

TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Prademagene zamikeracel (Zevaskyn®)	CRITERIA ID: TX.CC.PHAR.56
BUSINESS UNIT: Superior HealthPlan	FUNCTIONAL AREA: Pharmacy
EFFECTIVE DATE: 4/14/2026	PRODUCT(S): STAR, STAR+PLUS, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	REGULATOR MOST RECENT APPROVAL DATE(S): N/A

CRITERIA STATEMENT:

The purpose of this clinical criteria is to provide a guide to medical necessity reviews for prademagene zamikeracel (Zevaskyn®).

PURPOSE:

Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

SCOPE:

This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:

PDAC = Precision Drug Action Committee

UM = Utilization Management

POLICY:

It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of prademagene zamikeracel (Zevaskyn®); procedure code: J3389.

Description/Mechanism of Action:

Prademagene zamikeracel is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in individuals with recessive dystrophic epidermolysis bullosa (RDEB). In individuals with recessive dystrophic epidermolysis bullosa (RDEB), mutations in both copies of the COL7A1 gene lead to a deficiency or absence of collagen type VII (C7) protein. The C7 protein is crucial for forming anchoring fibrils (AFs) that connect the epidermis to the dermis. This disruption results in fragile skin, blistering, and severe wounds. Prademagene zamikeracel is a treatment that involves gene-modifying an individual's own cells using a retroviral vector (RVV) transduction to express the COL7A1 gene, enabling the production of the C7 protein.

FDA Approved Indications:

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).

Formulations:

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) and consisting of patient's own, viable, gene-modified cells that contain functional copies of the COL7A1 gene, which express collagen 7 (C7) protein.

PROCEDURE:

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Approval Criteria

A. Recessive dystrophic epidermolysis bullosa (RDEB) (must meet all):

1. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
2. Client is at least 6 years and older.
3. Client has a confirmed diagnosis of RDEB (diagnosis code: Q81.2), confirmed by biopsy and genetic testing detecting biallelic mutation(s) in the COL7A1 gene.
4. Client has chronic cutaneous stage 2 wound(s) adequate for treatment which meets the following:
 - a. Cutaneous wound open/present for at least 6 months.
 - b. Stage 2 wounds with an area of greater than or equal to 20 cm².
 - c. Wound has not previously been treated with Zevaskyn.
5. Client's target wound(s) is not infected.
6. Client's wound area shows no current evidence or history of squamous cell carcinoma.
7. Client does not have severe hypersensitivity (i.e., anaphylaxis) to vancomycin or amikacin.
8. Authorization will not be approved for administration to wounds previously treated with Zevaskyn.

Approval duration: 12 months

II. Continuation criteria

A. Recessive dystrophic epidermolysis bullosa (RDEB) (must meet all):

1. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
2. Re-authorization for the same wound is not permitted. Client must meet the initial approval criteria if the request is for previously untreated or newly developed wounds.
3. Absence of unacceptable toxicity from Zevaskyn (e.g., severe hypersensitivity reactions and development of new malignancies).
4. Client shows positive response to treatment as defined by improvement (healing) of treated wound sites and/or reduction in skin infections.

Approval duration: 12 months

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		04/14/2026

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