Vyjuvek™ (beremagene geperpavec-svdt) (Topical) Clinical Criteria

Length of Authorization: Coverage will be provided for 6 months and may be renewed.

Dosing Limits:

- **Quantity Limit (max daily dose) [NDC Unit]:**
  - Vyjuvek single-dose vial containing 5×109 PFU/mL: 1 vial every 7 days.

Initial Approval Criteria[1]:

Coverage is provided in the following conditions:

- Member is at least 6 months of age; AND

Universal Criteria[1]

- Member has not received a skin graft in the area to be treated within the prior 3 months; AND
- Will not be used concurrently in the same wound with another disease-modifying therapeutic agent indicated for DEB (e.g., birch triterpenes, etc.) (NOTE: this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.); AND

Dystrophic Epidermolysis Bullosa (DEB) † Φ [1,2]

- Member has a diagnosis of dystrophic epidermolysis bullosa as established by detection of mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing; AND
- Member has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Renewal Criteria[1]

Coverage can be renewed based on the following criteria:

- Member continues to meet the indication-specific relevant criteria; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: any severe medication reactions warranting therapy discontinuation, etc.; AND
- Disease response with treatment as defined by improvement (healing) of treated wound sites, and/or reduction in skin infections, etc., as attested by his/her physician; AND
- Member requires continued treatment due to new or existing open wounds

References

1. Vyjuvek™ [package insert]. Pittsburgh, PA; Krystal Biotech, Inc.; May 2023. Accessed April 2024.
2. Guide SV, Gonzalez ME, Bagci S, et al. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. N Engl J Med 2022; 387:2211-2219. DOI: 10.1056/NEJMoa2206663.
3. Pfender EG, Lucky AW. Dystrophic Epidermolysis Bullosa. GeneReviews. https://www.ncbi.nlm.nih.gov/books/NBK1304/. Initial Posting: August 21, 2006; Last Update: