RX.PA.087.MPC Vyjuvek™ (beremagene geperpavec-svdt)

The purpose of this policy is to define the prior authorization process for Vyjuvek™ (beremagene geperpavec-svdt) biological suspension mixed with excipient gel for topical application.

Vyjuvek™ (beremagene geperpavec-svdt) 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.

PROCEDURE

A. Initial Authorization Criteria:

1. Dystrophic Epidermolysis Bullosa. All requests must meet the following criteria:

- Member must be 6 months of age or older
- Must have a documented diagnosis of dystrophic epidermolysis bullosa evidenced by a mutation in the collagen type VII alpha 1 chain (COL7A1) gene
- Provider must attest that female members of child bearing potential will have a documented confirmed negative pregnancy test (within 30 days of starting treatment)
- Male and female members of childbearing potential must use a reliable birth control method throughout treatment and for 3 months post last dose of Vyjuvek
- Provider attestation of ALL of the following:
    a) Adequate granulation tissue of wounds
    b) Excellent vascularization of wounds
    c) No evidence of active wound infection
    d) No evidence or history of squamous cell carcinoma
    e) No history of skin grafts within the past 3 months
- Dose does not exceed FDA approved indication
- The medication is prescribed by or in consultation with a dermatologist or wound care specialist
- Must provide documentation of wound size(s) at baseline

B. Reauthorization Criteria:

1. Dystrophic Epidermolysis Bullosa.

MPC Renewal:

- All prior authorization renewals are reviewed on a 6 month interval basis to determine the Medical Necessity for continuation of therapy.
- Documentation of a positive clinical response, as determined by at least one of the following:
    - Decrease in wound size

  - Decrease in pain severity for wound sites
  - Increase in granulation tissue
- Member must have documentation of incomplete wound closures
- Vyjuvek must not be applied on target wounds that have completely healed
- Male and female members of childbearing potential must use a reliable birth control method throughout treatment and for 3 months post last dose of Vyjuvek
- The medication is prescribed by or in consultation with a dermatologist or wound care specialist

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC) and have been taking Vyjuvek have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).Provider has a documented clinical response, as determined by at least one of the following:
  - Decrease in wound size
  - Decrease in pain severity for wound sites
  - Increase in granulation tissue
- Member must have documentation of incomplete wound closures
- Vyjuvek must not be applied on target wounds that have completely healed
- Male and female members of childbearing potential must use a reliable birth control method throughout treatment and for 3 months post last dose of Vyjuvek
- The medication is prescribed by or in consultation with a dermatologist or wound care specialist

C. Vyjuvek will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Up to 3 months
Reauthorization	• Up to 6 months

Codes:

Code	Description
J3590	Unclassified Biologics

REFERENCES

1. Vyjuvek™ [prescribing information]. Pittsburgh, PA: Krystal Biotech, Inc.; May 2023.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual policy review. Update to reauthorization criteria for non-MPC renewals	*02/2024*
New Policy	*09/2023*