Neighborhood Health Plan OF RHODE ISLAND™
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Vyjuvek™ (beremagene geperpavec-svdt) (Topical)

Effective Date: 10/01/2023
Review Date: 9/14/2023, 12/07/2023, 01/04/2024, 08/07/2024

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Coverage will be provided for six (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]:

- 1 vial every 7 days

III. Summary of Evidence

Vyjuvek (beremagene geperpavec-svdt) is indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutations in the collage VII alpha 1 chain (COL7A1) gene. The approval of Vyjuvek was based on the outcome of the GEM-3 double-blind, intra-subject, placebo-controlled, 26-week trial with 31 patients which randomized comparable wounds on a single subject to Vyjuvek or placebo gel. Once weekly treatment was continued until wound closure, then resumed if the wound reopened. The primary endpoint was improved wound healing as defined as complete wound closure at 24 weeks confirmed by two consecutive study visits two weeks apart. Vyjuvek statistically significantly met this outcome versus placebo with 65% of patients experiencing wound closure versus 26% in placebo (p=0.012).

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

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

Universal Criteria

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

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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; **AND**
- Patient has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring); **AND**
- Patient does not have a history of squamous cell carcinoma in the affected wound(s) that will receive treatment; **AND**
- Vyjuvek is prescribed by, or in consultation with, a wound care specialist who specializes in the treatment of DEB; **AND**
- Vyjuvek will not be administered to wound(s) that are currently healed; **AND**
- Vyjuvek will not be given in combination with Filsuvez (birch triterpenes)

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

V. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the indication-specific relevant criteria identified in section IV; **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 documentation of improvement (healing) of treated wound sites, reduction in skin infections, etc.; **AND**
- Patient requires continued treatment due to new or existing open wounds

VI. 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>
</td></tr>
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	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 *****For wound area over 60 cm^2, recommend calculating the total dose based on this table until the maximum weekly dose is reached.
• 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.	

VII. Billing Code/Availability Information

HCPCS Code:

- J3401 - beremagene geperpavec-svdt for topical administration c containing nominal 5 x 10^9 pfu/ml vector genomes, per 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-xx

VIII. References

1. Vyjuvek™ [package insert]. Pittsburgh, PA; Krystal Biotech, Inc.; July 2023. Accessed November 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

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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
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

Policy Rationale:

Vyjuvek was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Vyjuvek according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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