VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Vyalev Prior Authorization Policy
- Vyalev™ (foscarbidopa and foslevodopa subcutaneous injection – AbbVie)

REVIEW DATE: 10/30/2024

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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vyalev. 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, 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.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/30/2024