

Reference number(s)
5996-A

## SPECIALTY GUIDELINE MANAGEMENT

### VYJUVEK (beremagene geperpavec-svdt)

#### POLICY

##### I. 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 Indication

Vyjuvek is indicated for the treatment of wounds in patients 6 months of age and older 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.

##### II. DOCUMENTATION

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

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

##### III. PRESCRIBER SPECIALTIES

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

##### IV. CRITERIA FOR INITIAL APPROVAL

##### **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:

- A. Member is 6 months of age or older.
- B. Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
- C. Member has genetic test results confirming a mutation in the COL7A1 gene.
- D. Member does not have a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.
- E. The requested medication will be administered once weekly to the affected wound(s) by a healthcare professional either at a healthcare professional setting (e.g., clinic) or a home setting.
- F. The requested medication will not be administered to wound(s) that are currently healed.

##### V. REFERENCES

1. Vyjuvek [package insert]. Pittsburgh, PA: Krystal Biotech, Inc.; May 2023.

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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.