TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Beremagene geperpavec-svdt (Vyjuvek®)	**CRITERIA ID:** TX.CC.PHAR.30
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 02/01/2024	**PRODUCT(S):** STAR, STAR Plus, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 4/3/2024, 7/17/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for beremagene geperpavec-svdt (Vyjuvek®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner, in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
DEB = dystrophic epidermolysis bullosa
COL7A1 = collagen type VII alpha 1 chain

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of beremagene geperpavec-svdt (Vyjuvek®); procedure code: J3401.

Description/Mechanism of Action:
Beremagene geperpavec-svdt (Vyjuvek®) is a live, replication defective, HSV-1 based vector that has been genetically modified to express the human type VII collagen (COL7) protein. Upon topical application, beremagene geperpavec-svdt can transduce both keratinocytes and fibroblasts. Following entry of beremagene geperpavec-svdt into the cells, the vector genome is deposited in the nucleus to transcribe collagen type VII alpha 1 chain (COL7A1) genes. The resulting transcription allows for production and secretion of COL7 by the cell in its mature form. These COL7 molecules arrange themselves into long, thin bundles that form anchoring fibrils, which hold the epidermis and dermis together and are essential for maintaining the integrity of the skin. Dystrophic epidermolysis bullosa (DEB) results from reduced or absent levels of COL7A1 caused by mutations in the COL7A1 gene.

FDA Approved Indications:
Beremagene geperpavec-svdt (Vyjuvek®) is a herpes-simplex virus type 1 (HSV-1) vector-based topical gene therapy indicated for the treatment of wounds in adults and pediatric patients 6 months and older with dystrophic epidermolysis bullosa (DEB).

PROCEDURE:

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Dystrophic epidermolysis bullosa (must meet all):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 6 months of age or older.
3. The client has a confirmed diagnosis of dystrophic epidermolysis bullosa (DEB) (diagnosis code Q81.2).
4. Documentation of genetic testing that confirms the client has a mutation in the collagen type VII alpha 1 chain (COL7A1) gene.
5. The client does not have current evidence or history of squamous cell carcinoma or active infection in the area requiring Vyjuvek application.
6. For female clients of childbearing age, the prescribing physician attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment with Vyjuvek.

Approval duration: 6 months

II. Continued Therapy (must meet all):

A. Dystrophic epidermolysis bullosa (must meet all):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client continues to meet all initial criteria requirements and is currently treated with no severe adverse reactions.
3. The client has experienced positive clinical response to therapy as documented by any of the following:
    a. Reduction in the number of wounds, decrease in wound size, increase in granulation tissue, and/or complete wound closure.
    b. The client has not experienced any complications while being treated with Vyjuvek.

Approval duration: 6 months

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook
Vyjuvek Prescribing Information. Pittsburgh, PA: Krystal Biotech; May 2023. Available at: https://www.krystallabel.com/pdf/vyjuvek-us-pi.pdf

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	01/01/2024
Ad hoc review	Updated II.B to II.A. Updated II.A.1. to The client continues to meet all initial criteria requirements and is currently treated with no severe	4/3/2024

	adverse reactions. Added II.A.2 to include The client has experienced positive clinical response to therapy as documented by any of the following: Reduction in the number of wounds, decrease in wound size, increase in granulation tissue, and/or complete wound closure or The client has not experienced any complications while being treated with Vyjuvek. Updated to TX.CC.PHAR format template Added Centene copyright statement Made corrections in Description and indications from Nadofaragene firadenovec (Adstiladrin to beremagene geperpavec-svdt (Vyjuvek)	
Ad hoc review	The initial criteria for female clients of childbearing age was updated as follows: The prescribing physician attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment with beremagene geperpavec-svdt (Vyjuvek)	7/17/2024