SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

Drug Requested: Vyalev™ (foscarbidopa and foslevodopa subcutaneous injection) **J7356 (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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

❑ 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.

Recommended Dosage: The maximum recommended daily dosage is 3,525 mg of the foslevodopa component (equivalent to approximately 2,500 mg levodopa)

Quantity Limit: 6 cartons every 30 days. One 10 mL vial = 480 billable units of foscarbidopa & 480 billable units of foslevodopa; 1 carton (7 vials) = 3360 billable units of foscarbidopa & 3360 billable units of foslevodopa

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: 12 months

(Continued on next page)

- ❑ Prescribed by or in consultation with a neurologist
- ❑ Member is 18 years of age or older
- ❑ Member has a diagnosis of advanced Parkinson's disease (PD) with complicated motor fluctuations
- ❑ Member does **NOT** have a diagnosis of atypical PD or secondary PD
- ❑ Member is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements
- ❑ Provider has submitted documentation which confirm member's symptoms have **NOT** been adequately controlled with optimal medical therapy using **ALL** the following agents:
  - ❑ An oral extended-release carbidopa-levodopa therapy
  - ❑ Dopamine agonist (e.g., Apokyn®, Neupro®, pramipexole, ropinirole)
  - ❑ **ONE** agent from any of the following classes:
    - ❑ Catechol-0-methyl transferase (COMT) inhibitor (e.g., entacapone, Ongentys®, tolcapone)
    - ❑ Monoamine oxidase B (MAO-B) inhibitor (e.g., rasagiline, selegiline, Xadago®)
    - ❑ Adenosine receptor antagonist (e.g., Nourianz®)
- ❑ Member is **NOT** currently taking a nonselective MAO inhibitor (such as phenelzine or tranylcypromine)

Reauthorization: 12 months. 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
- ❑ Provider has submitted documentation which confirms member has experienced clinically significant improvement or stabilization in clinical signs and symptoms of disease

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

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.****

***Approved by Pharmacy and Therapeutics Committee: 1/23/2025**
REVISED/UPDATED/REFORMATTED: ~~2/28/2025;~~ **6/13/2025**