Medical Policy:

Vyjuvek (beremagene geperpavec-svdt)

Last review date: 6/17/2024



Applicable Products:

Vyjuvek (beremagene geperpavec-svdt)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Must have a diagnosis of Dystrophic Epidermolysis Bullosa (DEB); AND
- Member meets ALL of the following documentation must be provided:
 - Mutation in the collagen type VII alpha 1 chain (COL7A1) gene
 - Wound to be treated is open and clean with adequate granulation tissue, excellent vascularization, and no appearance of active infection
 - o The member does not have current evidence or a history of squamous cell carcinoma in the area to be treated
 - o The member does not have evidence of an active systemic infection
 - o The member has not received a skin graft in the past 3 months
 - o Treatment is prescribed by or in consultation with a specialist (dermatologist, geneticist)
 - The dose does not exceed one single dose vial (containing 5x109 plaque forming units (PFU) per mL) every 7 days; AND
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; AND
 - The member had a beneficial response to treatment with evidence of improved wound healing (closure or reduction in wound area from baseline); AND
 - Absence of unacceptable toxicity

Length of Authorization:

6 months

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.