ALASKA MEDICAID
Prior Authorization Criteria

Vyjuvek™
(beramagene geperpavec-svdt)

FDA INDICATIONS AND USAGE[1]

Vyjuvek is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.

APPROVAL CRITERIA[1,2,3]

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a dermatologist **AND**;
3. Patient has the diagnosis of dystrophic epidermolysis bullosa (DEB) **AND**;
4. Patient has a mutation in the collagen type VII alpha 1 chain gene confirmed by genetic testing **AND**;
5. Documentation of baseline size of target wounds has been provided **AND;**
6. Provider has attested that wounds to be treated meet all of the following:
    a. Adequate granulation tissue is present
    b. Tissue is well vascularized
    c. No evidence of active infection is present
    d. No evidence of squamous cell carcinoma

DENIAL CRITERIA [1]

1. Failure to meet approval criteria

CAUTIONS[1]

- The safety of Vyjuvek in pregnancy or lactation has not been established.
- Avoid direct contact with treated would and dressings of treated wounds for approximately 24 hours following application.

DURATION OF APPROVAL

- Initial Approval: up to 6 months
- Reauthorization Approval: up to 6 months

QUANTITY LIMIT[1]

- Patients age 6 months to <3 years old: 3.2ml per 28 days
- Patients age ≥3 years old: 6.4ml per 28 days
- HCPCS: J3401

REFERENCES / FOOTNOTES:

1. Vyjuvek [prescribing information]. Pittsburg, PA: Krystal Biotech; May 2023
2. Guide S, 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. NIH: U.S. National Library of Medicine. Ph 3 Efficacy and Safety of B-VEC for the Treatment of DEB (GEM-3). https://clinicaltrials.gov/ct2/show/NCT04491604?term=beremagene&draw=2&rank=3. Accessed 10/20/2023.