

## Vyjuvek (Beremagene Geperpavec)

**Policy Number: 073**

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X	X	X
No Prior Authorization			

Vyjuvek (beremagene geperpavec) is a topical gene therapy based on a replication-defective herpes simplex virus 1 vector, indicated for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB).

### Criteria

1. Criteria

Authorization may be granted to members when **ALL** of the following criteria are met:

- A. Age  $\geq$ 6 months
- B. Diagnosis of DEB with mutation(s) in the *collagen type VII (COL7A1)* gene
- C. At least one open wound with granulation tissue, good vascularity, and no evidence of infection
- D. Prescriber is a dermatologist or other specialist with expertise in DEB
- E. If treated with Vyjuvek within the past year, documentation shows adequate treatment response
- F. Appropriate dosing (see below)

2. Dosing and administration

- Vyjuvek is applied weekly to open wounds until wounds closed.
- Dosing is dependent on wound area. See prescribing information on FDA package insert.
- Maximum weekly dose is  $1.6 \times 10^9$  plaque forming units (PFU), or 0.8 mL, for children 6 months to <3 years old, and  $3.2 \times 10^9$  PFU, or 1.6 mL, for patients  $\geq$ 3 years old.

### MassHealth variation

Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for coverage determinations for members of the MGB ACO. Criteria for Vyjuvek are found in [Table 72: Agents Not Otherwise Specified](#).

### Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations.

### Codes

**The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.**

**This list of codes applies to commercial and MassHealth plans only.**

Authorized CPT/HCPCS Codes	Code Description
J3401	Beremagene gepervavec-svdt for topical administration, containing nominal $5 \times 10^9$ PFU/mL vector genomes, per 0.1 mL

**Effective**

April 2024: Effective Date

**References**

Beremagene gepervavec-svdt [package insert]. Pittsburgh: Krystal Biotech, 2023.

Guide SV, Gonzalez ME, Bağcı IS, et al. Trial of beremagene geperpavec (B-VEC) for dystrophic epidermolysis bullosa. *NEJM* 2022;387:2211-9.

Gurevich I, Agarwal P, Zhang P. In vivo topical gene therapy for recessive dystrophic epidermolysis bullosa: a phase 1 and 2 trial. *Nature Medicine* 2022;28:780-8.

