

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2357-1
Program	Prior Authorization/Medical Necessity
Medication	Vyalev™ (foscarbidopa/foslevodopa)
P&T Approval Date	12/2024
Effective Date	3/1/2025

1. Background:

Vyalev (foscarbidopa/foslevodopa) is indicated for the treatment of motor fluctuations in patients with advanced Parkinson’s disease. Vyalev should s administered continuously, 24 hours a day, as a subcutaneous infusion with the Vyafuser pump. Patients selected for treatment with Vyalev should be capable of understanding and using the pump themselves or with assistance from a caregiver.

2. Coverage Criteria ^a:

<p>A. <u>Initial Authorization</u></p> <p>1. Vyalev will be approved based on all of the following criteria:</p> <ul style="list-style-type: none"> a. Diagnosis of advanced Parkinson’s disease <p style="text-align: center;">-AND-</p> <ul style="list-style-type: none"> b. Patient has inadequately controlled motor fluctuations despite being treated with optimized oral therapies (e.g. levodopa) <p style="text-align: center;">-AND-</p> <ul style="list-style-type: none"> c. Prescribed by or in consultation with a neurologist <p>Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Vyalev will be approved based on the following criterion:</p> <ul style="list-style-type: none"> a. Documentation of positive clinical response to Vyalev therapy demonstrated by an increase in “On” time without troublesome dyskinesia. <p>Authorization will be issued for 12 months.</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Vyalev [package insert]. North Chicago, IL: AbbVie, Inc.; October 2024.
2. International Parkinson and Movement Disorder Society Evidence-Based Medicine Review: Update on Treatments for the Motor Symptoms of Parkinson's Disease. *Movement Disorders*. 2018.

Program	Prior Authorization/Medical Necessity - Vyalev
Change Control	
Date	Change
12/2024	New program.