Mass General Brigham
Health Plan

Medical Policy
Zevaskyn (prademagene zamikeracel)

Policy Number: 101

Contents

Overview

Zevaskyn is a cutaneous gene therapy constructed of autologous skin sheets transduced with a retroviral vector carrying normal copies of the collagen type VII alpha 1 chain (COL7A1) gene to help heal chronic open wounds in adult and pediatric patients with Recessive Dystrophic Epidermolysis Bullosa (RDEB).

FDA-Approved Indication

- The treatment of wounds in adult and pediatric patients with RDEB.

Medicare Variation

Prior Authorization Required	Yes ☒ No ☐

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **As of Mass General Brigham Health Plan's most recent policy review, Medicare had:**

- Medicare Benefit Policy Manual Chapter 15 - Covered Medical and Other Health Services

When CMS documentation references FDA labeling, Mass General Brigham Health Plan develops coverage criteria to clarify medical necessity of the requested services. Mass General Brigham Health Plan coverage criteria align with FDA labeling without contradicting existing determinations and enhance the clarity of medical necessity requirements, documentation requirements, and clinical indications.

Criteria

The member meets all of the following criteria:

1. The member is at least six years of age; and

2. The member has a confirmed diagnosis of RDEB with a genetic test showing biallelic mutations of the COL7A1 gene; and

3. The member has at least one wound to be treated.

Dosage

- Zevaskyn is supplied as single-dose cellular sheets each measuring 41.25 cm^2 (5.5 cm x 7.5 cm).
- Up to twelve collagen 7-expressing cellular sheets are supplied for each surgical session; supplied as up to 3 containers containing up to 4 sheets.

Mass General Brigham ACO Variation

Prior Authorization Required	Yes ☒ No ☐

Prior authorization requests for Zevaskyn for Mass General Brigham ACO members should be submitted to the MassHealth Drug Utilization Review Program. Criteria for Zevaskyn are found in Table 72: Agents Not Otherwise Classified.

One Care and Senior Care Options Variation

Prior Authorization Required	Yes ☒ No ☐

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its One Care and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, or the member does not meet the medical necessity criteria for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. **See Medicare Advantage criteria and exclusions, above. If Medicare Advantage criteria are not met, then MassHealth criteria are applied.**

Commercial and Qualified Health Plans Variation

Zevaskyn is considered Experimental and Investigational and therefore not covered for Commercial and Qualified Health Plan members.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Authorized Code	Code Description
J3389	Topical administration, prademagene zamikeracel, per treatment

Summary of Evidence

Prademagene zamikeracel is an autologous retroviral vector-mediated gene-corrected keratinocyte therapy designed to treat wounds in patients with RDEB, a severe inherited blistering disorder that leads to profound skin fragility, chronic nonhealing wounds, scarring, pain, nutritional compromise, and a greatly elevated risk of squamous cell carcinoma. Per Murrell (2025), traditional management has long centered on supportive measures such as wound protection, infection control, nutritional optimization, and malignancy surveillance. As no curative therapy existed, the emergence of genetically corrected autologous cell-sheet treatments has marked a significant advance in the field.

The pivotal evidence supporting Zevaskyn's approval came from the VIITAL phase 3 trial, a two-center, randomized, intrapatient-controlled, open-label study published by Tang, et al. in The Lancet in 2025. The trial enrolled 11 individuals with RDEB and compared 43 chronic wounds treated with prademagene zamikeracel to 43 matched control wounds treated with standard care. At 24 weeks, 81% of Zevaskyn-treated wounds (35/43) achieved at least 50% re-epithelialization, whereas only 16% (7/43) of control wounds reached the same threshold. Higher levels of healing were also observed: 65% (28/43) of treated wounds achieved ≥75% healing compared with only 7% (3/43) of controls. Pain outcomes favored the gene-corrected grafts as well. Mean change in pain from baseline to week 24, Zevaskyn-treated wounds demonstrated a mean 3.1-point reduction on the Wong-Baker Faces scale versus a 0.9-point reduction for controls. No serious adverse events were attributed to the therapy within the study period, and no cases of squamous cell carcinoma arose at treated sites.

Long-term evidence supporting durability of gene-corrected autologous keratinocyte grafts comes from an earlier EB-101 study by So, et al. in the Orphanet Journal of Rare Diseases in 2022. In a cohort of seven RDEB patients followed for a mean of 5.9 years after receiving a total of 42 grafts, 70% of treated sites maintained at least 50% healing at five years. Participants with sites achieving at least 50% long-term healing reported essentially no pain or itch, in contrast to persistent symptoms in sites with less than 50% healing. Over the multiyear follow-up, investigators reported no serious treatment-related adverse events, no chronic autoimmunity to type VII collagen, no evidence of replication-competent retrovirus, and no therapy-related malignancies. These data provide important reassurance regarding both the longevity and safety of this therapeutic approach.

Overall, the collected evidence positions prademagene zamikeracel as a transformative therapy that directly addresses the molecular cause of RDEB. Compared with standard care, Zevaskyn provides markedly improved wound healing, substantial pain reduction, and sustained long-term benefit as demonstrated in precursor studies. Despite ongoing considerations related to access, cost, and long-term monitoring, the therapy represents a major advancement in the management of a previously refractory and life-limiting disorder.

Effective Dates

March 2026: Effective date.

References

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