

Vyjuvek® (beremagene geperpavec-svdt) (Topical)

Document Number: IC-0709

Last Review Date: 07/01/2026

Date of Origin: 07/05/2023

Dates Reviewed: 07/2023, 02/2024, 05/2024, 07/2025, 10/2025, 07/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 25 billable units every 7 days

III. Initial Approval Criteria ¹

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

Universal Criteria ¹

- Will not be used concurrently, in the same wound, with another disease-modifying therapeutic agent (e.g., prademagene zamikeracel, birch triterpenes, etc.) indicated for Dystrophic Epidermolysis Bullosa (DEB) (**NOTE: this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.**); **AND**
- Member does NOT have current evidence or a history of squamous cell carcinoma (SCC) in the area to be treated; **AND**
- Member does NOT have an active infection on the area to be treated; **AND**

Dystrophic Epidermolysis Bullosa (DEB) † Φ ^{1,2}

- Member has a diagnosis of dystrophic epidermolysis bullosa (DEB) as established by detection of mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene on molecular genetic testing; **AND**
- Member has open cutaneous wound(s)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Prior authorization validity can be renewed based on the following criteria:

- Member continues to meet the universal and indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: any severe medication reactions warranting therapy discontinuation, etc.; **AND**
- The member has had clinical benefit with the requested agent [e.g., improvement (healing) of treated wound sites, and/or reduction in skin infections, etc.]; **AND**
- Member requires continued treatment due to new or existing open wounds

V. Dosage/Administration ¹

Indication	Dose																					
Dystrophic Epidermolysis Bullosa (DEB)	Vyjuvek gel is applied topically to wound(s) once a week. Apply Vyjuvek gel to the selected wound(s) in droplets spaced evenly within the wound, approximately 1cm-by-1cm apart. <table><tr><th>Age Range</th><th>Maximum Weekly Dose [plaque forming units (PFU)]</th><th>Maximum Weekly Volume (mL) *</th></tr><tr><td><3 years old</td><td>2 × 10⁹</td><td>1</td></tr><tr><td>≥3 years old</td><td>4 × 10⁹</td><td>2</td></tr></table> *Maximum weekly volume after mixing Vyjuvek biological suspension with excipient gel. <table><tr><th>Wound Area (cm²) *</th><th>Dose (PFU)</th><th>Volume (mL)</th></tr><tr><td><20</td><td>4×10⁸</td><td>0.2</td></tr><tr><td>20 to <40</td><td>8×10⁸</td><td>0.4</td></tr><tr><td>40 to 60</td><td>1.2×10⁹</td><td>0.6</td></tr></table> *For wound area over 60 cm², recommend calculating the total dose based on this table until the maximum weekly dose is reached.	Age Range	Maximum Weekly Dose [plaque forming units (PFU)]	Maximum Weekly Volume (mL) *	<3 years old	2 × 10 ⁹	1	≥3 years old	4 × 10 ⁹	2	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
Age Range	Maximum Weekly Dose [plaque forming units (PFU)]	Maximum Weekly Volume (mL) *																				
<3 years old	2 × 10 ⁹	1																				
≥3 years old	4 × 10 ⁹	2																				
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																				
- It may not be possible to apply Vyjuvek gel to all the wounds at each treatment visit. - Apply Vyjuvek gel to wounds until they are closed before selecting new wound(s) to treat. Prioritize weekly treatment to previously treated wounds if they re-open. - If a dose is missed, apply Vyjuvek gel as soon as possible and resume weekly dosing thereafter. - The Vyjuvek gel prepared at the pharmacy, should be applied by a healthcare professional (HCP), member, or caregiver either at a																						

healthcare professional setting (e.g., clinic) or at a home setting.

- Individuals who are pregnant should not prepare or apply Vyjuvek gel and should avoid direct contact with the treated wounds or dressings from treated wounds.

VI. Billing Code/Availability Information

HCPCS Code:

- J3401 – Beremagene geperpavec-svdt for topical administration, containing nominal 5×10^9 pfu/ml vector genomes, per 0.1 ml; 1 billable unit = 0.1 mL

NDC:

- Vyjuvek 1.0 mL extractable volume in a single-use, single-dose vial containing 5×10^9 PFU/mL: 82194-0510-02 (outer carton) and 82194-0501-01 (inner drug vial)

VII. References

1. Vyjuvek [package insert]. Pittsburgh, PA; Krystal Biotech, Inc.; September 2025. Accessed May 2026.
2. Guide SV, Gonzalez ME, Bagci S, et al. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. N Engl J Med 2022; 387:2211-2219. DOI: 10.1056/NEJMoa2206663.
3. Lucky AW, Pope E, Crawford S. Dystrophic Epidermolysis Bullosa. GeneReviews. <https://www.ncbi.nlm.nih.gov/books/NBK1304/>. Initial Posting: August 21, 2006; Last Update: August 7, 2025. Accessed June 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
Q81.2	Epidermolysis Bullosa Dystrophic

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC