

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Vyjuvek under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Vyjuvek

Policy/Guideline:

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).

Prescriber Specialties

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

Initial 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 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 collagen type VII alpha 1 chain (COL7A1) gene.
- D. Member does not have a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.

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AETNA BETTER HEALTH®						
Coverage Policy/Guideline						
Name:	Vyjuvek			Page:		2 of 2
Effective Date: 1/29/2025				Last Review Date:		12/6/2024
Applies to:	⊠Illinois	⊠Maryland	⊠Florida I	Kids	⊠Pennsylva	ania Kids

- 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.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: 4 cartons per 28 days

References:

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