Vyjuvek™ (beremagene geperpavec-svdt)
(Topical)

Document Number: IC-0709

Last Review Date: 07/05/2023
Date of Origin: 07/05/2023
Dates Reviewed: 07/2023

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Vyjuvek single-dose vial containing 5×10^9 PFU/mL: 1 vial every 7 days

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

- 10 billable units every 7 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 6 months of age; **AND**

Universal Criteria

- Patient has not received a skin graft within the prior 3 months; **AND**

Dystrophic Epidermolysis Bullosa (DEB) † Φ [1,2]

- Patient has a diagnosis of dystrophic epidermolysis bullosa as established by detection of mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene on molecular genetic testing; **AND**
- Patient has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected

† FDA Approved Indication(s); ‡ Compendia approved indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the 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**
- Disease response with treatment as defined by improvement (healing) of treated wound sites, reduction in skin infections, etc.; **AND**
- Patient requires continued treatment due to new or existing open wounds

V. Dosage/Administration

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Wound treatment of dystrophic epidermolysis bullosa (DEB)</td><td>Vyjuvek gel is applied topically to wound(s), by a healthcare professional, 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 (milliliter; mL) *</th></tr>
<tr><td>6 months to <3 years old</td><td>1.6×10^9</td><td>0.8</td></tr>
<tr><td>≥3 years old</td><td>3.2×10^9</td><td>1.6</td></tr>
<tr><td colspan="3">*Maximum weekly volume after mixing VYJUVEK biological suspension with excipient gel.</td></tr>
</table>
<table>
<tr><th>Wound Area (cm^2) *</th><th>Dose (PFU)</th><th>Volume (mL)</th></tr>
<tr><td><20</td><td>4×10^8</td><td>0.2</td></tr>
<tr><td>20 to <40</td><td>8×10^8</td><td>0.4</td></tr>
<tr><td>40 to 60</td><td>1.2×10^9</td><td>0.6</td></tr>
<tr><td colspan="3">*For wound area over 60 cm^2, recommend calculating the total dose based on this table until the maximum weekly dose is reached.</td></tr>
</table></td></tr>
<tr><td colspan="2">• 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.
• Only a healthcare professional (HCP) should apply Vyjuvek gel either at a healthcare professional setting (e.g., clinic) or the 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.</td></tr>
</table>

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics *(Discontinue use on 01/01/2024)*
- J3401 – Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/ml vector genomes, per 0.1 ml; 1 billable unit = 0.1 mL *(Effective 01/01/2024)*

NDC:

- Vyjuvek 1.0 mL extractable volume in a single-use, single-dose vial containing 5×10^9 PFU/mL: 82194-0510-xx

VII. References

1. Vyjuvek™ [package insert]. Pittsburgh, PA; Krystal Biotech, Inc.; May 2023. Accessed May 2023.
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. Pfender EG, Lucky AW. Dystrophic Epidermolysis Bullosa. GeneReviews. https://www.ncbi.nlm.nih.gov/books/NBK1304/ (Accessed on May 25, 2020).

Appendix 1 – Covered Diagnosis Codes

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

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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