Medical Policy:

Vyjuvek (beremagene geperpavec-svdt) topical gel

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.391	January 2, 2025	July 28, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Vyjuvek is indicated for the treatment of wounds in patients ≥ 6 months of age with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.

Dystrophic epidermolysis bullosa (DEB) is caused by mutation(s) in the COL7A1 gene, which results in reduced or absent levels of biologically active COL7. Upon topical application to the wounds, VYJUVEK can transduce both keratinocytes and fibroblasts. Following entry of VYJUVEK into the cells, the vector genome is deposited in the nucleus. Once in the nucleus, transcription of the encoded human COL7A1 is initiated. The resulting transcripts allow for production and secretion of COL7 by the cell in its mature form. These COL7 molecules arrange themselves into long, thin bundles that form anchoring fibrils. The anchoring fibrils hold the epidermis and dermis together and are essential for maintaining the integrity of the skin. Patients with autosomal dominant DEB (DDEB) have lower than normal functional anchoring fibrils, and patients with RDEB have no functional anchoring fibrils.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

1 vial every 7 days

Age Range	Maximum Weekly Dose (plaque forming units; PFU)	Maximum Weekly Volume (milliliter; mL)*
6 months to <3 years old	1.6×10^9	0.8
≥3 years old	3.2×10^9	1.6

**Maximum weekly volume after mixing VYJUVEK biological suspension with excipient gel*

Guideline

I. Initial Criteria

1. Dystrophic Epidermolysis Bullosa (DEB)

A. Diagnosis of DEB as evidenced by detection of mutation(s) in the *collagen type VII alpha 1 chain (COL7A1*) gene on molecular genetic testing; **AND**
B. Patient has not received a skin graft in the area to be treated within the prior 3 months; **AND**
C. Patient is ≥ 6 months of age; **AND**
D. Patient has at least one clinical feature of dystrophic epidermolysis bullosa; **AND**
E. Provider attestation of at least one cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected; **AND**
F. Squamous cell carcinoma has been ruled out for the target wound(s); **AND**
G. The medication is prescribed by or in consultation with a dermatologist or wound care specialist.

II. Continuation Criteria

1. Dystrophic Epidermolysis Bullosa (DEB), Treatment of open wounds

A. Patient continues to meet the indication-specific relevant criteria identified in Initial Criteria; **AND**
B. Absence of unacceptable toxicity from the drug. (Examples of unacceptable toxicity include any severe medication reactions warranting therapy discontinuation, etc.); **AND**
C. 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**
D. Patient requires continued treatment due to new or existing open wound

Applicable Procedure Codes

Code	Description
J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/ml vector genomes, per 0.1 ml

Applicable NDCs

Code	Description
82194-0510-02	Vyjuvek topical Gel 2.5mL

ICD-10 Diagnoses

Code	Description
Q81.2	Epidermolysis bullosa

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: Updated title from “suspension” to “gel” Initial Criteria: Added: “Patient has at least one clinical feature of dystrophic epidermolysis bullosa; AND Squamous cell carcinoma has been ruled out for the target wound(s); AND The medication is prescribed by or in consultation with a dermatologist or wound care specialist.”
EmblemHealth & ConnectiCare	2/26/2024	Removed: diagnosis “of recessive” from Initial criteria, updated NDCs
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Updated J Code, no criteria changes
EmblemHealth & ConnectiCare	11/13/2023	Initial Criteria: Dystrophic Epidermolysis Bullosa (DEB),Removed “ Treatment of open wounds” from Title Added “detection of mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing; AND” to the following statement: “Diagnosis of recessive DEB (RDEB) as evidenced by detection of mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing; AND” Removed ”two copies of positive COL7A1 gene mutation by one of the following (i. ii. OR iii.) i. Immunofluorescence mapping; OR ii. Transmission electron microscopy; OR iii. Antigenic mapping; AND Prescribed by, or in consultation with, a geneticist, dermatologist, or histopathologist; AND” Added: ” Patient has not received a skin graft in the area to be treated within the prior 3 months; AND” Removed: “AND Provider attestation that member is concomitantly receiving standard of care preventative or treatment therapies for wound care (e.g., polymeric membrane, superabsorbent dressings, soft-silicone foam, enzyme alginogel, protease)” DEB Continuation Criteria Removed “Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters (i. or ii.): i. Decrease in wound size; OR ii. Decrease in pain severity per primary wound site associated with dressing changes; AND B. Provider attestation that member continues to have incomplete wound closures that are clean in appearance with adequate granulation tissue, have excellent vascularization, and do not appear infected” Added: “Patient continues to meet the indication-specific relevant criteria identified in Initial Criteria; 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 wound”
EmblemHealth & ConnectiCare	07/28/2023	New Policy

References

1. Product Information: VYJUVEK™ topical suspension, beremagene geperpavec-svdt topical suspension. Krystal Biotech Inc (per FDA), Pittsburgh, PA, 2023.