Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 306.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Vyjuvek (beremagene geperpavec-svdt)

I. Policy:
Vyjuvek (beremagene geperpavec-svdt)

II. Purpose/Objective:
To provide a policy of coverage regarding Vyjuvek (beremagene geperpavec-svdt)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Beremagene geperpavec is a herpes simplex virus-1 (HSV-1) vector-based gene therapy that may transduce both keratinocytes and fibroblasts within the nucleus of the cells allowing for production and secretion of COL7; the COL7 molecules form anchoring fibrils, which hold the epidermis and dermis together and help maintain skin integrity. Patients with dystrophic epidermolysis bullosa have lower than normal or no functioning anchoring fibrils.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Vyjuvek (beremagene geperpavec-svdt) will be considered medically necessary for ALL lines of business when ALL of the following criteria are met:

- Medical record documentation that Vyjuvek is prescribed by or in consultation with a dermatologist who specializes in epidermolysis bullosa (EB) management **AND**
- Medical record documentation of age greater than or equal to 6 months **AND**
- Medical record documentation of diagnosis of dystrophic epidermolysis bullosa (DEB) **AND**
- Medical record documentation of genetic testing confirming mutation(s) in the COL7A1 gene **AND**
- Medical record documentation of at least one open dystrophic epidermolysis bullosa (DEB) wound **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months and will require medical record documentation of clinical response to prior dystrophic epidermolysis bullosa (DEB) wounds treated with Vyjuvek therapy and lack of toxicity. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMIT: 2.5 mL (1 vial) per week, or 10 mL (4 vials) every 28 days

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Vyjuvek [Prescribing Information]. Pittsburgh, PA. Krystal Biotech, Inc. May 2023.
2. IPD Analytics. Vyjuvek 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 Chain (COL7A1) Gene. New Drug Approval Review. Published July 2023. Accessed Oct 2023. https://www.ipdanalytics.com
3. NEJM. Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa. https://www.nejm.org/doi/10.1056/NEJMoa2206663?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed. Published Dec 2022. Accessed Oct 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/21/23

Revised:

Reviewed:

MA UM Committee approval: Pending