Louisiana Medicaid
Beremagene Geperpavec-svdt (Vyjuvek™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for beremagene geperpavec-svdt (Vyjuvek™).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 6 months of age on date of the request; **AND**
- The recipient has a diagnosis of dystrophic epidermolysis bullosa confirmed by **BOTH** of the following:
    - Skin biopsy of an induced blister with immunofluorescence mapping (IFM) and/or transmission electron microscopy (TEM); **AND**
    - Genetic test results showing mutations in the collagen type VII alpha 1 chain (COL7A1) gene; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a geneticist or dermatologist; **AND**
- The following is true and is **stated on the request** - The recipient does not have current evidence or history of squamous cell carcinoma in the area that will undergo treatment; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, prior treatment requirements and required storage and handling procedures; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 6 months

References

Bruckner AL and Murrell DF. Diagnosis of epidermolysis bullosa. In: UpToDate. Shefner JM (Ed), UpToDate, Waltham, MA.

Gurevich I, Agarwal P, Zhang P, Dolorito JA, Oliver S, Liu H, Reitze N, Sarma N, Bagci IS, Sridhar K, Kakarla V, Yenamandra VK, O'Malley M, Prisco M, Tufa SF, Keene DR, South AP, Krishnan SM, Marinkovich MP. In vivo topical gene therapy for recessive dystrophic epidermolysis bullosa: a phase 1 and 2 trial. Nat Med. 2022 Apr;28(4):780-788. doi: 10.1038/s41591-022-01737-y. Epub 2022 Mar 28. PMID: 35347281; PMCID: PMC9018416.

Vyjuvek (beremagene geperpavec-svdt) [package insert]. Pittsburgh, PA: Krystal Biotech, Inc; May 2023. https://www.fda.gov/media/168350/download

Revision / Date	Implementation Date
Policy created / July 2023	January 2024