



POLICY NUMBER: RX.PA.087.MPC
REVISION DATE: 09/2023

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

Non-MPC Renewal:

- Members who have previously been taking Vyjuvek and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
- Member has not been receiving medication samples for Vyjuvek
- 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.



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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>New Policy</i>	<i>09/2023</i>