Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the
Blue Cross Blue Shield Association

Title: Vyjuvek

Professional / Institutional
Original Effective Date: January 1, 2024
Latest Review Date: January 8, 2026
Current Effective Date: January 8, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

<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>

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter

II. Dosing Limits

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

- 25 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 [1]

- Patient has not received a skin graft in the area to be treated within the prior 3 months; **AND**
- Will not be used concurrently in the same wound with another disease-modifying therapeutic agent indicated for DEB (e.g., birch triterpenes, etc.) *(**NOTE:** this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.)*; **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 Recommended 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, and/or reduction in skin infections, etc., as attested by his/her physician; **AND**
- Patient requires continued treatment due to new or existing open wounds

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS Code:

- 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

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)

REVISIONS	
Posted 12-01-2023 Effective 01-01-2024	Policy added to the bcbsks.com web site.
11-20-2024	Policy is maintained by Prime Therapeutics LLC. Policy Updates: • Added documentation to the policy for genetic test(s) confirmation of mutations(s) in the COL7A1 gene • Removed diagnostic testing requirements. • Standardized wording. • Added the disallowance requirement for combination therapy on the same wound of gene therapy products.
Posted: 12-09-2025 Effective: 01-08-2026	Updated Clinical Rationale Section Clinical Criteria for Approval ▪ Removed: Clinical Criteria for Approval Initial Evaluation Target Agent(s) will be approved when ALL of the following are met: 1. The patient has a diagnosis of dystrophic epidermolysis bullosa (DEB) AND 2. The patient has a genetic test result(s) showing mutation(s) in the COL7A1 gene (medical records required) AND 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 4. The patient does NOT have current evidence or a history of squamous cell carcinoma on the area to be treated AND

REVISIONS	
	5. The patient does NOT have an active infection on the area to be treated AND 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 7. The patient will NOT be using the requested agent in combination with Filsuvez or another gene therapy agent on the same area to be treated for the requested indication AND 8. The patient does NOT have any FDA labeled contraindications to the requested agent AND 9. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication Length of Approval: 6 months Renewal Evaluation Target Agents(s) will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria [Note: patients not previously approved for the requested agent will require initial evaluation review] AND 2. The patient has had clinical benefit with the requested agent AND 3. The patient does NOT have current evidence or a history of squamous cell carcinoma on the area to be treated AND 4. The patient does NOT have an active infection on the area to be treated AND 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 6. The patient will NOT be using the requested agent in combination with Filsuvez or another gene therapy agent on the same area to be treated for the requested indication AND 7. The patient does NOT have any FDA labeled contraindications to the requested agent AND 8. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication Length of Approval: 12 months ▪ Added: Initial Approval Criteria [1] Coverage is provided in the following conditions: • Patient is at least 6 months of age; AND Universal Criteria [1] • Patient has not received a skin graft in the area to be treated within the prior 3 months; AND • Will not be used concurrently in the same wound with another disease-modifying therapeutic agent indicated for DEB (e.g., birch triterpenes, etc.) *(NOTE: this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.)*; 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 Recommended 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 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, and/or reduction in skin infections, etc., as attested by his/her physician; AND • Patient requires continued treatment due to new or existing open wounds
	Policy Maintained by Prime Therapeutics LLC

REFERENCES

1. Vyjuvek™ [package insert]. Pittsburgh, PA; Krystal Biotech, Inc.; May 2023. Accessed May 2025.
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/. Initial Posting: August 21, 2006; Last Update: May 8, 2025. Accessed on June 04, 2025.