

Reference number(s)
6700-A

Specialty Guideline Management

Vyalev

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vyalev	foscarbidopa/foslevodopa

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Vyalev is indicated for the treatment of motor fluctuations in adults with advanced Parkinson’s disease (PD).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization for review:

Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

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Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist or a specialist in the treatment of Parkinson's disease.

Coverage Criteria

Parkinson's Disease¹⁻³

Authorization of 12 months may be granted for treatment of motor fluctuations in members with advanced Parkinson's disease when all of the following criteria are met:

- The member is levodopa responsive with clearly defined "on" periods.
- The member has "off" periods of at least 2.5 hours per day despite optimization efforts.
- The member must have had an inadequate response or intolerable adverse event with oral carbidopa/levodopa and one of the following anti-Parkinson agents:
 - Dopamine agonist (e.g., pramipexole, ropinirole)
 - Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline)
 - Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone)

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for advanced Parkinson's disease who have demonstrated a positive clinical response with the requested medication.

References

1. Vyalev [package insert]. North Chicago, IL: AbbVie Inc.; October 2024.
2. 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; (12):1099-1109. doi: 10.1016/S1474-4422(22)00400-8
3. National Institute for Health and Care Excellence (NICE) guideline: Parkinson's disease in adults. Published July 19, 2017. Accessed October 25, 2024. <https://www.nice.org.uk/guidance/ng71/resources/parkinsons-disease-in-adults-pdf-1837629189061>.