Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Vyjuvek™ (Beramagene Geperpavec-Svdt)

Effective: August 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

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

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, is for the treatment of dystrophic epidermolysis bullosa (DEB) in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) 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 for this has been symptomatic care and 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 for adult and pediatric patients with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members and CMS for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations.

When CMS and MassHealth do not provide guidance, the Plan's internally developed medical necessity guidelines are used. CMS coverage guidelines are not established for this service. Point32Health covers Vyjuvek in accordance with MassHealth coverage criteria.

For the therapy Vyjuvek, evidence is sufficient for coverage based on FDA approval in May 2023 and updated guidance in September 2025.. This approval was based on the GEM-3 trial, where 67% of Vyjuvek treated wounds completely healed (defined as 100% wound closure as indicated by skin re-epithelialization without drainage for 2 consecutive weeks), compared to 22% of wounds treated with the placebo. In the study, complete healing was seen in 71% of wounds treated with Vyjuvek compared to 20% of wounds treated with the placebo. Given the effectiveness of Vyjuvek, FDA approval, and lack of alternative treatment options for patients with DEB, Vyjuvek would be an appropriate weekly treatment option for select Members.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

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

1. Diagnosis of dystrophic epidermolysis bullosa (DEB); and
2. Prescriber is a specialist (e.g., dermatologist, geneticist, histopathologist) or consult notes from a specialist are provided; **and**
3. Prescriber provides documentation of a copy of a genetic test confirming diagnosis of dystrophic epidermolysis bullosa (e.g., mutation(s) of COL7A1 gene); **and**
4. Documentation of 1 or more cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected; **and**
5. Prescriber provides documentation of appropriate dosing.

Reauthorization Criteria

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

1. Complete wound healing of 1 or more wound after six months of treatment; **and**
2. Documentation of 1 or more cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected.

Limitations

- 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 used on the same target wounds as other topicals or gene therapies for a diagnosis of DEB, e.g., Filsuvez or Zevaskyn
- Initial approval will be for 6 months. Reauthorization will be for 12 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, 2023.
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 November 1, 2023.
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 October 1, 2024.
- September 17, 2024: Reviewed and approved by UM Committee added limitation for combination use with Vyjuvek and Filsuvez will not be approved, effective October 1, 2024.
- August 20, 2025: Reviewed by MPAC for annual review, renewed without changes effective October 1, 2025
- September 17, 2025: Reviewed by the UM Committee, renewed without changes effective October 1, 2025
- September 17, 2025: Reviewed by MPAC, under limitations added language that Vyjuvek will not be used on the same target wounds as other topical or gene therapies, effective November 1, 2025
- September 18, 2025: Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template; template updated, language for Carelink removed
- June 17, 2026: Reviewed by MPAC for Annual review; MNG updated to reflect FDA label expansion to cover for members of all ages, effective August 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.