PHARMACY POLICY STATEMENT
Michigan Medicaid

DRUG NAME	Zevaskyn (prademagene zamikeracel)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

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).
DEB is one of four types of epidermolysis bullosa (EB). It is a rare genetic disease with skin fragility and mechanically induced blistering that can lead to infections, scarring, disfigurement, and pain. DEB is caused by mutations in COL7A1, the gene that codes collagen type VII (C7), the major component of anchoring fibrils in part of the skin. DEB can be autosomal dominant (DDEB) and have lower than normal functional anchoring fibrils, or less often (and more severe), recessive (RDEB) with no functional anchoring fibrils.
Zevaskyn consists of a patient's own cells that have been gene modified to express the COL7A1 gene to produce the C7 protein. These cells are formed into cellular sheets for topical application onto wounds.

Zevaskyn (prademagene zamikeracel) will be considered for coverage when the following criteria are met:

Recessive Dystrophic Epidermolysis Bullosa (RDEB)

For **initial** authorization:
1. Member is at least 6 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a documented diagnosis of RDEB confirmed by 2 mutations in the *COL7A1* gene with recessive inheritance patterns per genetic test report; AND
4. Member has positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin; AND
5. Member's wound(s) to be treated are at least 20 cm^2 and have been present for at least 6 months; AND
6. Zevaskyn will NOT be used concurrently with any other disease-modifying drug for EB applied to the same wound.
7. **Dosage allowed/Quantity limit:** Dose is based on surface area of wound(s). One sheet covers 41.25 cm^2. Up to 12 sheets may be manufactured from the patient biopsies and supplied for potential use. Apply in a single surgical session.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Zevaskyn will not be reauthorized. It is a one-time surgical application.

HAP CareSource considers Zevaskyn (prademagene zamikeracel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/07/2025	New policy for Zevaskyn created.
12/18/2025	Added "Zevaskyn will NOT be used concurrently with any other disease-modifying drug for EB applied to the same wound"

References:

1. Zevaskyn [prescribing information]. Abeona Therapeutics Inc.; 2025.
2. Eichstadt S, Barriga M, Ponakala A, et al. Phase 1/2a clinical trial of gene-corrected autologous cell therapy for recessive dystrophic epidermolysis bullosa. *JCI Insight*. 2019;4(19):e130554. Published 2019 Oct 3. doi:10.1172/jci.insight.130554
3. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. *Br J Dermatol*. 2020;182(3):574-592. doi:10.1111/bjd.18128
4. Has C, El Hachem M, Bučková H, et al. Practical management of epidermolysis bullosa: consensus clinical position statement from the European Reference Network for Rare Skin Diseases. *J Eur Acad Dermatol Venereol*. 2021;35(12):2349-2360. doi:10.1111/jdv.17629
5. Has C, Bauer JW, Bodemer C, et al. Consensus reclassification of inherited epidermolysis bullosa and other disorders with skin fragility. *Br J Dermatol*. 2020;183(4):614-627. doi:10.1111/bjd.18921

Effective date: 04/01/2026
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