# Drug Coverage Policy

**Effective Date……04/15/2025**
**Coverage Policy Number……IP0717**
**Policy Title……Vyalev**

# Parkinson's Disease – Vyalev

- Vyalev™ (foscarbidopa and foslevodopa subcutaneous injection – AbbVie)

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

**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]

**Guidelines**
The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018).[2] The review categorically divides treatment recommendations by Parkinson's disease characteristics. Vyalev is not addressed in current guidelines.

**Clinical Efficacy**
The efficacy of Vyalev for the treatment of motor fluctuations in adults with advanced Parkinson's disease has been evaluated in one pivotal study.[1,3] The study included patients ≥ 30 years of age with idiopathic and levodopa-responsive Parkinson's Disease. An open-label trial followed patients for up to 52 weeks.[4] The primary efficacy endpoint evaluated changes from baseline in normalized "off" and "on" time and the percentage of patients reporting morning akinesias.

## Coverage Policy

**Policy Statement**
Prior Authorization is required for medical benefit coverage of Vyalev. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vyalev as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Vyalev to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Vyalev is considered medically necessary when the following are met:**

**FDA-Approved Indication**

1. **Parkinson's Disease.** 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 is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND
   - **C)** Patient has tried an oral carbidopa/levodopa therapy 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
   - **D)** 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).
   - **E)** The medication is prescribed by or in consultation with a neurologist.

   **Dosing.** Approve up to 3,525 mg foslevodopa (equivalent to approximately 2,500 mg levodopa) every day.

**Vyalev for any other use is considered not medically necessary. Criteria will be updated as new published data are available.**

## Coding Information

**Note:** 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

| HCPCS Codes | Description |
|---|---|
| J3490 | Unclassified drugs (Effective until 6/30/2025) |
| J7356 | Injection, foscarbidopa 0.25 mg/foslevodopa 5 mg (Effective Date 7/1/2025) |

## 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.
3. 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;21(12):1099-1109.
4. Aldred J, Freire-Alvarez E, Amelin AV, et al. Continuous subcutaneous foslevodopa/foscarbidopa in Parkinson's disease: safety and efficacy results from a 12-month, single-arm, open-label, phase 3 study. *Neurol Ther*. 2023;12(6):1937-1958.


## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| New | New policy | 04/15/2025 |
| Selected Revision | **Updated HCPCS Coding**<br><br>**Added** HCPCS code:<br>• J7356 (Codes Effective 7/1/2025)<br><br>**Updated** the description for J3490 to include the note "Code effective until 6/30/2025 | 4/15/2025 |

The policy effective date is in force until updated or retired.