

MEDICAL POLICY

Zevaskyn® (prademagene zamikeracel)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Zevaskyn (prademagene zamikeracel) is indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

POLICY

Zevaskyn (prademagene zamikeracel) is considered **not medically necessary** for all indications due to insufficient evidence to determine clinical efficacy, inconsistent clinical trial results, important safety concerns, and uncertainty of the risk-benefit profile.

CLINICAL RATIONALE

Zevaskyn (prademagene zamikeracel) is the third product approved for treatment of dystrophic epidermolysis bullosa (DEB) in adult and pediatric patients. It is an autologous cell-based gene therapy manufactured from the patient's own skin cells that have been genetically modified to express functional type VII collagen. These sheets are surgically grafted onto chronic wounds.

Clinical Studies

The FDA approval of Zevaskyn (prademagene zamikeracel) was based on efficacy data from a phase III, multi-center, randomized, inpatient-controlled trial (VIITAL) in participants with genetically confirmed COL7A1-related recessive dystrophic epidermolysis bullosa (RDEB). In this study, 43 chronic wounds across participants were treated with a single surgical application of Zevaskyn and compared to matched control wounds receiving standard of care. Participants were between 6 and 45 years of age.

One co-primary objectives of the VIITAL trial was the proportion of RDEB wound sites with greater than or equal to 50% healing from baseline, comparing treated with untreated wound sites at Week 24 (Month 6). At 6 months post treatment, 35 (81%) of the wounds treated with Zevaskyn achieved greater than or equal to 50% healing from baseline compared to 7 (16%) wounds treated with standard of care ($P < 0.0001$).

The second co-primary objective of the VIITAL trial was the pain reduction associated with wound dressing change assessed by the mean differences in scores of the Wong-Baker FACES scale between treated and untreated wounds at Week 24 (Month 6). At 6 months post treatment there was a statistically significant difference between the Zevaskyn treated group versus the control group (-3.07 vs. -0.9, $P = 0.0002$).

The most common adverse reactions (incidence $\geq 5\%$) in the clinical study were procedural pain ($n = 3$; 27%) and pruritus ($n = 1$; 9%). Other warnings and precautions include hypersensitivity reactions to vancomycin, amikacin, or product excipients, retroviral vector-mediated insertional oncogenesis, and transmission of infectious agents due to use of human- and bovine-derived reagents during manufacturing. Participants of the VIITAL trial will be followed during a 15-year long-term extension trial to further assess efficacy, safety, oncogenic risk and durability.

In summary, long-term safety and efficacy is currently insufficient for the treatment of dystrophic epidermolysis bullosa with Zevaskyn. Although short-term data from the VIITAL trial demonstrated statistically significant improvement in wound healing at 6 months compared to control wounds, the durability of response beyond this period remains uncertain.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3590 – Unclassified biologics
- J3490 – Unclassified drugs
- C9399 – Unclassified drugs or biologicals

REFERENCES

Zevaskyn (prademagene zamikeracel) [prescribing information]. Cleveland, OH: Abeona Therapeutics, Inc.; April 2025.

POLICY HISTORY

Policy #: 05.05.96

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Revised:

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