CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 5996-A |

# Specialty Guideline Management Vyjuvek

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Vyjuvek | beremagene geperpavec-svdt |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications1

Vyjuvek is 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.

All other indications are considered experimental/investigational and not medically necessary

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

* Medical records documenting clinical manifestations of disease.
* Genetic test results confirming a mutation in the COL7A1 gene.

## Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or wound care specialist.

## Coverage Criteria

### Dystrophic Epidermolysis Bullosa (DEB)1,2

Authorization of 12 months may be granted for treatment of wounds in members with dystrophic epidermolysis bullosa (DEB) when all of the following criteria are met:

* Member is 6 months of age or older.
* Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
* Member has genetic test results confirming a mutation in the COL7A1 gene.
* Member has one or more open wounds that will be treated (i.e., target wounds)
* Target wound(s) meet all of the following:
  + Wound is clear in appearance and does not appear to be infected
  + Wound has adequate granulation tissue and vascularization
  + Member does not have a history of squamous cell carcinoma in the affected wound(s) that will receive treatment.
* The requested medication will be administered once weekly to the affected wound(s) by a healthcare professional either at a healthcare professional setting (e.g., clinic) or a home setting.
* The requested medication will not be administered to wound(s) that are currently healed.

## References

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