VYJUVEK (PREAUTHORIZATION REQUIRED)

X.216

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POLICY

Vyjuvek® (beremagene geperpavec) is FDA approved:

Target Agents:

Brand (generic)	GPI (NDC)	Multisource Code	Quantity Limit (per day or as listed)
Vyjuvek (beremagene geperpavec)			

Initial Evaluation

I. Target Agent(s) may be considered **medically necessary** when ALL of the following are met:

A. The patient has a diagnosis of dystrophic epidermolysis bullosa as confirmed by ONE of the following:

i. Immunofluorescence mapping (IFM) **OR**

ii. Transmission electron microscopy (TEM) **OR**

iii. Genetic testing **AND**

B. ONE of the following:

i. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

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for the requested indication **AND**

C. The patient does NOT have serum antibodies to type VII collagen **AND**

D. The patient does NOT have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment **AND**

E. The patient does NOT have an active infection in that area that will undergo treatment **AND**

F. The patient does NOT have evidence of a systemic infection **AND**

G. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

H. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

I. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication

Length of Approval: 3 months

Renewal Evaluation

I. Renewal of Target Agent(s) may be considered **medically necessary** when

A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**

B. The patient has had clinical benefit with the requested agent **AND**

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D. The patient does NOT have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment **AND**

E. The patient dose NOT have an active infection in the area that will undergo treatment **AND**

F. The patient does NOT have evidence of a systemic infection **AND**

G. The prescriber is a specialist in the are of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

H. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

I. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication.

Length of Approval: 12 months

Dates

Original Effective
08-31-2023
Last Review
11-06-2024
Next Review
11-08-2025

CLINICAL RATIONALE

Epidermolysis bullosa (EB) encompasses a number of disorders characterized by recurrent blister formation as the result of structural fragility within the skin and selected other tissues caused by mutations in CLO7A1, the gene encoding the anchoring fibril component, collagen VII. All types and subtypes of EB are rare; the overall incidence and prevalence of the disease within the United States is approximately 19 per one million live births and 8 per one million population, respectively. Clinical manifestations range widely, from localized blistering of the hands and feet to generalized blistering of the skin and oral cavity, and

structural stability or adhesion of the keratinocyte to the underlying dermis. EB is best diagnosed and subclassified by the collective findings obtained via detailed personal and family history, in concert with the results of immunofluorescence antigenic mapping, transmission electron microscopy, and in some cases, by DNA analysis. Optimal patient management requires a multidisciplinary approach and revolves around the protection of susceptible tissues against trauma, use of sophisticated wound care dressings, aggressive nutritional support, and early medical or surgical interventions to correct whenever possible the extracutaneous complications. Prognosis varies considerably and is based on both EB subtype and the overall health of the patient. Currently, there is no cure for EB. Supportive care includes daily wound care, bandaging, and pain management as needed.

Vyjuvek (beremagene geperpavec) is a replication-defective and nonintegrating, modified herpes simplex virus 1 vector that is topically applied to deliver a functional version of the COL7A1 gene directly to skin cells. Treatment with Vyjuvek seeks to restore the production of type VII collagen inpatients with EB. The GEM-1 trial evaluated the efficacy and safety of Vyjuvek in healing skin wounds in nine adult and pediatric patients. After 12 weeks, complete wound closure (reduction in wound area from baseline greater than or equal to 95 percent) was observed in 83 percent of the Vyjuvek treated wounds compared with 14 percent of the wounds treated with placebo. In many cases, the wound-healing duration was longer than 6 months. Adverse effects were mild and included fever, rash, and itching. Exclusion criteria included the presence of medical illness expected to complicate participation, presence of serum antibodies to type collagen VII, active infection in the area that will undergo treatment, evidence of systemic infection, and current evidence or a history of squamous cell carcinoma in the area that will undergo treatment. The GEM-3 trial was a multi-center, randomized, double-blind placebo-controlled phase 3 trial that enrolled 31 people aged 6 months or older. GEM-3 also met the primary and secondary efficacy endpoints in complete wound healing relative to placebo. An open-label extension study is underway to assess the long-term safety and efficacy of Vyjuvek for patients greater than or equal to 6 months of age, regardless of prior enrollment in GEM-3.

Safety

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Quick Code Search

Use this feature to find out if a procedure and diagnosis code pair will be approved, denied or held for review. Simply put in the procedure code, then the diagnosis code, then click "Add Code Pair". If the codes are listed in this policy, we will help you by showing a dropdown to help you.

Procedure

Please type a procedure code

Enter at least the first 3 characters of the code

Diagnosis

Please type a diagnosis code

Enter at least the first 3 characters of the code

Add

CODES

+ **HCPCS**

REFERENCES

2010

Fine JD. Inherited epidermolysis bullosa. Orphanet J Rare Dis. 2010 May 28;5:12. doi: 10.1186/1750-1172-5-12

2022

Gurevich I, Agarwal P, Zhang P, et al. In vivo topical gene therapy for recessive dystrophic epidermolysis bullosa: a phase 1 and 2 trial. Nat Med. 2022;28(4):780-788. doi:10.1038/s41591-022-01737-y

2022

New GEM-3 Phase 3 Results for B-VEC Presented at 2022 AAD Annual Meeting. https://practicaldermatology.com/news/new-gem-3-phase-3-results-for-b-vec-presented-at-2022-aad-annual-meeting

REVISIONS

12-21-2023

Adding new code J3401 effective 01/01/2024

12-01-2023

Policy reviewed at Medical Policy Committee meeting on 11/8/2023 – no changes to policy.