



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Vyalev

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Effective Date: 1/29/2025

Last Review Date: 12/6/2024

Applies to: Illinois New Jersey Maryland Florida Kids
 Pennsylvania Kids Virginia Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Vyalev under the patient's prescription drug benefit.

Description:

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

Applicable Drug List:

Vyalev

Policy/Guideline:

Initial 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 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.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:

12 mg/240 mg per mL (10 mL single-dose vial): 56 vials per 30 days

References:

1. Vyalev [package insert]. North Chicago, IL: AbbVie Inc.; October 2024.



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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>.