



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Vyalev

Page: 1 of 2

Effective Date: 3/23/2026

Last Review Date: 2/6/2026

Applies to: Illinois
 Florida Kids

New Jersey
 Pennsylvania Kids

Maryland
 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).

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

Applicable Drug List:

Vyalev

Policy/Guideline:

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.

Prescriber Specialties

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

Initial Coverage Criteria

Parkinson's Disease

Authorization of 12 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)



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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.
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>.