blue california
Promise Health Plan

beremagene geperpavec-svdt (Vyjuvek)

Medical Benefit Drug Policy

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

Drug Details

USP Category: Genetic or Enzyme Disorder
Mechanism of Action: Gene transfer therapy
HCPCS: J3401 per 0.1 ml

How supplied:
NDC: 82194-510-02: $5x10^9$ PFU/mL 1 single-dose vial of Vyjuvek & 1 single-dose vial of excipient gel

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

- Dystrophic epidermolysis bullosa (DEB)

Special Instructions and pertinent Information

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

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Dystrophic epidermolysis bullosa (DEB)

1. Prescribed by or in consultation with a dermatologist or relevant specialist, AND
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)
6 months to <3 years old	1.6×10^9	0.8
≥ 3 years old	3.2×10^9	1.6

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

Coverage Period
Initial: 1 year
Reauthorization if meets below: Yearly

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

Additional Information:

Provides a reference on dose per approximate size of the wound. ***Per PI***

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]. Pittsburgh, PA: Krystal Biotech, Inc.; 5/2023.

Policy Update

Date of Last Annual Review: 3Q2023
Date of last revision: 3/1/2024
Changes from previous policy version:

- No clinical change to policy following revision.

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