SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Vyjuvek™ (beremagene geperpavec-svdt) **(J3401) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) [NDC Unit]:

- Vyjuvek single-dose vial containing $5x10^9$ PFU/mL
- NDC: 82194-0510-02

B. Max Units (per dose and over time):

- 1 vial (2.5 mL) every 7 days
- 1 vial = 1 billable unit

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Section A: Age and wound size documentation [will define maximum weekly dose in PFUs and volume]

Age Range	Maximum Weekly Dose in plaque forming units (PFU)	Maximum Weekly Volume (mL)
6 months to < 3 years old	1.6×10^9	0.8
≥ 3 years old	3.2×10^9	1.6
Wound Area (cm^2)*	**Dose (PFU)**	**Volume (mL)**
<20	4×10^8	0.2
20 to <40	8×10^8	0.4
40 to 60	1.2×10^9	0.6
Baseline Wound Assessment: Provider please note – Member's age, wound size & calculated volume at baseline MUST be submitted with request		
❑ Member's Age: _____	❑ Wound Size: _____	❑ Calculated Required Volume: _____

*For wound area over 60 cm^2, recommend calculating the total dose based on this table until the maximum weekly dose is reached.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months (26 weeks of therapy, maximum dose of 26 billable units)

- ❑ Member is 6 months of age or older
- ❑ Member has **NOT** received a skin graft within the prior 3 months
- ❑ Provider is a specialist in dermatology, or specializes in/consulted with a specialist knowledgeable in the treatment of Dystrophic Epidermolysis Bullosa (DEB)
- ❑ Member's diagnosis of Dystrophic Epidermolysis Bullosa (DEB) has been confirmed by **BOTH** of the following:
  - ❑ Detection of mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing **(laboratory documentation must be submitted)**
  - ❑ Evidence of cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do **NOT** appear infected **(documentation must be submitted)**
- ❑ Provider documents clearly that wound sites being treated do **NOT** have any current evidence or history of squamous-cell carcinoma

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- ❑ Provider **MUST** submit member's baseline wound assessment to include body surface area location, wound size/measurements, and dosing requirements **(please refer to Section A)**
- ❑ Provider confirms a negative pregnancy test, and members of childbearing potential must use a reliable birth control method throughout the duration of treatment and for three (3) months post last dose

Reauthorization: 6 months (26 weeks of therapy, maximum dose of 26 billable units):
Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe medication reactions warranting therapy discontinuation)
- ❑ Member has experienced positive disease response with treatment as defined by improvement (healing) of treated wound sites, reduction in skin infections, etc. with the following documentation attached **[Provider please note: This criterion will outline medical necessity that the member requires continued treatment due to new or existing open wounds; see/complete Section A]**
  - ❑ Provider wound assessment to include **ALL** the following:
    - ❑ Body surface area location: _____
    - ❑ Wound size/measurements: _____
    - ❑ Dosing requirement: _____

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.