

beremagene geperpavec-svdt (Vyjuvek)

HCPCS: J3401 beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10⁹ pfu/ml vector genomes, per 0.1 ml (Vyjuvek)

LOB:	MCAL
Duration of Approval:	Six months
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Vyjuvek (beremagene geperpavec-svdt)

****All requests must be approved by a Medical Director****

PA CRITERIA FOR APPROVAL:**New Therapy**

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication is prescribed by a dermatologist or wound care specialist **AND**
3. Copy of genetic testing confirming mutations in the collagen type VII alpha 1 chain (COL7A1) gene **AND**
4. Chart notes provided showing clinical features of dystrophic epidermolysis bullosa (e.g., skin blistering, skin erosion, scarring) **AND**
5. The target wounds meet **ALL** of the following **(a-c)**:
 - a. Wound has adequate granulation tissue and vascularization
 - b. Wound is clean in appearance and does not appear infected
 - c. Wound area has no evidence of squamous cell carcinoma**AND**
6. Member has not received a skin graft in the past three months **AND**
7. Vyjuvek will not be applied to wounds that are currently healed or previously treated with Zevaskyn or Filsuvez **AND**
8. Request is for FDA-recommended dosing (**Note:** Each carton of Vyjuvek contains one single-dose vial [1 mL] of Vyjuvek suspension and one single-dose vial [1.5 mL] of excipient gel to be mixed together prior to administration. Each dose can be billed as 2.5 mL [25 billable units] per seven days to account for wastage.)

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or AHFS) indication **AND**
2. The medication is prescribed by a dermatologist or wound care specialist **AND**
3. Chart notes provided showing **ALL** of the following **(a-b)**:
 - a. Member has positive response to therapy (e.g., decrease in wound size from baseline, increase in granulation tissue, reduction in the number of wounds, significant wound healing)
 - b. Member requires continued treatment due to new or existing open wound**AND**
4. Request is for FDA-recommended dosing (**Note:** Each carton of Vyjuvek contains one single-dose vial [1 mL] of Vyjuvek suspension and one single-dose vial [1.5 mL] of excipient gel to be mixed together prior to administration. Each dose can be billed as 2.5 mL [25 billable units] per seven days to account for wastage.)

beremagene geperpavec-svdt (Vyjuvek)

HCPCS: J3401 beremagene geperpavec-svdt for topical administration, containing nominal 5×10^9 pfu/ml vector genomes, per 0.1 ml (Vyjuvek)

OTHER INFORMATION:

HCPCS	Description	Brand name
J3401	beremagene geperpavec-svdt for topical administration, containing nominal 5×10^9 pfu/ml vector genomes, per 0.1 ml (Vyjuvek)	Vyjuvek

REFERENCES:

1. Vyjuvek Prescribing Information. www.krystallabel.com/pdf/vyjuvek-us-pi.pdf. 09/2025.