MEDICAL MUTUAL®

Drug Policy

Policy:	**20250320**	**Initial Effective Date:** **03/20/2025**
Code(s):	**HCPCS J3490, J3590 or J9999**	**Annual Review Date:** **03/20/2025**
SUBJECT:	Vyalev™ (foscarbidopa and foslevodopa subcutaneous injection – AbbVie)	**Last Revised Date:** **03/20/2025**

☐Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Vyalev, a combination continuous subcutaneous infusion of foscarbidopa and foslevodopa, is indicated for the treatment of motor fluctuations in adults with advanced **Parkinson's disease**.[1]

POLICY STATEMENT

This policy involves the use of Vyalev. Prior authorization is recommended for pharmacy and medical benefit coverage of Vyalev. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Vyalev as well as the monitoring required for AEs and long-term efficacy, initial approval requires Vyalev be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vyalev is recommended in those who meet the following criteria:

1. **Parkinson's Disease, Initial Therapy.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is diagnosed with advanced Parkinson's disease; AND
   - **B)** Patient is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND

C) Patient has an average "off" time of at least 2.5 hours per day; AND
D) Patient has tried Crexont OR Rytary (carbidopa-levodopa extended-release capsules)* and meets ONE of the following (i or ii):
  i. Patient had significant intolerance, according to the prescriber; OR
  ii. Patient had inadequate efficacy, according to the prescriber; AND
E) Patient has previously tried or is currently receiving ONE other treatment for "off" episodes*; AND
Note: Examples of treatment for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Ongentys (opicapone capsules), or Xadago (safinamide tablets).
F) The medication is prescribed by or in consultation with a neurologist.

2. **Parkinson's Disease, Continuation of Therapy.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is diagnosed with advanced Parkinson's disease; AND
B) Patient has tried Crexont OR Rytary (carbidopa-levodopa extended-release capsules)* and meets ONE of the following (i or ii):
  i. Patient had significant intolerance, according to the prescriber; OR
  ii. Patient had inadequate efficacy, according to the prescriber; AND
C) Patient has previously tried or currently receiving ONE other treatment for "off" episodes*; AND
Note: Examples of treatment for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Ongentys (opicapone capsules), or Xadago (safinamide tablets).
D) The medication is prescribed by or in consultation with a neurologist.
E) There is clinically significant improvement or stabilization in clinical signs and symptoms of disease defined as an increase of on-time with a decrease in the number of off episodes compared to baseline*.

Dosing in Vyalev. *Dosing must meet the following:*
VYALEV (foscarbidopa and foslevodopa) is administered as a subcutaneous infusion with the VYAFUSER pump.

VYALEV Base Continuous Dosage and Hourly Infusion Rate
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)], as shown in the steps below.

Step 1: Calculate the TLD for the levodopa-containing medications that VYALEV is replacing. All dosages should be converted to the equivalent dosage of immediate-release levodopa to obtain the TLD. Prescribers should adjust the total dose of levodopa-containing products for COMT inhibitor use. See the Prescribing Information for the respective drugs for conversions or adjustments. Do not include rescue or as needed levodopa or any other anti-Parkinsonian medication or therapy, including medications taken outside of awake time (e.g., night-time dosing) in this calculation.

Step 2: Determine the total daily dosage (mg) of VYALEV foslevodopa component by multiplying the TLD by 1.3. The conversion factor takes into account the molecular weight and bioavailability of foslevodopa compared to levodopa.

Step 3: Determine the total daily volume (mL) of VYALEV by dividing the total daily dosage (mg) of VYALEV by 240. Each 1 mL of VYALEV contains 240 mg of foslevodopa.

Step 4: Determine the hourly base continuous infusion rate of VYALEV by dividing the total daily volume (mL) of VYALEV by the 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. See Dosage and Administration (2.3) for adjustment of and alternate infusion rates for lower overnight dosages.

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

Optional Loading Dose
If VYALEV therapy is being initiated in an "Off" state or the patient has not been receiving their base continuous infusion for more than 3 hours, a loading dose can be administered immediately prior to starting or re-starting the base continuous hourly infusion. Loading doses can be administered either with VYALEV or patients can continue using oral immediate-release carbidopa/levodopa tablets. The loading dose should be calculated from the first morning dose of oral immediate release carbidopa/levodopa the patient took before starting treatment with VYALEV. If VYALEV is used for the loading dose, multiply the first morning dose of oral immediate release levodopa by 1.3 and divide by 240 to determine the loading dose of VYALEV.

The pump is capable of delivering a loading dose ranging from 0.1 mL to a maximum of 3 mL, in increments of 0.1 mL.

Extra Dose
An extra dose volume can be programmed to 1 of 5 options (see Table 1). The "extra dose" feature is limited to no more than 1 extra dose per hour. If 2 or more extra doses are used by the patient during the 24-hour/day treatment period, a revision of the base continuous infusion rate should be considered (refer to the Healthcare Professional Instructions for Use of VYAFUSER Pump details).

Table 1. Extra Dose Option for VYALEV

VYALEV extra dose volume	Approximate equivalent levodopa dose*
0.1 mL	17 mg
0.15 mL	25.5 mg
0.2 mL	34 mg
0.25 mL	42.5mg
0.3 mL	51 mg

*See Step 1

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vyalev has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vyalev™ subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; October 2024.
2. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord*. 2018;33(8):1248-1266.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3490 and J3590 or J9999

†When *unclassified drugs* (J3490) or *unclassified biologics* (J3590) or *unclassified antineoplastics* (J9999) is determined to be Vyalev

Edits and Denials:

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Prior approval: Prior approval is required for Vyalev **(HCPCS Codes J3490 , J3590, J9999)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3490, J3590, J9999** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3490	Unclassified drugs
J3590	Unclassified biologics
J9999	Unclassified antineoplastics