CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Vyjuvek (beremagene geperpavec-svdt)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Vyjuvek, approved by the FDA in 2023, is a herpes-simplex virus type 1 (HSV-1) vector-based topical gene therapy indicated for the treatment of wounds 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.
DEB is one of four types of epidermolysis bullosa (EB). It is a rare genetic disease with skin fragility and mechanically induced blistering that can lead to infections, scarring, and disfigurement. DEB is caused by mutations in *COL7A1*, the gene that codes collagen type VII (C7), the major component of anchoring fibrils in part of the skin. DEB can be autosomal dominant (DDEB) and have lower than normal functional anchoring fibrils, or less often (and more severe), recessive (RDEB) with no functional anchoring fibrils.
Vyjuvek gel addresses the underlying cause of DEB by delivering functional copies of the *COL7A1* gene to restore C7. In the GEM-3 clinical trial, complete wound healing at 3 and 6 months in DEB patients was more likely with Vyjuvek than placebo.

Vyjuvek (beremagene geperpavec-svdt) will be considered for coverage when the following criteria are met:

Dystrophic Epidermolysis Bullosa (DEB)

For **initial** authorization:
1. Member is at least 6 months of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of DEB confirmed by mutation(s) in the *COL7A1* gene; AND
4. Member has at least 1 open wound to be treated, that is clean and does not appear infected; AND
5. Member will continue standard wound care.
6. **Dosage allowed/Quantity limit:** Apply topically once a week to open wound(s).

Table 1 Maximum Weekly Dose by Age

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.

QL: 4 vials per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show successful wound healing with Vyjuvek treatment; AND
2. Reopening of previously treated wound and/or a different open wound is to be treated.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Vyjuvek (beremagene geperpavec-svdt) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/10/2023	New policy for Vyjuvek created.

References:

1. Vyjuvek [prescribing information]. Krystal Biotech, Inc.; 2023.
2. 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
3. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. Br J *Dermatol*. 2020;182(3):574-592. doi:10.1111/bjd.18128
4. Has C, Bauer JW, Bodemer C, et al. Consensus reclassification of inherited epidermolysis bullosa and other disorders with skin fragility. *Br J Dermatol*. 2020;183(4):614-627. doi:10.1111/bjd.18921

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