

prademagene zamikeracel (Zevaskyn)

HCPCS: J3389 Topical administration, prademagene zamikeracel, per treatment (Zevaskyn)

LOB:	MCAL
Duration of Approval:	One treatment per lifetime
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Zevaskyn (prademagene zamikeracel)

****All requests must be approved by a Medical Director******PA CRITERIA FOR APPROVAL:**

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication is prescribed by a dermatologist **AND**
3. Copy of genetic testing confirming biallelic pathogenic mutations in the collagen type VII alpha 1 chain (COL7A1) gene **AND**
4. The member has positive expression of the noncollagenous region 1 of the type 7 collagen protein (NC1+) in the skin **AND**
5. Chart notes provided showing clinical features of dystrophic epidermolysis bullosa (e.g., skin blistering, skin erosion, scarring) **AND**
6. The target wounds meets **ALL** of the following (a–d):
 - a. At least one wound with an area $\geq 20 \text{ cm}^2$
 - b. At least one stage 2 chronic wound defined as open for six or more months
 - c. Wound area has no history of squamous cell carcinoma
 - d. No active infection**AND**
7. The member has a history of failure, contraindications or reasons for intolerance to Vyjuvek and Filsuvez **AND**
8. Zevaskyn should not be applied to wounds that are currently healed or previously treated with Vyjuvek or Filsuvez **AND**
9. The member has not been previously treated with Zevaskyn

(Note: Per package insert, up to 12 cellular sheets [each measuring 41.25cm²] may be manufactured from the patient biopsies and supplied for potential use.)

OTHER INFORMATION:

HCPCS	Description	Brand name
J3389	Topical administration, prademagene zamikeracel, per treatment	Zevaskyn
**Refer to DHCS Physician-Administered Drugs (PADs) Special Billing for <u>Zevaskyn</u> for billing information and follow allowable number of units to approve. **		

REFERENCES:

1. Zevaskyn Prescribing Information.
https://d1io3yog0oux5.cloudfront.net/165201703b10131751044901cf3650d8/abeonatherapeutics/db/536/4189/description/Mar_2026_US-REG-ZEV-240001.pdf. 03/2026.