Generic Name: beremagene geperpavec-svdt

Applicable Drugs: Vyjuvek (beremagene geperpavec-svdt)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/13/2023

Date Last Reviewed / Revised: 11/13/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met)

I. Diagnosis of dystrophic epidermolysis bullosa (DEB) and the following criteria A through D are met:
   A. Documentation of pathogenic, or likely pathogenic, mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene
   B. Documentation of baseline number and size of wounds
   C. Documentation of recurrent or chronic open wound(s) to receive treatment that meet all of the following criteria i though iv:
      i. Adequate granulation tissue
      ii. Excellent vascularization
      iii. No evidence of active wound infection
      iv. No evidence of history of squamous cell carcinoma
   D. Documentation of the size of the wound(s) to be treated and calculated dose of Vyjuvek not to exceed the recommended dose per wound size and maximum weekly dose. See Appendix Table 1 and Table 2 for dosing.

II. Minimum age requirement: 6 months old

III. Treatment must be prescribed by or in consultation with a dermatologist with expertise in the treatment of DEB.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

EXCLUSION CRITERIA

- Current or history of squamous cell carcinoma
- Concurrent immunotherapy, chemotherapy, or investigational products.
- Pregnancy

OTHER CRITERIA

- Treatment beyond 26 weeks is under investigation and will not be authorized.

Quantity / Days Supply Restrictions

- 1 carton per 7 days
    - Each carton contains 1 single-dose viral of Vyjuvek biological suspension and 1 single-dose vial of excipient gel for mixing.

Approval Length

- **Authorization:** 3 months

Re-Authorization: 3 months with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and clinical benefits of treatment (eg, decrease in wound size, increase in granulation tissue, complete wound closure, etc).

Appendix

Table 1. Maximum Dose

Age Range	Maximum Weekly Dose, PFU	Maximum Weekly Volume, mL*+
6 months <3 years old	1.6×10^9	0.8
≥3 years old	3.2×10^9	1.6

* Treatment of all wounds may not be possible at each visit.
\+ Maximum volume is the volume after mixing B-VEC suspension with excipient gel.
PFU plaque-forming units

Table 2. Dose per wound size[2]

Wound area (cm^2)*	Dose (PFU)	Volume (mL)+
<20	4×10^8	0.2
20 to <40	8×10^8	0.4
40 to 60	$1.2\ 10^9$	0.6

* For wounds > 60 cm^2, the total dose is calculated based on this table until the maximum weekly dose in Table 1 is reached.
\+ Maximum volume is the volume after mixing B-VEC suspension with excipient gel.

References

1. Vyjuvek. Prescribing information. Krystal Biotech Inc; 2023. Accessed October 14, 2023. https://www.krystallabel.com/pdf/vyjuvek-us-pi.pdf
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