SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Zevaskyn™ (prademagene zamikeracel) **(J3389)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- ☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) [NDC Unit]:

- A single-dose of up to twelve cellular sheets each measuring 41.25 cm^2 (5.5 cm x 7.5 cm)
- 4 sheets per single transport container; 3 containers per manufactured lot; NDC 84103-007-01

B. Max Units (per dose and over time):

- 1 container (FOUR, 5.5 cm x 7.5 cm sheets)
- 3 total containers

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Recommended Dosage:

- One sheet of Zevaskyn covers an area of 41.25 cm^2
- Up to twelve ZEVASKYN sheets may be manufactured from the patient biopsies and supplied for potential use

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Authorization Criteria: One-time authorization

- ❑ Member is 6 years of age or older
- ❑ Provider is a specialist in dermatology, or specializes in/consulted with a specialist knowledgeable in the treatment of Dystrophic Epidermolysis Bullosa (DEB) practicing at a Qualified Treatment Center
- ❑ Member's diagnosis of Dystrophic Epidermolysis Bullosa (DEB) has been confirmed by **ALL** the following:
  - ❑ Detection of two mutation(s) with recessive inheritance patterns in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing (laboratory documentation must be submitted)
  - ❑ Positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin
  - ❑ Evidence of cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do **NOT** appear infected (documentation must be submitted)
- ❑ Provider has completed, and submitted, the results of an indirect immunofluorescence (IIF) assay showing absence of an immune response to the type VII collagen protein
- ❑ Member does **NOT** have a history of squamous cell carcinoma (SCC) in the area that will undergo treatment application
- ❑ Member does **NOT** have severe hypersensitivity (i.e., anaphylaxis) to vancomycin or amikacin
- ❑ Provider attests that treatment/sheets will only be applied to partial-thickness RDEB wounds that have been open chronically for ≥ 6 months
- ❑ Member has the presence of partial-thickness RDEB open wounds meeting **ALL** the following wound site characteristics:
  - ❑ Wound area is ≥ 20 cm2
  - ❑ Wound(s) present for ≥ 6 months
  - ❑ Stage 2 wound
- ❑ Member has had a proper trial of therapy with Vyjuvek™ (beremagene geperpavec-svdt) for at least 6 months (1 treatment cycle) **(verified by chart notes and/or paid claims)**

  NOTE: Requirement for prior disease-modifying therapy demonstrates inadequate initial treatment history resulting in chronic wound characteristics as noted above. Preclusion to prior treatment requirement will be assessed on a case-by-case basis when clinical presentation, severity, and chronicity of member's DEB condition is properly documented conveying the potential for increased morbidity in selecting other treatment.

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- ❑ Zevaskyn will **NOT** be used concurrently, in the same wound, with another disease-modifying therapeutic agent indicated for DEB (e.g., birch triterpenes, beremagene geperpavecetc) **[NOTE: this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.]**

Reauthorization: One-time authorization. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ All criteria in initial authorization section has been met
- ❑ Member shows disease response to treatment as defined by improvement (healing) of treated wound sites, and/or reduction in skin infections (Wound care documentation is required)
- ❑ Member requires continued* treatment due to **NEW** expansion of pre-existing, or development of **NEW** (de novo), open wounds **[*NOTE: Zevaskyn is intended as a one-time treatment per area. Re-treatment of wounds that were previously grafted would be considered investigational, at this time, and will not be renewed; wound care documentation is required]**
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, development of new malignancies, contracting a serious infectious disease or agent)

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: 9/25/2025
REVISED/UPDATED/REFORMATTED: ~~10/23/2025,~~ **1/02/2026**