

Vyjuvek™ (beremagene geperpavec-svdt)

When requesting Vyjuvek™ (beremagene geperpavec-svdt), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Vyjuvek is 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.

Coverage Guidelines

Dystrophic Epidermolysis Bullosa

The individual must meet all of the following criteria for approval:

- Has a diagnosis of dystrophic epidermolysis bullosa confirmed by genetic testing showing a pathogenic mutation in the *collagen type VII alpha 1 chain (COL7A1)* gene;
- Is 6 months of age or older;
- Has at least one clinical feature of dystrophic epidermolysis bullosa (e.g., blistering, scarring);
- Has one or more open wounds;
- Vyjuvek is prescribed by or in consultation with a dermatologist or wound care specialist with expertise in the management of dystrophic epidermolysis bullosa.

Approval duration: 6 months

Dosing Recommendation

The recommended dose of Vyjuvek gel is based on age. Vyjuvek gel is applied topically to wound(s) once a week.

Maximum Weekly Dose by Age

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

References

1. Vyjuvek™ biological suspension [prescribing information]. Pittsburgh, PA: Krystal Biotech; May 2023.
2. Guide SV, Gonzalez ME, Bagci IS, et al. Trial of beremagene geperavec (B-VEC) for dystrophic epidermolysis bullosa. *N Engl J Med*. 2022;387(24):2211-2219.
3. Payne AS. Topical gene therapy for epidermolysis bullosa. *N Engl J Med*. 2022;387(24):2281-2284.
4. Has C, Bauer JW, Bolling MC et al. Consensus and reclassification of inherited epidermolysis bullosa and other disorders with skin fragility. *Br J Dermatol*. 2020;183:614-627.
5. Has C, El Hachem M, Buckova H, et al. Practical management of epidermolysis bullosa: consensus clinical position statement from the European Reference Network for Rare Skin Diseases. *J Eur Acad Derm Venereol*. 2021;35:2349-2360.
6. Denyer J, Pillay E, Clapham J. Best practice guidelines for skin and wound care in epidermolysis bullosa. An International Consensus. *Wounds International*. 2017. Available at: https://af13d689-15eb-4199-8733-e91a7bb8ae3f.usrfiles.com/ugd/af13d6_01ed147ab87e49c584c20a917c47f19f.pdf. Accessed on: June 26, 2023