Vyjuvek (beremagene geperpavec-svdt)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Vyjuvek is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial Requests:
   1. Medical records documenting clinical manifestations of the disease.
   2. Genetic test results confirming a mutation in the COL7A1 gene.
B. Continuation Requests: Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or wound care specialist with expertise in the treatment of dystrophic epidermolysis bullosa (DEB).

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Criteria for Initial Approval

Authorization of 6 months may be granted for treatment of wounds in members with dystrophic epidermolysis bullosa (DEB) when all of the following criteria are met:

A. Member has a diagnosis of dystrophic epidermolysis bullosa (DEB).
B. Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
C. Member has genetic test results confirming a mutation in the COL7A1 gene.
D. Member does not have current evidence or a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.
E. Member does not have an active infection in the affected wound(s) that will receive treatment.
F. Vyjuvek will not be used in combination with Filsuvez (birch triterpenes) or Zevaskyn (prademagene zamikeracel).

Continuation of Therapy

Authorization of 6 months may be granted for treatment of wounds in members with dystrophic epidermolysis bullosa (DEB) when all of the following criteria are met:

A. Member achieves or maintains a positive clinical response to Vyjuvek therapy (e.g., decrease in wound size, increase in granulation tissue, complete wound closure).
B. Member does not have current evidence or a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.
C. Member does not have an active infection in the affected wound(s) that will receive treatment.
D. Vyjuvek will not be used in combination with Filsuvez (birch triterpenes) or Zevaskyn (prademagene zamikeracel).

Vyjuvek is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

<table>
<tr><th>Medication</th><th>Standard Limit</th><th>FDA-recommended dosing</th></tr>
<tr><td>Vyjuvek 5×10^9 PFU carton</td><td>4 cartons per 28 days</td><td>• Apply to selected wound(s) once a week.

<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>2×10^9</td><td>1 mL</td></tr>
<tr><td>≥ 3 years old</td><td>4×10^9</td><td>2 mL</td></tr>
</table>
* maximum weekly volume is the volume after mixing Vyjuvek biological suspension with the excipient gel.</td></tr>
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PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3401 – Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/ml vector genomes, per 0.1 ml (effective 1/1/2024)
- J3490 – Unclassified drugs (when specified as [Vyjuvek] (beremagene geperpavec-svdt))
- J3590 – Unclassified biologics (when specified as [Vyjuvek] (beremagene geperpavec-svdt))
- C9399 – Unclassified drugs or biologicals

REFERENCES

- Vyjuvek [package insert]. Pittsburgh, PA: Krystal Biotech, Inc.; September 2025.
- Guide SV, Gonzalez ME, Bağcı IS, et al. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. N Engl J Med. 2022;387(24):2211-2219.

POLICY HISTORY

Policy #: 05.05.11
Original Effective Date: November 2, 2023
Reviewed: October 2025
Revised: October 2025
Current Effective Date: December 19, 2025

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