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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Topical Products	**Original Policy Date:**	July 21, 2023
Subject:	Vyjuvek	**Page:**	1 of 4

Last Review Date: March 6, 2026

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 adult and pediatric patients 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).

The safety and effectiveness of Vyjuvek have been established in pediatric patients with DEB (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

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:
    a. Age <3 years: 1 mL weekly
    b. Age ≥3 years: 2 mL weekly

Prior – Approval *Renewal* Requirements

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 with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the COL7A1 gene. The safety and effectiveness of Vyjuvek have been established in pediatric patients with DEB (1).

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

References

1. Vyjuvek [package insert]. Pittsburgh, PA: Krystal Biotech, Inc.; September 2025.

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.
June 2024	Annual review
September 2024	Annual review
September 2025	Annual review
February 2026	Per PI update, removed age requirement and modified FDA labeled dosing requirement
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.