CVS Caremark®

| 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 Indications

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

## 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)
  + 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.