) transduction to express the COL7A1 gene to produce the C7 protein. These cells are formed into cellular sheets for topical application onto wounds (1).

Regulatory Status
FDA-approved indication: Zevaskyn is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB) Zevaskyn is supplied as a single-dose of up to twelve cellular sheets each measuring 41.25 cm2 (5.5 cm x 7.5 cm) (1).

Zevaskyn has been associated with hypersensitivity reactions to vancomycin, amikacin, or product excipients, retroviral vector (RRV)-mediated insertional oncogenesis, or transmission of infectious agents. Monitor for signs and symptoms of hypersensitivity reaction, development of malignancies, and infectious diseases (1).

The safety and effectiveness of Zevaskyn in pediatric patients have been established (1).

Related policies
Filsuvez, Vyjuvek

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zevaskyn may be considered **medically necessary** if the conditions indicated below are met.

Zevaskyn may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Wounds associated with recessive dystrophic epidermolysis bullosa (RDEB)

AND ALL of the following:

1. Documented biallelic pathogenic mutations in the collagen type VII alpha 1 chain (COL7A1) gene
2. Positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin
3. Presence of at least one chronic wound (e.g., stage 2 wounds that have an area ≥ 20 cm^2 and have been present for at least 3 months) that will be treated
4. Presence of clinical manifestations of RDEB, such as extensive skin blistering, skin erosions, or scarring
5. Prescribed by or in consultation with a dermatologist or a wound care specialist
6. **NO** active infection, active squamous cell carcinoma, or history of squamous cell carcinoma in the targeted wound(s)

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 12 sheets (one-time treatment per wound area)

Duration 6 months

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Zevaskyn is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in patients with recessive dystrophic epidermolysis bullosa (RDEB). Zevaskyn has been associated with hypersensitivity reactions to vancomycin, amikacin, or product excipients, retroviral vector (RRV)-mediated insertional oncogenesis, or transmission of infectious agents. The safety and effectiveness of Zevaskyn in pediatric patients have been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Zevaskyn while maintaining optimal therapeutic outcomes.

References

1. Zevaskyn [package insert]. Cleveland, OH: Abeona Therapeutics Inc.; April 2025.

Policy History

Date	Action
September 2025	Addition to PA. Annual review. Per Association, removed age requirement, removed no dual treatment with Filsuvez and Vyjuvek, reduced age of wound from 6 months to 3 months, removed Prescriber agrees that the affected wound has not been previously treated with Zevaskyn criteria; added statement in the regulatory section that Zevaskyn is supplied as a single-dose of up to twelve cellular sheets each measuring 41.25 cm2 (5.5

cm x 7.5 cm) as per the package insert and added the following statement to the quantity subsection: (one-time treatment per wound area).

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.