VYALEV® COMPLETE

GUIDE TO PRIOR AUTHORIZATIONS

Navigating coverage requirements for VYALEV®

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use
12 mg/240 mg per mL

INDICATION

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

SAFETY CONSIDERATIONS

VYALEV is **contraindicated** in patients who currently take or have taken (within 2 weeks) a nonselective monoamine oxidase (MAO) inhibitor, as concurrent use can cause hypertension. VYALEV may cause **sudden falling asleep** during daily activities and somnolence; **hallucinations/psychosis**; compulsive behavior or **lack of impulse control**; **infusion site reactions and infections**; **withdrawal-emergent hyperpyrexia** and confusion; **dyskinesia**; **vitamin B6 deficiency and seizures**; **cardiovascular ischemic events**; or worsening **glaucoma**.

The **most common adverse reactions** for VYALEV (VYALEV incidence at least 10% and greater than oral carbidopa/levodopa incidence) were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, and dyskinesia.

This is for informational purposes only and is not intended to provide reimbursement or legal advice.
The information presented here does not guarantee payment or coverage.

Please see additional Important Safety Information for VYALEV® on page 4.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

UNDERSTAND VYALEV® PRIOR AUTHORIZATION (PA) REQUIREMENTS

Some commercial insurance plans may require a PA before agreeing to cover VYALEV®. To help you with verifying this, VYALEV® Complete can perform a benefit verification (BV) to determine PA requirements per plan.

NOTE: It is important to be thorough and accurate when filling out the PA form to prevent unnecessary delays in treatment initiation.

PA requirements can vary by plan, but coverage consideration criteria often include:

- Parkinson's disease diagnosis with presence of bradykinesia and at least 1 of the following: tremor, rigidity, and postural instability
- Duration of patient's condition
- Clinical course (eg, worsening or improving) and prognosis
- Patient responsiveness to levodopa with clearly defined "on" periods
- Motor fluctuations as documented with "off" periods for a minimum of 2.5 hours/day despite current medical therapy
- Other therapeutic interventions used and the results
- Concomitant medications unrelated to Parkinson's disease

Contact your VYALEV® Complete Field Reimbursement Manager for questions about PA requirements at 1-866-4VYALEV (1-866-489-2538).

PA requirements may vary by payer, so check with your patient's health plan for an accurate list of requirements before submitting the request.

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SUBMITTING PA REQUESTS

Here are some suggested best practices when submitting a PA request with a payer.

When submitting a PA request, be sure to:

- Verify the patient's insurance has not changed
- Confirm that you have the required payer-specific form and any relevant documentation, such as:
  - Past diagnostic information
  - Patient medical records
  - A letter of medical necessity, if required
- Complete all sections of the PA form
- Submit the PA form through the appropriate channel (phone, fax, email, payer's website, etc)
- Adhere to the timeline of the PA process
- Inquire about the timing of the process once the request is submitted, and update your patient on the request status

Tips to keep track of the PA process:

1. **Log the date and time of calls,** who you spoke with, and their contact information.
2. **Keep a copy** of all PA documentation.
3. **Follow up with the payer** if your facility does not receive notification of the decision in a timely manner.
4. **Record the PA approval code and date** in the patient's medical record.

For VYALEV® access and reimbursement questions, call your VYALEV® Complete Field Reimbursement Manager at 1-866-4VYALEV (1-866-489-2538).

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IMPORTANT SAFETY INFORMATION

Contraindications

VYALEV® (foscarbidopa/foslevodopa) is contraindicated in patients who are currently taking or have taken (within 2 weeks) a nonselective monoamine oxidase (MAO) inhibitor, as concurrent use can cause hypertension.

Warnings and Precautions

Falling Asleep During Activities of Daily Living and Somnolence: Patients treated with levodopa (the active metabolite of VYALEV) have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes resulted in accidents. Although many of these patients reported somnolence while on levodopa, some perceived that they had no warning signs, such as excessive drowsiness, and believed they were alert immediately prior to the event (sleep attack). Some of these events have been reported more than one year after initiation of treatment. For this reason, prescribers should continually assess VYALEV-treated patients for drowsiness or sleepiness. Advise patients about the potential to develop drowsiness with VYALEV and ask about factors that may increase risk of somnolence. Consider discontinuing VYALEV in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation. If VYALEV is continued, patients should be advised not to drive and to avoid other potentially dangerous activities that might result in harm if the patient becomes somnolent. There is insufficient information to establish that dose reduction will eliminate episodes of falling asleep while engaged in activities of daily living.

Hallucinations/Psychosis: There is an increased risk for hallucinations and psychosis in patients taking VYALEV. Hallucinations associated with levodopa may present shortly after the initiation of therapy and may be responsive to dose reduction of VYALEV or other concomitantly administered medications. Patients with a major psychotic disorder should not be treated with VYALEV.

Impulse Control/Compulsive Behaviors: Patients may experience intense urges while on VYALEV. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while on VYALEV. Consider reducing the dose or discontinuing VYALEV if a patient develops such urges.

Infusion Site Reactions and Infections: VYALEV can cause infusion site reactions and infections. Various types of reactions at the infusion site have been reported, including erythema, pain, edema, nodules, warmth, swelling, and others. The most frequent infusion site infection reported was cellulitis. If an infection is suspected at the infusion site, the cannula should be removed. In such a case, either a new cannula should be placed at a new infusion site or, in the event of a prolonged interruption, prescribe an oral carbidopa/levodopa product until the patient is able to resume VYALEV.

Withdrawal-emergent hyperpyrexia and confusion, a symptom complex that resembles neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction, withdrawal, or change in dopaminergic therapy. Avoid sudden discontinuation or rapid dose reduction of VYALEV.

Dyskinesia: VYALEV may cause or exacerbate dyskinesias, which may require a dose reduction of VYALEV or other medicines used to treat Parkinson's disease.

Vitamin B6 Deficiency and Seizures: Treatment with carbidopa/levodopa (the active metabolites of VYALEV) may contribute to reduced vitamin B6 levels and higher doses of carbidopa/levodopa may increase the risk. Seizures associated with vitamin B6 deficiency have been reported in patients taking carbidopa/levodopa. Evaluate vitamin B6 levels prior to initiation of VYALEV and during treatment or if symptoms of vitamin B6 deficiency are identified and supplement with vitamin B6 as necessary.

Cardiovascular Ischemic Events: Myocardial infarction and arrhythmia were reported in patients taking carbidopa/levodopa (the active metabolites of VYALEV). Ask patients about symptoms of ischemic heart disease and arrhythmia, especially those with a history of myocardial infarction or cardiac arrhythmias.

Glaucoma: Monitor patients with glaucoma after starting VYALEV as it may cause increased intraocular pressure.

Adverse Reactions

The most common adverse reactions for VYALEV that occurred in ≥3% of patients, and at least 2% difference from oral immediate-release carbidopa/levodopa, were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, dyskinesia, On and Off phenomenon, balance disorder, constipation, peripheral swelling, agitation, insomnia, psychotic disorder, and dyspnea.

Drug Interactions

- The use of nonselective MAO inhibitors is contraindicated. Use of selective MAO-B inhibitors may be associated with orthostatic hypotension.
- Concurrent administration with antihypertensives can cause symptomatic postural hypotension, which may require a dose adjustment of the antihypertensive.
- Coadministration with dopamine D2 antagonists or isoniazid may reduce the effectiveness of VYALEV.

Dosage Forms and Strengths

VYALEV (foscarbidopa and foslevodopa) injection for subcutaneous use is available in a 120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL (12 mg foscarbidopa and 240 mg foslevodopa per mL) solution.

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US-VYAL-260143 April 2026 034784

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