

foscarbidopa and foslevodopa (Vyalev)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Administration

Drug Details

USP Category: ANTI-PARKINSON AGENTS

Mechanism of Action: Prodrug combination of carbidopa and levodopa

HCPCS:

J7356: Injection, foscarbidopa 0.25 mg/foslevodopa 5 mg

How Supplied:

120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL (single dose glass vial)

Condition(s) listed in policy (see coverage criteria for details)

- Parkinson's Disease (PD), advanced

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Parkinson's Disease (PD), advanced

Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a neurologist
2. Patient has motor fluctuations inadequately controlled by current medications, including BOTH of the following:
 - a. Oral carbidopa/levodopa
 - b. ONE of the following:
 - i. COMT inhibitor
 - ii. Dopamine agonist
 - iii. MAO-B inhibitor
 - iv. Amantadine

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Effective: 07/01/2025

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Covered Doses:

Up to 3,525 mg of the foslevodopa component (equivalent to approximately 2,500 mg levodopa) given as a subcutaneous 24-hour infusion with the Vyafuser pump.

Coverage Period:

Initial: 3 months

Reauthorization: Yearly if meets the below

1. Patient has a clinical response (e.g., experiences less "off" time)
2. Dose does not exceed the FDA-approved maximum

ICD-10:

G20.A2, G20.B1, G20.B2

References

1. Vyalev (foscarnet and foslevodopa). Prescribing Information. AbbVie Inc., North Chicago, IL: 10/2024.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- HCPCS: Added J7356, effective 7/1/2025.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee