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 adult and pediatric patients 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 initial authorization:

- 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;
- Has at least one clinical feature of dystrophic epidermolysis bullosa (e.g., blistering, scarring);
- Has one or more open wounds;
- Target wound meets all of the following:
    - Is clean in appearance and does not appear to be infected; AND
    - Has adequate granulation and vascularization; AND
    - There is no evidence or clinical suspicion of squamous cell carcinoma at the target wound(s);
- Vyjuvek is prescribed by or in consultation with a dermatologist or wound care specialist.

The individual must meet **all** of the following criteria for reauthorization:
Note: If a new wound or a reopened recurrent wound is being treated, refer to initial authorization criteria.

- Target wound remains open;
- Target wound has decreased in size from baseline;
- Vyjuvek is prescribed by or in consultation with a dermatologist or wound care specialist.

Approval duration (initial and renewal): 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)
<3 years old	2×10^9	1
≥3 years old	4×10^9	2

References

1. Vyjuvek™ biological suspension [prescribing information]. Pittsburgh, PA: Krystal Biotech; September 2025.
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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: October 28, 2025.
7. Kern JS, Sprecher E, Fernandez MF, et al. Efficacy and safety of Olegel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. *Br J Dermatol*. 2023;188:12-21.