Medical Necessity Guidelines

Medical Benefit Drugs

Vyjuvek™ (Beramagene Geperpavec-Svdt)

Effective: September 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Vyjuvek (Beramagene Geperpavec-Svdt), approved by the Food and Drug Administration, for the treatment of dystrophic epidermolysis bullosa (DEB) in adult and pediatric patients with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Specifically, it is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy. Patients with this recessively inherited condition have defects in their Type VII collagen caused by mutation(s) in the COL7A1 gene resulting in a lack of protein that helps strengthen and support the outer and middle layers of the skin. This leads to extensive blistering of the skin and mucous membranes. The mainstay of treatment has been symptomatic care, prevention of new blisters, and wound care. With the introduction of this new first ever gene therapy, Vyjuvek provides a treatment option other than standard treatment for DEB wound management.

Diagnostic criteria for DEB is done through genetic testing, immunofluorescence mapping (IFM) and/or transmission of electron microscopy (TEM) to determine the precise subclassification of epidermolysis.

Food and Drug Administration (FDA) Approved Indications:

- Indicated for the treatment of wounds in adult and pediatric patients with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.
- The application was granted orphan drug, fast track, regenerative medicine advanced therapy, and priority review designations by the FDA as well as a rare pediatric disease priority review voucher.

The Plan may cover Vyjuvek for Members with dystrophic epidermolysis bullosa (DEB) when **All** the following clinical criteria are met:

1. Member has a confirmed diagnosis of dystrophic epidermolysis bullosa (DEB) (mutation(s) in the COL7A1 gene) by genetic testing; **and**
2. Prescriber is a specialist (e.g., dermatologist, geneticist, histopathologist) or consult notes from a specialist are provided; **and**
3. Vyjuvek will be administered once weekly to the affected wound(s) by a healthcare professional, member or caregiver at a health care professional setting, such as a clinic or a home setting **and**;
4. Member has at least one recurrent or chronic wound and **both** of the following:
    a. Adequate granulation tissue and excellent vascularization;
    b. Wound has no evidence of active wound infection; **and**
5. Member does not have history or current evidence of squamous cell carcinoma in the area that will undergo treatment; **and**
6. Dosing of Vyjuvek is in accordance with the United States Food and Drug Administration (FDA) approved labeling and does not exceed a maximum of 26 weekly doses (6 months) as defined by **one** of the following:
    a. Age < 3 years: Topical gel: maximum, 2×10^9 PFU or 1mL weekly; **or**
    b. Age ≥ 3 years: Topical gel: maximum, 4×10^9 PFU or 2 mL weekly.

Initial Therapy will be approved for 6 months and no more than 26 doses

Reauthorization Criteria

Continued treatment with Vyjuvek may be medically necessary when **All** of the following criteria are met:

1. Clinical documentation must be provided to confirm that Vyjuvek is providing clinical benefit (e.g., decrease in wound size, increase in granulation tissue, decrease in pain severity); **and**
2. Vyjuvek is prescribed by, or in consultation with, a dermatologist, geneticist, histopathologist or consult notes from a specialist with expertise in the treatment of DEB; **and**
3. Documentation of wound(s) being treated meet **All** of the following criteria:
    a. Adequate granulation tissue and excellent vascularization
    b. No evidence of active wound infection
    c. No evidence or history of squamous cell carcinoma; **and**
4. Dosing of Vyjuvek is in accordance with the FDA dosing recommendations as noted above.

Reauthorization will be issued for no more than 6 months and no more than 26 doses

Limitations

- The Plan may not cover Vyjuvek in members who are pregnant as there is no data to inform a drug-associated risk
- The Plan will not cover Vyjuvek for any conditions other than FDA-approved indications. All other uses are considered experimental or investigational
- Vyjuvek will not be administered simultaneously on the same target wounds as other topicals or gene therapies for a diagnosis of DEB, e.g., Filsuvez or Zevaskyn
- Vyjuvek will not be administered to wounds) that are currently healed
- Initial approval will be for 6 months. Reauthorization, if approved, will be for no more than 6 months

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3401	Beremagene Geperpavec-SVDT for topical administration, containing nominal 5 X 10^9 PFU/ML vector genomes, per 0.1 ML

References:

1. Guide SV, Gonzalez ME, Bağcı IS, Agostini B, Chen H, Feeney G, Steimer M, Kapadia B, Sridhar K, Quesada Sanchez L, Gonzalez F, Van Ligten M, Parry TJ, Chitra S, Kammerman LA, Krishnan S, Marinkovich MP. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. n Engl J Med. 2022 Dec 15;387(24):2211- 2219. doi: 10.1056/NEJMoa2206663. PMID: 36516090..

2. Murrell DF. Overview of the management of epidermolysis bullosa. In: UpToDate. Shefner JM (Ed), UpToDate, Waltham, MA. (Accessed on November 1, 2022).
3. IPD Analytics. Payer & Provider Insights. November 2022. https://www.ipdanalytics.com. Accessed November 21, 2023.
4. Marinkovich MP, Gonzalez ME, et al. (2022, March 25-29). GEM-3: A Phase 3 Study of Beremagene Geperpavec (B-VEC), an Investigational Topical Gene Therapy, for the Treatment of Dystrophic Epidermolysis Bullosa (DEB). 2022 American Academy of Dermatology Annual Meeting. Boston, MA, United States https://ir.krystalbio.com/static-files/bb74b04e-7e3d-44f8-afda-5469a3cf16b4. Accessed
5. Vyjuvek [package insert]. Pittsburg, PA: Krystal Biotech, Inc.; September 2025.

Approval And Revision History

December 20, 2023: Reviewed by the Medical Policy Approval Committee (MPAC), effective January 1, 2024

Subsequent endorsement date(s) and changes made:

- July 22, 2024: Reviewed by MPAC, added limitation for combination use with Vyjuvek and Filsuvez will not be approved, effective September 1, 2024.
- August 20, 2025: Reviewed by MPAC for annual review, renewed without changes effective October 1, 2025
- September 17, 2025: Reviewed by MPAC, clarified criteria for prescriber and under limitations added language that Vyjuveck will not be used on the same target wounds as other topical or gene therapies, effective November 1, 2025
- June 17, 2026: Reviewed by MPAC for Annual review; MNG updated to reflect FDA label expansion to cover for members of all ages and to allow for application by patient and/or caregiver, effective August 1, 2026
- July 15, 2026: Reviewed by MPAC for annual review, renewed without changes effective September 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.