

May 8, 2026

PRIOR AUTHORIZATION FOR ZEVASKYN EFFECTIVE APRIL 1, 2026

BACKGROUND

HHSC has added Zevaskyn (procedure code J3389) as a benefit for Medicaid and CHIP, effective April 1, 2026, and will require prior authorization for those programs, effective May 1, 2026.

KEY DETAILS

Zevaskyn (prademagene zamikeracel) 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).

ACTION

Authorization requirements

- HHSC requires prior authorization for Zevaskyn (prademagene zamikeracel).
- The prior authorization request for this surgical topical application may be approved for 12 months for patients who meet the following requirements:
 - a. Patient is at least 6 years and older.
 - b. Patient has a confirmed diagnosis of RDEB (diagnosis code: Q81.2), confirmed by biopsy and genetic testing detecting biallelic mutation(s) in the *COL7A1* gene.
 - c. Patient has chronic cutaneous stage 2 wound(s) adequate for treatment which meets the following:
 - i. Cutaneous wound open/present for at least 6 months.
 - ii. Stage 2 wounds with an area of greater than or equal to 20 cm².
 - iii. Wound has not previously been treated with Zevaskyn.
 - d. Patient's target wound(s) is not infected.
 - e. Patient's wound area shows no current evidence or history of squamous cell carcinoma.
 - f. Patient does not have severe hypersensitivity (i.e., anaphylaxis) to vancomycin or amikacin.
 - g. Authorization will not be approved for administration to wounds previously treated with Zevaskyn.
- For continued therapy, patient must meet the following requirements:
 - a. Re-authorization for the same wound is not permitted. Patient must meet the initial approval criteria if the request is for previously untreated or newly developed wounds.
 - b. Absence of unacceptable toxicity from Zevaskyn (e.g., severe hypersensitivity reactions and development of new malignancies).
 - c. Patient shows positive response to treatment as defined by improvement (healing) of treated wound sites and/or reduction in skin infections.

ADDITIONAL INFORMATION

HHSC approved this updated clinical prior authorization for use. Community Health Choice will implement the clinical coverage criteria on May 1, 2026.

QUESTIONS

For any questions regarding this notice, please contact your Community Provider Performance Manager (provider representative). E-mail: ProviderRelationsInquiries@CommunityHealthChoice.org