| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
|---|---|
| Original Development Date:<br>Original Effective Date:<br>Revision Date: | September 19, 2024 |

# Vyjuvek™ (beremagene geperpavec-svdt)

**LENGTH OF AUTHORIZATION**: 6 months

**REVIEW CRITERIA**:

- Patient must be ≥ 6 months of age.
- Patient has not received a skin graft within the past 3 months; **AND**
- Patient has a genetically confirmed diagnosis of dystrophic epidermolysis bullosa with mutation in the *collagen type VII alpha 1 chain (COL7A1)* gene; **AND**
- Patient has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected.

**CONTINUATION OF THERAPY:**

- Patient must continue to meet the above criteria; **AND**
- Patient has not experienced any unacceptable toxicity from the drug (e.g., severe medication reactions resulting in discontinuation of therapy); **AND**
- Patient must have disease response as defined by improvement (healing) of treated wound(s), reduction in skin infections, etc.; **AND**
- Patient requires continued treatment for new and/or existing open wounds.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at (vyjuvekhcp.com).
- Available as a $5\times10^9$ PFU/mL biological suspension in a 1mL single-dose vial for extraction.