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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	October 1, 2023
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	July 21, 2023
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**Last Review Date:** September 8, 2023

## Vyjuvek

### Description

#### Vyjuvek (beremagene geperpavec-svdt)

#### Background

Dystrophic epidermolysis bullosa (DEB) is caused by mutation(s) in the COL7A1 gene, which results in reduced or absent levels of biologically active COL7. Vyjuvek (beremagene geperpavec-svdt) can transduce both keratinocytes and fibroblasts. Following entry of Vyjuvek into the cells, the vector genome is deposited in the nucleus. Once in the nucleus, transcription of the encoded human COL7A1 is initiated. The resulting transcripts allow for production and secretion of COL7 by the cell in its mature form. These COL7 molecules arrange themselves into long, thin bundles that form anchoring fibrils. The anchoring fibrils hold the epidermis and dermis together and are essential for maintaining the integrity of the skin. Patients with autosomal dominant DEB (DDEB) have lower than normal functional anchoring fibrils, and patients with RDEB have no functional anchoring fibrils (1).

#### Regulatory Status

FDA-approved indication: Vyjuvek is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene (1).

Direct contact with treated wounds and dressings of treated wounds should be avoided for approximately 24 hours following application (1).

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Safety and effectiveness of Vyjuvek in pediatric patients below the age of 6 months have not been established (1).

### Related policies

Regranex, Santyl

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Vyjuvek may be considered **medically necessary** if the conditions indicated below are met.

Vyjuvek may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 6 months of age or older

### Diagnosis

Patient must have the following:

Wounds associated with dystrophic epidermolysis bullosa (DEB)

**AND ALL** of the following:

1. Documented mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene
2. Presence of clinical manifestations of DEB, such as chronic and recurring wounds of the skin, blistering of skin, and blistering, ulcerations, and scarring of visceral mucosal tissues
3. Prescribed by or in consultation with a dermatologist or a provider who specializes in DEB
4. Females of reproductive potential **only**: patient is not pregnant or breastfeeding
5. **NO** active infection, active squamous cell carcinoma, or history of squamous cell carcinoma in the targeted wound(s)
6. Prescriber will not exceed the FDA labeled dose of 1.6 mL weekly

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## Prior – Approval *Renewal* Requirements

**Age** 6 months of age or older

### Diagnosis

Patient must have the following:

Wounds associated with dystrophic epidermolysis bullosa (DEB)

**AND** the following:

1. Patient has had clinical improvement while on Vyjuvek (e.g., partial or complete wound closure)

### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Duration** 6 months

#### Prior – Approval *Renewal* Limits

**Duration** 12 months

### Rationale

#### Summary

Vyjuvek is indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the COL7A1 gene. Safety and effectiveness of Vyjuvek in patients under the age of 6 months have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Vyjuvek while maintaining optimal therapeutic outcomes.

#### References

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

## Policy History

Date	Action
July 2023	Addition to PA
September 2023	Annual review. Aligned criteria with association policy: changed approval duration to 6 months for initiation and added initiation requirements for presence of clinical manifestations of DEB, prescriber specialty, not pregnant or breastfeeding, no active infection or squamous cell carcinoma, and FDA dosing agreement.

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.**