Reference number(s)
5996-A

Specialty Guideline Management
Vyjuvek

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
Vyjuvek	beremagene geperpavec-svdt

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

Vyjuvek is indicated for the treatment of wounds in adult and pediatric patients with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.

All other indications are considered experimental/investigational and not medically necessary

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Medical records documenting clinical manifestations of disease.
- Genetic test results confirming a mutation in the COL7A1 gene.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or wound care specialist.

Coverage Criteria

Dystrophic Epidermolysis Bullosa (DEB)

Authorization of 12 months may be granted for treatment of wounds in members with dystrophic epidermolysis bullosa (DEB) when all of the following criteria are met:

- Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
- Member has genetic test results confirming a mutation in the COL7A1 gene.
- Member has one or more open wounds that will be treated (i.e., target wounds).
- Target wound(s) meet all of the following:
    - Wound is clear in appearance and does not appear to be infected
    - Wound has adequate granulation tissue and vascularization
    - Member does not have a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.
- The requested medication will be administered once weekly to the affected wound(s) by a healthcare professional, patient, or caregiver either at a healthcare professional setting (e.g., clinic) or a home setting.
- The requested medication will not be administered to wound(s) that are currently healed.

References

1. Vyjuvek [package insert]. Pittsburgh, PA: Krystal Biotech, Inc.; September 2025.
2. Guide SV, Gonzalez ME, Bağcı IS, et al. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. N Engl J Med. 2022;387(24):2211-2219.