



## PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 03/25/2026

### **INSTRUCTIONS FOR USE**

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

### **CIGNA NATIONAL FORMULARY COVERAGE:**

#### **OVERVIEW**

Vyalev, a combination continuous subcutaneous infusion of foscarnidopa and foslevodopa, is indicated for the treatment of motor fluctuations in adults with advanced **Parkinson's disease**.<sup>1</sup>

#### **Guidelines**

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018); an update specific to motor fluctuations was published in 2025.<sup>2,3</sup> In the 2025 update, subcutaneous infusion of levodopa was regarded as likely efficacious for treatment of motor fluctuations.

#### **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.

- **Vyalev™ (foscarbidopa and foslevodopa subcutaneous injection – AbbVie)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### **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; AND  
Note: Examples of “off” episodes include muscle stiffness, slow movements, or difficulty starting movements.
  - 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 is currently receiving ONE other treatment for “off” episodes; AND  
Note: Examples of treatment for “off” episodes include pramipexole, ropinirole, Neupro (rotigotine transdermal system), apomorphine, selegiline, rasagiline, Xadago (safinamide tablets), tolcapone, entacapone, Ongentys (opicapone capsules), Nourianz (istradefylline tablets), or amantadine.
  - E)** The medication is prescribed by or in consultation with a neurologist.

### **CONDITIONS NOT COVERED**

- **Vyalev™ (foscarbidopa and foslevodopa subcutaneous injection – AbbVie)**

**is(are) considered not medically necessary for ANY other use(s); 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. de Bie RMA, Katzenschlager R, Swinnen BEKS, et al. Update on treatments for Parkinson's Disease motor fluctuations – an International Parkinson and Movement Disorder Society Evidence-Based Medicine Review. *Mov Disord.* 2025 May;40(5):776-794.

## HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/30/2024
Annual Revision	No criteria changes	10/22/2025
Early Annual Revision	<b>Parkinson's Disease:</b> Examples of off episodes were moved to a Note. The list of examples of treatments for Parkinson's disease off episodes was updated to remove cabergoline and to add Neupro (rotigotine transdermal system), apomorphine, Nourianz (istradefylline tablets), and amantadine.	03/25/2026

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