Utilization Review Policy 353

POLICY: Parkinson's Disease – Vyalev Utilization Management Medical Policy
- Vyalev™ (foscarbidopa and foslevodopa subcutaneous injection – AbbVie)

EFFECTIVE DATE: 2/1/2025
LAST REVISION DATE: 10/30/2024

COVERAGE CRITERIA FOR: All Aspirus Plans

OVERVIEW

Vyalev, a combination continuous subcutaneous infusion of foscarbidopa and foslevodopa, is indicated for the treatment of motor fluctuations in adults with advanced **Parkinson's disease**.[1]

Guidelines

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018).[2] The review categorically divides treatment recommendations by Parkinson's disease characteristics. Vyalev is not addressed in current guidelines.

Clinical Efficacy

The efficacy of Vyalev for the treatment of motor fluctuations in adults with advanced Parkinson's disease has been evaluated in one pivotal study.[1,3] The study included patients ≥ 30 years of age with idiopathic and levodopa-responsive Parkinson's Disease. An open-label trial followed patients for up to 52 weeks.[4] The primary efficacy endpoint evaluated changes from baseline in normalized "off" and "on" time and the percentage of patients reporting morning akinesias.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Vyalev. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vyalev as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Vyalev to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vyalev is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Parkinson's Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is diagnosed with advanced Parkinson's disease; AND
   - **B)** Patient is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND
   - **C)** Patient has tried an oral carbidopa/levodopa therapy and meets ONE of the following (i or ii):
     - **i.** Patient had significant intolerance, according to the prescriber; OR
     - **ii.** Patient had inadequate efficacy, according to the prescriber; AND
   - **D)** Patient has previously tried or currently receiving ONE other treatment for "off" episodes; AND

     Note: Examples of treatment for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Ongentys (opicapone capsules), or Xadago (safinamide tablets).
   - **E)** The medication is prescribed by or in consultation with a neurologist.

   Dosing. Approve up to 3,525 mg foslevodopa (equivalent to approximately 2,500 mg levodopa) every day.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vyalev is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vyalev™ subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; October 2024.
2. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord*. 2018;33(8):1248-1266.
3. 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;21(12):1099-1109.

4. Aldred J, Freire-Alvarez E, Amelin AV, et al. Continuous subcutaneous foslevodopa/foscarbidopa in Parkinson's disease: safety and efficacy results from a 12-month, single-arm, open-label, phase 3 study. *Neurol Ther*. 2023;12(6):1937-1958.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/30/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	12/16/2024