SmartPA Criteria Proposal

Drug/Drug Class:	Vyjuvek Clinical Edit
First Implementation Date:	TBD
Proposed Date:	October 17, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Vyjuvek™ (beremagene geperpavec-svdt)

Why Issue Selected: On May 19, 2023, the U.S. Food and Drug Administration (FDA) approved Vyjuvek™ (beremagene geperpavec-svdt) for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutations(s) in the collagen type VII alpha 1 chain *(COL7A1)* gene.

Epidermolysis bullosa (EB) is a genetic skin disorder that causes abnormalities in the cohesion of the layers of the epidermis resulting in skin fragility. EB is caused by mutations involving several genes that encode for structural proteins within keratin intermediate filaments, desmosome cell junctions, and hemidesmosome attachment complexes. Symptoms of EB vary widely among affected patients. Clinical manifestations include blisters, erosions, nonhealing ulcerations, and scars in response to mild skin trauma. Patients often present with extracutaneous manifestations including hair and nail abnormalities, ocular blisters, oral blisters, gastrointestinal complications, and genitourinary complications. Severe cases of EB may result in malnutrition, anemia, infection, skin cancer, and death. The National Epidermolysis Bullosa Registry (NEBR) estimates the incidence of EB to be approximately 20 per million live births.

Vyjuvek is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy and is the first-in-class topical gene therapy treatment approved for DEB. Further disease management is mostly supportive focusing on wound care, pain control, controlling infections, nutritional support, and prevention and treatment of complications.

Due to the high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Vyjuvek.

Program-Specific Information:

Drug	Cost per vial (WAC)	Cost per month (WAC)*	Cost per year (WAC)*
VYJUVEK	$24,250	$48,500	$630,500

*Cost based on estimated usage of 26 vials per year

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:

☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Vyjuvek™ (beremagene geperpavec-svdt)
- Age range: All appropriate MO HealthNet participants aged 6 months and older

Approval Criteria

Initial Approval Criteria

- Must meet all of the following:
  - Prescribed by or in consultation with a dermatologist or other specialist in the treated disease state;
  - Participant is aged 6 months or older;
  - Documented diagnosis of dystrophic epidermolysis bullosa (DEB) confirmed by genetic testing showing pathogenic variant(s) in the *COL7A1* gene; **AND**
  - Documented baseline number and size of wounds
- Initial approval period: 6 months

Continuation of Therapy

- Must meet all of the following:
  - Documented benefit of therapy defined as reduction in number or size of wounds
- Continuation approval period: 12 months

Denial Criteria

- Therapy will deny with presence of one of the following:
  - Any approval criteria are not met; **OR**
  - Participant is currently pregnant

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- Vyjuvek™ (beremagene geperpavec-svdt) [package insert]. Pittsburgh, PA: Krystal Biotech, Inc.; May 2023.
- NIH: U.S. National Library of Medicine. Ph 3 Efficacy and Safety of B-VEC for the Treatment of DEB (GEM-3). https://clinicaltrials.gov/ct2/show/NCT04491604?term=beremagene&draw=2&rank=3. Accessed June 16, 2023.
- IPD analytics. New drug review. Vyjuvek. July 2023.

- Laimer M, Bauer J, Murrel D. Epidermolysis bullosa: Epidemiology, pathogenesis, classification, and clinical features. UpToDate. https://www.uptodate.com/contents/epidermolysis-bullosa-epidemiology-pathogenesis-classification-and-clinical-features?search=dystrophic%20epidermolysis%20bullosa&source=search_result&selectedTitle=1~19&usage_type=default&display_rank=1#H61550613. Accessed June 16, 2023.
- Murrell D. Overview of the management of epidermolysis bullosa. UpToDate. https://www.uptodate.com/contents/overview-of-the-management-of-epidermolysis-bullosa?search=dystrophic%20epidermolysis%20bullosa&topicRef=15449&source=see_link#H70257089. Accessed June 16, 2023.