

Pharmacy Drug Policy & Procedure

Policy Name:	Vyjuvek (beremagene geperpavec)	Policy#:	3205P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Vyjuvek (beremagene geperpavec)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Vyjuvek (beremagene geperpavec) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of dystrophic epidermolysis bullosa (DEB) confirmed by gene testing
 - Gene testing must be submitted to support pathogenic mutations in COL7A1 gene
- 1.2 Documentation to support open skin wounds
 - Application is limited to open skin wounds only
- 1.3 Age 6 months or older
- 1.4 Prescribed by or in consultation with a dermatologist (skin doctor) who specializes in epidermolysis bullosa management
- 1.5 Clinical review of documentation confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 History of squamous cell carcinoma or actively receiving cancer treatment
- 2.2 History of skin graft within previous 3 months

3. Managed Dose Limit

- 3.1 10mL (4 vials) per 28 days

4. Approval Period

- 4.1 Initial: 24 weekly doses over 12 months
- 4.2 1st Reauthorization: 24 weekly doses over 12 months with documentation supporting clinical improvement with therapy such as 100% complete wound closing
- 4.3 2nd Reauthorization and beyond: 52 weekly doses over 12 months with documentation supporting continued clinical improvement on therapy such as 100% complete wound closing

CPT Codes

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HCPCS Codes

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

1. Vyjuvek (beremagene geperpavec) [prescribing information]. Pittsburgh, PA: Krystal Biotech, Inc; May 2023.
2. International consensus best practice guidelines skin and wound care in epidermolysis bullosa. Wounds 2017.
3. Has C, El Hachem M, Bučková H, et al. Practical management of epidermolysis bullosa: consensus clinical position statement from the European Reference Network for Rare Skin Diseases. J Eur Acad Dermatol Venereol 2021; 35:2349.
4. American Academy of Dermatology Association. Diseases & conditions. Epidermolysis bullosa: Signs and symptoms. <https://www.aad.org/public/diseases/a-z/epidermolysis-bullosa-symptoms>. Accessed 8/2023.
5. Guide SV, Gonzalez ME, Bağcı IS, et al. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. N Engl J Med 2022; 387:2211.

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DISCLAIMER

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