

## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Parkinson's Disease – Vyalev Utilization Management Medical Policy

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

**REVIEW DATE:** 03/25/2026

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### 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**.<sup>1</sup>

### Guidelines

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018); an update specific to motor fluctuations was published in 2025.<sup>2,3</sup> In the 2025 update, subcutaneous infusion of levodopa was regarded as likely efficacious for treatment of motor fluctuations.

### POLICY STATEMENT

Prior Authorization is recommended 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, approval requires Vyalev to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

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

#### FDA-Approved Indication

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- 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; AND  
Note: Examples of "off" episodes include muscle stiffness, slow movements, or difficulty starting movements.
  - 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 is currently receiving ONE other treatment for "off" episodes; AND  
Note: Examples of treatment for "off" episodes include pramipexole, ropinirole, Neupro (rotigotine transdermal system), apomorphine, selegiline, rasagiline, Xadago (safinamide tablets),

tolcapone, entacapone, Ongentys (opicapone capsules), Nourianz (istradefylline tablets), or amantadine.

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) administered subcutaneously every day.

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### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vyalev is not recommended in the following situations:

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

### 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. de Bie RMA, Katzenschlager R, Swinnen BEKS, et al. Update on treatments for Parkinson's Disease motor fluctuations – an International Parkinson and Movement Disorder Society Evidence-Based Medicine Review. *Mov Disord.* 2025 May;40(5):776-794.

### HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/30/2024
Annual Revision	No criteria changes	10/22/2025
Early Annual Revision	<b>Policy Statement:</b> In the statement “approval requires Vyalev to be prescribed by or in consultation with a physician who specializes in the condition being treated”, the preceding word “initial” was removed to clarify that all approvals (initial and reauthorization) require that Vyalev is prescribed by or in consultation with a specialist. <b>Parkinson’s Disease:</b> Examples of off episodes were moved to a Note. The list of examples of treatments for Parkinson’s disease off episodes was updated to remove cabergoline and to add Neupro (rotigotine transdermal system), apomorphine, Nourianz (istradefylline tablets), and amantadine.	03/25/2026