Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Zevaskyn® (prademagene zamikeracel)

Effective: July 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☒ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Recessive dystrophic epidermolysis bullosa (RDEB) is a rare inherited connective tissue disorder characterized by severe skin wounds that cause pain and can lead to systemic complications impacting the length and quality of life. People with RDEB have extremely fragile skin due to mutations in both copies of the COL7A1 gene that expresses Type VIII collagen. This leads to extensive blistering and severe wounds, often covering 30-80% of the body. Before EB treatments were approved, management focused on supportive care, including wound care, pain management, infection control, nutritional support, and complication prevention.

Recently approved treatments for DEB include topical gene therapy Vyjuvek® for the treatment of wounds in patients with DEB and mutations in the COL7A1 gene, Filsuvez®, a topical gel that promotes general wound healing of DEB-associated wounds, and Zevaskyn, the first and only autologous cell sheet-based gene therapy for the treatment of wounds in adults and pediatric patients with RDEB.

Food and Drug Administration (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)
- 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. The recommended dose of ZEVASKYN is based on the surface area of the wound(s). One sheet of ZEVASKYN covers an area of 41.25 cm2 .

For the therapy Zevaskyn® (prademagene Zamikeracel), evidence is sufficient for coverage based on the FDA approval in April 2025. This approval was based on the pivotal Phase 3 VIITAL study, a multi-center, randomized, intrapatient-controlled trial that met its two co-primary efficacy endpoints demonstrating statistically significant healing of ≥ 50% from baseline in large chronic RDEB wounds, and pain reduction from baseline as assessed by the Wong-Baker FACES scale, as evaluated at six months after

treatment. Across 43 large and chronic wounds treated with a single Zevaskyn application, 81% of wounds showed ≥ 50% healing at 6 months, vs. 16% in 43 matched control wounds treated with standard of care.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan may cover **Zevaskyn** when **All** the following clinical criteria are met:

1. Documentation of all of the following is required:
    a. Diagnosis of recessive dystrophic epidermolysis bullosa (RDEB); **and**
    b. **One** of the following:
        i. Member is ≥ 6 years of age; **or**
        ii. **Both** of the following:
            1. Member is ≥ 6 months to < 6 years of age; **and**
            2. Provider attestation that member is able to remain immobile and keep surgical area undisturbed for five to ten days post transplantation; **and**
    c. Copy of a genetic test confirming diagnosis of RDEB (e.g., biallelic mutations of COL7A1 gene); **and**
    d. Prescriber is a specialist (i.e., dermatologist) in the treatment of RDEB or consult notes from a specialist are provided; **and**
    e. Member has at least one wound site requiring treatment with **All** of the following:
        i. Wound area must be ≥ 20 cm2; **and**
        ii. Wound has been open for ≥ 6 months; **and**
        iii. Wound is classified as Stage 2, defined as partial thickness loss of dermis presenting as a shallow open ulcer with a pink or red wound bed, without slough or bruising; **and**
        iv. Wound is free of infection; **and**
    f. Total number and size of wound site(s) intended for treatment; **and**
    g. Anticipated number of sheets required for treatment of wound site(s); **and**
    h. Inadequate response, adverse reaction, or contraindication to Vyjuvek; **and**
    i. Zevaskyn will not be used in combination with Vyjuvek or Filsuvez on the same target wounds; and
    j. Treatment procedure will be performed at a qualified treatment center; **and**
    k. **One** of the following:
        (i) The requested agent will not be used on wound(s) that are currently healed or have been previously treated with Zevaskyn; **or**
        (ii) Clinical rationale for retreatment of Zevaskyn on the same wound area.

Limitations

- The Plan will not cover Zevaskyn for any conditions other than FDA-approved indications. All other uses are considered experimental or investigational
- Zevaskyn will not be used in combination with Vyjuvek or Filsuvez on the same target wounds

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3389	Topical administration, prademagene zamikeracel, per treatment

References:

1. FDA. Zevaskyn [package insert]. Cleveland, OH: Abeona Therapeutics, Inc.; April 2025.
2. ClinicalTrials.gov. NCT04227106. Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB). Accessed August 4, 2025.

Approval And Revision History

February 18, 2026: Reviewed by the Medical Policy Approval Committee (MPAC), effective April 1, 2026

Subsequent endorsement dates and changes made:

- May 20, 2026: Reviewed by MPAC; renewed without changes effective July 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.