

## CAREFIRST: VYJUVEK

**Client Requested:** The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

#### **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.

### **I. PRESCRIBER SPECIALTIES**

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

### **II. CRITERIA FOR INITIAL APPROVAL**

#### **Dystrophic Epidermolysis Bullosa (DEB)**

Authorization of 6 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 and 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. Vyjuvek 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. Vyjuvek will not be administered to wound(s) that are currently healed.

### **III. CRITERIA FOR REAUTHORIZATION**

#### **Dystrophic Epidermolysis Bullosa (DEB)**

Reauthorization of 6 months may be granted upon receipt of documentation indicating clinical response to therapy.

#### **DOCUMENT HISTORY**

Created: Specialty Clinical Development (JS) 11/2023  
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