Policy Title:	Vyalev (foscarbidopa/foslevodopa) Subcutaneous infusion		
		Department:	PHA
Effective Date:	07/01/2025		
Review Date:	5/28/25		

Purpose: To support safe, effective, and appropriate use of Vyalev (foscarbidopa/foslevodopa)

Scope: Medicaid, Commercial, Medicare

Policy Statement:
Vyalev (foscarbidopa/foslevodopa) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:
Coverage of Vyalev (foscarbidopa/foslevodopa) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:
Vyalev is a combination of foscarbidopa (an aromatic amino acid decarboxylation inhibitor) and foslevodopa (an aromatic amino acid) indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD). The efficacy of Vyalev was established in a 12-week, randomized, double-blind, double-dummy, active-controlled, multicenter study (Study 1: NCT04380142) in patients with advanced PD. A total of 141 patients who were responsive to levodopa treatment, had motor fluctuations inadequately controlled by their current medications, and had experienced a minimum of 2.5 hours of "off" time per day as assessed by PD diaries, were randomized in a 1:1 ratio to receive either 24-hour/day continuous SC administration of Vyalev plus oral placebo capsules (N=74) or 24-hour/day continuous SC administration of placebo solution plus oral encapsulated carbidopa-levodopa immediate-release (IR) tablets (N=67). The primary endpoint was the mean change from baseline to Week 12 in the total daily mean "On" time without troublesome dyskinesia based on PD diary. The key secondary clinical outcome measure was the mean change from baseline to Week 12 in the total daily mean "Off" time. The "On" and "Off" time were normalized to a daily 16-hour awake period. Daily normalized "Off" and "On" times are averaged over valid PD diary days for each visit to obtain the average daily normalized times. Compared with oral carbidopa/levodopa, Vyalev showed a significantly greater increase in "on" time without troublesome dyskinesia (model-based mean [standard error (SE)] 2.72 [0.52] vs. 0.97 [0.50] hours; difference 1.75 hours, 95% confidence interval [CI], 0.46 to 3.05; P = 0.008) and a significantly greater reduction in "off" time (−2.75 [0.50] vs. −0.96 [0.49] hours; difference −1.79 hours, 95% CI, −3.03 to −0.54; P = 0.005). Common adverse reactions caused by Vyalev include infusion/catheter site reactions (62%) and infections (28%), hallucinations (12%), and dyskinesias (11%).

Initial Criteria:

- The drug is being prescribed by, or in consultation, with a neurologist or a specialist in movement disorders; AND
- The patient is 18 years of age and older; AND
- The patient has a diagnosis of idiopathic, levodopa-responsive advanced Parkinson's Disease with clearly defined "on" periods; AND
- The patient experiences "off" periods of at least 2.5 hours per day on their current drug regimen; AND
- The patient has a presence of persistent motor fluctuations despite optimization efforts; AND
- The patient is taking ≥400 mg of levodopa per day; AND
- The patient has had an inadequate response or intolerable adverse event with at least two of the following drugs from different therapeutic classes:
    - Dopamine agonist (e.g., pramipexole, ropinirole)
    - Catechol-O-methyl transferase (COMT) inhibitor (e.g., entacapone, tolcapone)
    - Monoamine oxidase B (MAO)-B inhibitor (e.g., selegiline, rasagiline); AND
- Vyalev is administered by a portable Vyafuser pump; AND
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- The drug continues to be prescribed by or in consultation with a neurologist or a specialist in movement disorders; AND
- The patient is tolerating and responding to medication (stabilization or absence of disease progression) and there continues to be a medical need for the medication.

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:

Vyalev was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Vyalev according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 5 mg foslevodopa)
Parkinson's Disease	The continuous infusion rate is based on total levodopa dosage (TLD). The hourly base continuous infusion rate (mL/hr) = [(TLD x 1.3) / 240] / [number of hours the patient is typically awake (e.g., 16 hours)]. Vyalev may be administered over the patient's waking hours or may be administered for 24 hours. The prescribed dose will be programmed into the Vyalev Pump by a healthcare professional (HCP) and should only be changed by an HCP. The maximum recommended daily dosage is 3,525 mg of the foslevodopa component (equivalent to approximately 2,500 mg levodopa).	3,525 mg foslevodopa per day

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J7356	Injection, foscarbidopa 0.25 mg/foslevodopa 5 mg

References:

1. Vyalev [package insert]. North Chicago, IL: AbbVie Inc.; October 2024.

2. Soileau MJ, Aldred J, Budur K, et al. Safety and efficacy of continuous subcutaneous foslevodopa-foscarbidopa in patients with advanced Parkinson's disease: a randomised, double-blind, active-controlled, phase 3 trial. Lancet Neurol. 2022; Vol 21(12):1099-1109.
3. National Institute for Health and Care Excellence (NICE) guideline: Parkinson's disease in adults. Published July 19, 2017. Accessed May 22, 2025. https://www.nice.org.uk/guidance/NG71