Medical Drug Clinical Criteria

Subject:	Vyjuvek (beremagene geperpavec)		
Document #:	CC-0243	**Publish Date:**	09/18/2023
Status:	Revised	**Last Review Date:**	08/18/2023

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Overview

This document addresses the use of Vyjuvek (beremagene geperpavec), a topical gene therapy approved by the Food and Drug Administration for the treatment of dystrophic epidermolysis bullosa (DEB). Dystrophic epidermolysis bullosa can be dominantly (DDEB) or recessively inherited (RDEB). Within this disease, there are defects in Type VII collagen caused by mutations in the COL7A1 gene. This defect results in lack of stable dermal-epidermal adhesion. As a result, individuals suffer from extensive blistering of the skin, including mucous membranes. Diagnosis confirmation through genetic testing, immunofluorescence mapping (IFM) and/or transmission of electron microscopy (TEM) can be done to determine a precise subclassification. Currently, there have not been any definitive treatments and symptomatic care is the mainstay of disease management. The prevention of new blisters along with wound care have been the primary treatment for this disease.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Vyjuvek (beremagene geperpavec)

Initial requests for Vyjuvek (beremagene geperpavec) may be approved if the following criteria are met:

I. Individual has a diagnosis of dystrophic epidermolysis bullosa (DEB); **AND,**
II. Documentation is provided that individual has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.

Continuation requests for Vyjuvek (beremagene geperpavec) may be approved if the following criteria are met:

I. Individual has clinically significant wound healing.

Requests for Vyjuvek (beremagene geperpavec) may not be approved for the following:

I. Individual has current evidence or a history of squamous cell carcinoma in the area that will undergo treatment; **OR,**
II. Individual has participated in an interventional clinical trial within the past 3 months (not including beremagene geperpavec administration); **OR,**
III. Individual has had a skin graft in the past 3 months; **OR,**
IV. When the above criteria are not met and for all other indications.

Initial Approval: 6 months
Continuation Approval: 1 year

Quantity Limits

Vyjuvek (beremagene geperpavec)

Drug	Limit
Vyjuvek (beremagene geperpavec)	4 vials per 28 days (each vial is 2.5 mL)

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

Q81.2	Epidermolysis bullosa dystrophica

Document History

Revised: 08/18/2023
Document History:

- 08/18/2023 – Select Review – Add continuation criteria; add initial and continuation approval durations. Coding Reviewed: No changes. Effective 1/1/2024 Added HCPCS J3401. Added ICD-10-CM Q81.2. Removed HCPCS J3490, J3590, all diagnoses pend.
- 06/12/2023 – New criteria for Vyjuvek (beremagene geperpavec). Coding Reviewed: Added HCPCS J3490, J3590. All diagnoses pend.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Clinical Study to Compare the Efficacy and Safety of Beremagene Geperpavec (B-VEC) Topical Gel with That of Placebo for the Treatment of Dystrophic Epidermolysis Bullosa (DEB). ClinicalTrials.gov identifier: NCT04491604. Updated August 3, 2022. https://www.clinicaltrials.gov/ct2/show/NCT04491604.
5. Guide SV, Gonzalez ME, Bağcı IS, et al. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. *N Engl J Med*. 2022 Dec 15;387(24):2211-2219. Available at: https://www.nejm.org/doi/10.1056/NEJMoa2206663?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.