beremagene geperpavec-svdt (Vyjuvek)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: DERMATOLOGICAL AGENTS
Mechanism of Action: Gene transfer therapy
HCPCS:
J3401:Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/ml vector genomes, per 0.1 ml
How Supplied:
5x10^9 PFU/mL 1 single-dose vial of Vyjuvek and 1 single-dose vial of excipient gel

Condition(s) listed in policy *(see coverage criteria for details)*

- Dystrophic Epidermolysis Bullosa (DEB)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Dystrophic Epidermolysis Bullosa (DEB)
Meets medical necessity if all the following are met:
1. Prescribed by or in consultation with a dermatologist or relevant specialist
2. Presence of mutation(s) in the collagen type VII alpha-1 chain (COL7A1) gene

Covered Doses:
Given as a topical treatment:

Age Range	Max Weekly Dose (PFU)	Max Weekly Volume (mL)
<3 years old	2 ×10^9	1
≥ 3 years old	4 ×10^9	2

Maximum weekly volume is the volume after mixing VYJUVEK biological suspension with excipient gel.

Coverage Period:
Initial: 1 year
Reauthorization: Yearly when both criteria below are met

1. Prescribed by or in consultation with a dermatologist or equivalent specialist
2. Patient continues to respond to Vyjuvek and requires continued retreatment

Additional Information

Reference on dose per approximate size of the wound.

Wound Area (cm^2)	Dose (PFU)	Volume (mL)
< 20	4×10^8	0.2
20 to <40	8×10^8	0.4
40 to 60	1.2×10^9	0.6

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Vyjuvek (beremagene geperpavec-svdt). Prescribing Information. Krystal Biotech, Inc., Pittsburgh, PA: 5/2023.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee