JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP118
		Effective Date	01/15/2025
		Approval Date	07/17/2024
	Subject **Vyjuvek**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Vyjuvek

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I. POLICY

A. Vyjuvek (beremagene geperpavec-svdt) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Vyjuvek may be approved for patients who meet the following:
   1. Patient is 6 months of age or older
   2. Documentation has been submitted showing all the following:
      a. Diagnosis of dystrophic epidermolysis bullosa (DEB)
      b. Genetic test results confirm a mutation in the COL7A1 gene
      c. Patient has clinical manifestations of disease (extensive skin blistering, skin erosions, scarring)
      d. Patient does not have a history of squamous cell carcinoma in the affected areas that will receive treatment
      e. Vyjuvek will be administered once weekly to the affected areas by a healthcare professional either at a healthcare professional setting (e.g., clinic) or a home setting
      f. Vyjuvek will not be administered to wounds that are currently healed

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Approval will be limited to 12 months of therapy

IV. EXCLUSIONS

A. Vyjuvek will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/ml vector genomes, per 0.1 ml	J3401

VII. REFERENCES

1. Vyjuvek [prescribing information]. Pittsburgh, PA: Krystal Biotech, Inc.; May 2023.
2. Guide SV, Gonzalez ME, Bagci IS, et al. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. N Engl J Med. 2022;387(24):2211-2219.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation
01/15/2025	Removed prescriber specialty requirement

Review Date: 07/17/2024

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