Reference number(s)
6716-A

Standard Medicare Part B 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 Indications

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Parkinson's Disease

Authorization of 6 months may be granted for treatment of motor fluctuations in members with advanced Parkinson's disease when all of the following criteria are met:

- 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)

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- Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline)
- Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone)

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Vyalev.
- Vyalev is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Vyalev.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- Safety and efficacy of continuous subcutaneous foslevodopa-foscarbidopa in patients with advanced Parkinson's disease: a randomised, double-blind, active-controlled, phase 3 trial
- 2017 National Institute for Health and Care Excellence (NICE) guideline: Parkinson's disease in adults

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Vyalev are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Vyalev for treatment of motor fluctuations in advanced Parkinson's disease can be found in a 12-week randomized, double-blind, active-controlled, phase 3 trial by Soileau et al. Patients with

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levodopa-responsive advanced Parkinson’s disease inadequately controlled on current therapy, including at least 2.5 hours of average daily “off” time, were randomly assigned (1:1) to continuous subcutaneous infusion of foslevodopa-foscarbidopa plus oral placebo or to oral immediate-release levodopa/carbidopa plus continuous subcutaneous infusion of placebo solution. During the oral levodopa-carbidopa stabilization period prior to the double-blind treatment period, all levodopa-containing medications and COMT inhibitors were converted to an equivalent amount of immediate-release levodopa/carbidopa. Non-levodopa-containing concomitant Parkinson’s disease medications (e.g., dopamine agonists, MAO-B inhibitors, and amantadine) were not included in the conversion algorithm and were allowed during the study but regimens had to remain unchanged until study completion. Compared with levodopa/carbidopa, foslevodopa/foscarbidopa showed a significantly greater increase in on time without troublesome dyskinesia.

The 2017 NICE guideline for Parkinson’s disease in adults provides recommendations for pharmacological management of motor symptoms. It is recommended to offer levodopa as first-line treatment to people in the early stages of Parkinson's disease whose motor symptoms impact their quality of life. A choice of dopamine agonists, levodopa, or MAO-B inhibitors may be considered for people in the early stages of Parkinson's disease whose motor symptoms do not impact on their quality of life. For people with Parkinson's disease who have developed dyskinesia or motor fluctuations despite optimal levodopa therapy, it is recommended to offer a choice of dopamine agonists, MAO-B inhibitors, or COMT inhibitors as an adjunct to levodopa.

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.

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