



MEDICAL COVERAGE POLICY

SERVICE: Beremagene geperpavec-svdt (Vyjuvek®)

Policy Number: 320

Effective Date: 10/01/2026

Last Review: 09/24/2026

Next Review: 09/24/2027

Important note: Unless otherwise indicated, medical policies will apply to all lines of business.

Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

SERVICE: Beremagene geperpavec-svdt (Vyjuvek®)

PRIOR AUTHORIZATION:

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

Baylor Scott & White Health Plan (BSWHP) may consider beremagene geperpavec-svdt (Vyjuvek®) medically necessary when documentation is submitted showing ALL of the following criteria are met:

Universal Criteria Applied To All Requests

1. Member has a diagnosis of confirmed **dystrophic epidermolysis bullosa (DEB)** with **all** the following:
 - a. Skin biopsy for immunohistochemistry (IHC) with fluorescence-labelled secondary antibodies (immunofluorescence mapping, IFM); **AND**
 - b. Confirmed of COL7A1 (*collagen type VII alpha 1*) gene mutation and Collagen VII (CVII) deficiency or absence by genetic test
- AND**
2. Member has appropriate clinical presentation, such as skin blistering, erosions, slow healing chronic wounds, scarring, milia, and itchy painful skin; **AND**
3. Provider has ruled out other related skin disorders with a similar clinical presentation; **AND**
4. Member is ≥ 6 months or older; **AND**
5. Beremagene geperpavec-svdt (Vyjuvek®) is prescribed by or in consultation with a dermatologist with experience in treating patients with DEB; **AND**
6. Beremagene geperpavec-svdt (Vyjuvek®) will be dosed and administered according to FDA approved labeling; **AND**
7. Member does not have any of the following:



MEDICAL COVERAGE POLICY

SERVICE: Beremagene geperpavec-svdt (Vyjuvek®)

Policy Number: 320

Effective Date: 10/01/2026

Last Review: 09/24/2026

Next Review: 09/24/2027

- a. Systemic infection such as hepatitis B or C, and human immunodeficiency virus (HIV).
- b. Squamous cell carcinoma lesions at or near candidate wounds.
- c. The member will not apply birch bark triterpenes (Filsuvez®), investigational gene or cell therapies onto candidate wounds leading up to the first application and after.
- d. The member will not apply beremagene geperpavec-svdt (Vyjuvek®) on wounds that were previously treated with prademagene zamikeracel (Zevaskyn®).
- e. Has not received a skin graft within the past three months.

Renewal requests:

1. Member meets all universal criteria; **AND**
2. Member has manageable or no side effects; **AND**
3. Member's previously beremagene-treated wounds show positive clinical response (e.g., reduction in wound area size, improvement in skin appearance, etc.)

Authorization duration – 1 year

BSWHP considers beremagene geperpavec-svdt (Vyjuvek®) for the treatment of all other indications to be experimental and investigational because the effectiveness of this strategy has not been established.

All requests will be reviewed by a clinical pharmacist and medical director.

BACKGROUND:

Epidermolysis Bullosa (EB) is a rare, progressive group of genetic disorders characterized by skin fragility, blistering, and chronic wounds, affecting approximately 200 newborns annually in the United States. Dystrophic Epidermolysis Bullosa (DEB), one of the most severe forms, is caused by mutations in the *COL7A1* gene, resulting in absent or deficient Collagen VII, a protein essential for anchoring the epidermis to the dermis. Without Collagen VII, even minor trauma causes skin separation and chronic non-healing wounds. Beyond the skin, DEB can lead to fusion of the fingers and toes (pseudosyndactyly), involvement of the esophagus and teeth, leading to malnutrition and anemia. Patients are at significantly increased risk of developing aggressive cutaneous squamous cell carcinomas, the leading cause of death in this population.

Beremagene geperpavec-svdt (Vyjuvek®) is a herpes-simplex type 1 (HSV-1) vector-based gene therapy that is supplied as a once weekly topical biological suspension and is indicated to treat wounds in adults and pediatric patients with DEB with mutation(s) in the *COL7A1* gene.

Beremagene geperpavec-svdt (Vyjuvek®) utilizes its HSV-1 vector to transduce both keratinocytes and fibroblasts upon topical wound application. After entering the cells, beremagene geperpavec-svdt (Vyjuvek®) deposits its vector genome, inducing the nuclear transcription of the human *COL7A1* gene.



MEDICAL COVERAGE POLICY

SERVICE: Beremagene geperpavec-svdt (Vyjuvek®)

Policy Number: 320

Effective Date: 10/01/2026

Last Review: 09/24/2026

Next Review: 09/24/2027

COL7A1 transcription triggers the production and formation of anchoring filaments, which adhere the epidermis to the dermis, allowing for the skin to heal normally.

Beremagene geperpavec-svdt (Vyjuvek®) itself does not incorporate the COL7A1 gene into the patient's chromosomes, therefore, beremagene geperpavec-svdt (Vyjuvek®) requires weekly applications on candidate wounds until fully healed before treating new wounds. Patients should be counseled that beremagene geperpavec-svdt (Vyjuvek®) requires ongoing administration for wound management and does not permanently correct underlying COL7A1 mutations or absence.

Beremagene geperpavec-svdt (Vyjuvek®)'s safety and efficacy were studied in the B-VEC for Dystrophic Epidermolysis Bullosa (GEM-3) trial, which is a double-blinded, placebo-controlled, randomized intra-patient, phase 3 trial. Patients were excluded if they had current or history of squamous cell carcinoma or active infections at wound candidate sites. Inclusion criteria for this trial included patients who were 6 months or older with confirmed DEB diagnosis via genetic testing. A total of 31 patients with a median age of 16 years old and median wound sizes between 10.4-10.6 cm² that underwent randomized treatment assignment of beremagene geperpavec-svdt (Vyjuvek®) or to control (1:1), which was a placebo gel.

The primary end point was complete wound healing of beremagene geperpavec-svdt (Vyjuvek®) treated wounds or to control treated wounds at 6 months (weeks 22 and 24, or weeks 24 and 26 which were considered as healed by trial investigator for two consecutive weeks with 100% wound closure from baseline). At six months, 67% of beremagene geperpavec-svdt (Vyjuvek®)-treated wounds showed complete healing compared to 22% of placebo-treated wounds (statistically significant difference of 46 percentage points; 95% confidence interval [CI], 24 to 68; P = 0.002). The secondary key endpoint was the percentage of complete wound healing at 3 months, with 71% of beremagene geperpavec-svdt (Vyjuvek®)-treated wounds compared to 20% of placebo-treated wounds (statistically significant difference, 51 percentage points; 95% CI, 29 to 73; P<0.001). No serious treatment-related adverse events occurred that led to treatment discontinuation. The most common adverse events observed included pruritus and chills.

CODES:

Important note: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
HPCS Codes:	J3401, Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10 ⁹ pfu/ml vector genomes per 0.1 ml.
ICD10 codes:	



MEDICAL COVERAGE POLICY

SERVICE: Beremagene geperpavec-svdt (Vyjuvek®)

Policy Number: 320

Effective Date: 10/01/2026

Last Review: 09/24/2026

Next Review: 09/24/2027

ICD10 Not covered:

POLICY HISTORY:

Status	Date	Action
New	09/24/2026	New policy

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Has C, Liu L, Bolling MC, Charlesworth AV, El Hachem M, Escámez MJ, Fuentes I, Büchel S, Hiremagalore R, Pohla-Gubo G, van den Akker PC, Wertheim-Tysarowska K, Zambruno G. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. *Br J Dermatol*. 2020 Mar;182(3):574-592. doi: 10.1111/bjd.18128. Epub 2019 Aug 9. PMID: 31090061; PMCID: PMC7064925.
2. Mayo Clinic Staff. Epidermolysis bullosa: symptoms and causes. Mayo Clinic. Updated June 12, 2024. Accessed June 5, 2026. <https://www.mayoclinic.org/diseases-conditions/epidermolysis-bullosa/symptoms-causes/syc-20361062>
3. Krystal Biotech, Inc. VYJUVEK® (beremagene geperpavec-svdt) biological suspension mixed with excipient gel for topical application prescribing information. Revised September 2025. Krystal Biotech, Inc. Accessed June 15, 2026.
4. Gurevich I, Agarwal P, Zhang P, Dolorito JA, Oliver S, Liu H, Reitze N, Sarma N, Bagci IS, Sridhar K, Kakarla V, Yenamandra VK, O'Malley M, Prisco M, Tufa SF, Keene DR, South AP, Krishnan SM, Marinkovich MP. In vivo topical gene therapy for recessive dystrophic epidermolysis bullosa: a phase 1 and 2 trial. *Nat Med*. 2022 Apr;28(4):780-788. doi: 10.1038/s41591-022-01737-y. Epub 2022 Mar 28. PMID: 35347281; PMCID: PMC9018416.
5. 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. doi:10.1056/NEJMoa2206663.
6. DEBRA of America. Understanding epidermolysis bullosa (EB). DEBRA of America. Accessed June 9, 2026. <https://www.debra.org/about-eb/understanding-epidermolysis-bullosa-eb>

Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.



MEDICAL COVERAGE POLICY

SERVICE: Beremagene geperpavec-svdt (Vyjuvek®)

Policy Number: 320

Effective Date: 10/01/2026

Last Review: 09/24/2026

Next Review: 09/24/2027

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.