Reference number(s)
6982-A

Standard Medicare Part B Management Zevaskyn

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Zevaskyn	prademagene zamikeracel

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

- Medical records documenting clinical manifestations of disease.
- Genetic test results confirming biallelic pathogenic mutations in the COL7A1 gene.

Coverage Criteria

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Recessive Dystrophic Epidermolysis Bullosa (RDEB)[1]

Authorization of three months for one dose total may be granted for treatment of wounds in members with recessive dystrophic epidermolysis bullosa (RDEB) when all of the following criteria are met:

- Member is 6 years of age or older.
- Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
- Member has genetic test results confirming biallelic pathogenic mutations in the COL7A1 gene.
- Member has at least one chronic wound that will be treated (open for 6 months or more).
- Member does not have a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.
- The requested medication will not be administered to wound(s) that are currently healed.
- Member will not use Vyjuvek (beremagene geperpavec-svdt) or Filsuvez (birch triterpenes) on wounds that have been previously treated with Zevaskyn.
- The requested medication will not be administered to wound(s) that have been previously treated with Zevaskyn.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Zevaskyn.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zevaskyn are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Zevaskyn [package insert]. Cleveland, OH: Abeona Therapeutics, Inc.; July 2025.

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