VYALEV® COMPLETE

DO YOU KNOW YOUR VYALEV® Field Reimbursement Manager?

Now that you've made the decision to treat a patient who has advanced Parkinson's Disease with VYALEV®, your FRM can provide education to support a more seamless access experience.

- **Access Requirements**
- **Enrollment and Prescription Processing**
- **Specialty Pharmacy**
- **Start Day and Follow-Ups**

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.

Please see additional Important Safety Information on pages 6 and 7.

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

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

VYALEV®

Get to know your FRM

Access Requirements → Enrollment and Prescription Processing → Specialty Pharmacy → Start Day and Follow-Ups

DID YOU KNOW missing documentation details are a primary reason for delays, denials, and treatment interruptions?

A patient has been identified for VYALEV® treatment. Now it's time to review payer criteria and **billing and coding guidelines** to **document diagnosis** and **medical necessity**, gather **clinical notes**, and complete the **VYALEV® enrollment form**.

Each step is crucial—and missing details can lead to **delays**, **denials**, and **treatment interruptions**.

Your FRM is the go-to expert for providing educational support for:

Payer access and policy requirements, diagnosis and procedure coding criteria, and documentation of **medical necessity**, to help you navigate **prior authorization** and **treatment approval processes**.

Connect with your FRM for education and resources on VYALEV® patient access requirements.

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VYALEV®

Get to know your FRM

Access Requirements → **Enrollment and Prescription Processing** → Specialty Pharmacy → Start Day and Follow-Ups

DID YOU KNOW every VYALEV® prescription requires VYALEV® Complete enrollment, drug and pump orders, and specialty pharmacy coordination?

Once VYALEV® Complete enrollment has been initiated, the next step is to **ensure prescriptions** are processed through a **Limited Distribution Network (LDN)** and fulfilled with a designated specialty pharmacy. **Missing steps in this process can lead to fulfillment and patient treatment delays.**

Your FRM can help you navigate this process by:

Providing education and resources on the VYALEV® enrollment and **specialty pharmacy processes** to help support **timely patient access**.

Connect with your FRM for education and resources to help navigate patient access for VYALEV®.

SAFETY CONSIDERATIONS

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Get to know your FRM

Access Requirements → Enrollment and Prescription Processing → **Specialty Pharmacy** → Start Day and Follow-Ups

DID YOU KNOW VYALEV® prescriptions are fulfilled through a Limited Distribution Network (LDN) specialty pharmacy?

Once your patient's VYALEV® prescription reaches the specialty pharmacy, the specialty pharmacy is responsible for **several important next steps**:

- Confirming coverage and securing treatment approval
- Providing financial assistance information if applicable
- Collecting payment
- Preparing the medication and pump
- Coordinating with the patient for their consent on delivery details

Your FRM is here to provide education and resources to help your office navigate the specialty pharmacy process.

Your FRM can **provide education to help your office understand and navigate** interactions and coordination with the LDN specialty pharmacy.

Contact your FRM to find out how the identified specialty pharmacy works within the VYALEV® LDN.

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Access Requirements → Enrollment and Prescription Processing → Specialty Pharmacy → **Start Day and Follow-Ups**

DID YOU KNOW VYALEV® and its pump are typically delivered to your patient's home, and should be brought to the office on their start day?

In preparing for the VYALEV® treatment start day, **your FRM can educate your office on the following**:

- Coordination with your patient on start day appointment, following delivery of medication and pump and Nurse Ambassador* education visit
- Connecting with your VYALEV® Account Executive on start day
- Planning follow-up appointments with your patient post-treatment start

A missed step can disrupt the patient's start day.

Your FRM is here to educate you on Start Day preparation.

Your FRM can offer education and resources to help your office prepare for patient **start days, to support timely access to treatment**.

Reach out to your FRM for education and support to help your office prepare for patient start days.

*Nurse Ambassadors are provided by AbbVie and do not provide medical advice or work under the direction of the prescribing healthcare professional (HCP). They are trained to direct patients to speak with their HCP about any treatment-related questions, including referrals.

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foscarbidopa/foslevodopa
Injection for subcutaneous use

INDICATION AND IMPORTANT SAFETY INFORMATION

FOR VYALEV® (foscarbidopa/foslevodopa)

INDICATION

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

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.

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IMPORTANT SAFETY INFORMATION (continued)

FOR VYALEV® (foscarbidopa/foslevodopa)

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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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Injection for subcutaneous use

Did you know your Field Reimbursement Manager (FRM) is your dedicated partner for VYALEV® access and reimbursement education and support?

Your FRM is your go-to expert for education and resources on payer criteria, and VYALEV® acquisition and fulfillment processes.

FRMs are VYALEV® access and reimbursement **subject matter experts** who offer in-person or virtual education and resources on payer criteria, **treatment approval processes**, documentation requirements, **product-specific acquisition**, and remittance.

If you have questions about clinical matters related to VYALEV®, please reach out to your Parkinson's Sales Professional for assistance.

Get to know your FRM and how they can support a seamless VYALEV® access and reimbursement journey.

To get started, contact your FRM today.

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