



# Instruction Guide for VYALEV Complete VYALEV™ COMPLETE Enrollment and Prescription Form

This page and the following sample Enrollment and Prescription form will guide you to provide all of the necessary details for a complete submission.

**Incomplete submissions of the VYALEV Enrollment and Prescription Form may delay getting your patient started on VYALEV.**

## Complete the VYALEV Enrollment and Prescription Form

- Patient name, address, phone, email, including authorized caregiver’s name and phone number
- Patient insurance information, including secondary and tertiary insurance information
- Consent form signed and dated by the patient
- Patient selection of their preferred specialty pharmacy
  - NOTE: If the insurance plan mandates a specific pharmacy, that pharmacy will be used instead
- If the patient resides in a facility, provide the facility’s information (e.g., facility name, address, contact, phone number)
- Healthcare provider name, address, and phone number
- Include healthcare provider name, address, NPI, signature, and date, where indicated
- Prescription details, including:
  - ICD-10 code
  - Pharmacy instructions (i.e., SIG codes)
  - Pump dose settings (base rate, high rate, low rate) and optional dose settings (extra dose and loading dose)
  - Minimum number of vials per month
  - Pump lockout times
  - Preferred cannula length (6 mm vs 9 mm)
  - Separate or alternative prescription, per state laws
- Select the “Patient Delivery System Training” option if the patient would benefit from it
  - This action is recommended to avoid additional outreach and delays
- Hand-written patient and prescriber signatures (stamp and digital signatures are not allowed)

**Additionally, refer to page 1 of the enrollment form for the minimum medical documentation required to be submitted.**

## Common missing information that can cause treatment delays includes:

- Incomplete chart notes (e.g., missing explicit notations documenting patient is levodopa-responsive and specifying total daily hours of off-time)
- Missing ICD-10 code to confirm diagnosis
- Incomplete checkbox selecting programmed or unprogrammed pump in the prescription

**If information is missing, a representative from the specialty pharmacy and/or VYALEV Complete will contact you to obtain the necessary information. Incomplete submissions of the VYALEV Enrollment and Prescription Form may delay patient’s therapy start.**

**If you have specific questions regarding clinical documentation requirements, contact the specialty pharmacy selected by your patient or specified by their insurance. Below are the phone numbers and phone tree menu options to reach a representative at participating specialty pharmacies:**

Specialty Pharmacy	Phone Number	Phone Tree Menu Options
Acaria Health	800-511-5144	N/A
Accredo	888-200-2811	Option 2, then option 3
CVS Specialty	877-437-8469	Option 2
Pharmacy Solutions	877-648-3738	Option 2



**VYALEV™**  
foscariodopa/foslevodopa  
Injection for subcutaneous use  
12 mg/240 mg per mL

# Sample

## VYALEV Enrollment and Prescription Form

VYALEV™ COMPLETE

VYALEV™ COMPLETE  
**Enrollment and Prescription Form**

VAP-090825-A09

Fax: 1-888-953-2762  
Call with questions: 1-866-489-2538

**Patient Information**

Patient Name: John Doe  
First Last  
Date of Birth: April / 17 / 1964  
Month Date Year

**Prescriber Contact Information**

Name: Susan Barber  
Phone #: 555-917-7262

**Important NOTE to Prescribers**

Help smooth the prescription process and reduce callbacks to your office by providing the required information.

**This form cannot be processed unless you submit the minimum documentation.** Requirements for coverage, including minimum documentation, may vary by payer. Updates by the prescriber may be needed if patient history changes. Information provided in and with this form may be used to enroll/offer VYALEV at no cost through VYALEV Complete.

**MINIMUM MEDICAL DOCUMENTATION THAT MUST BE SUBMITTED IN ATTACHED CHART NOTES**

VYALEV coverage consideration for motor fluctuations requires medical records from the last 6 months by a neurologist who prescribes and manages treatment with carbidopa-levodopa. **To ensure processing of this form, fax copies of each of the following records as part of the Chart Notes:**



**These documents must be faxed**

**Fax these documents to  
1-888-953-2762**

- Fully completed form
- Patient's insurance cards (both front and back)
- Patient's medical documentation
  - Diagnosis of Parkinson's disease
  - Documentation that the patient is levodopa-responsive
  - Motor fluctuations as documented with "off" periods for a minimum of 2.5 hours/day despite current medical therapy

**Indication<sup>1</sup>**

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

**Safety Considerations<sup>1</sup>**

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**; **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 page 5.  
Please see full **Prescribing Information** or visit [https://www.rxabbvie.com/pdf/vyalev\\_pi.pdf](https://www.rxabbvie.com/pdf/vyalev_pi.pdf).



**Clinical documentation is required. Please fax all documentation noted to ensure form completion.**

**MINIMUM MEDICAL DOCUMENTATION by a neurologist from the past 6 months MUST BE SUBMITTED IN ATTACHED CHART NOTES**

**Medical documentation from the last 6 months must include:**

**Chart notes must explicitly state:**

- Patient's diagnosis of Parkinson's disease
- Patient is levodopa responsive
- Specific number of hours of off-time per day

**On page 3:**

- Select an ICD-10 code to confirm diagnosis
- Select programmed vs unprogrammed pump

**Requirements for coverage, including minimum documentation, may vary by payer.**



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foscarihidopa/foslevodopa  
Injection for subcutaneous use  
12 mg/240 mg per mL

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### Enrollment and Prescription Form

VAP-090825-A09

Fax: 1-888-953-2762

Call with questions: 1-866-489-2538

#### 1. Patient Information

The prescriber and the patient or legally authorized person should fill out section 1 completely before the patient leaves the office.

Patient Name: John Doe

Date of Birth: April / 17 / 1964  
Month Date Year

Sex:  Male  Female

Phone #: 555-687-9763

Email: john.doe@email.com

Check here if patient is a veteran

Check here if an interpreter is needed

Language: \_\_\_\_\_

**Marketing Consent:** I consent to the collection, use, and disclosure of my health-related personal data to receive communications from AbbVie regarding its products, programs, services, clinical trials, research opportunities and for online targeted advertising, as further described in the "How We May Use Personal Data," "How We May Disclose Personal Data," and "Cookies and Similar Tracking and Data Collection Technologies" sections of our Privacy Notice. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting "Your Privacy Choices" on AbbVie's website.

By enrolling, you may receive your own Nurse Ambassador provided by AbbVie. Ambassadors do not work under the direction of your prescriber or give medical advice. They are trained to direct patients to their prescriber for treatment-related advice, including further referrals.

**Privacy Notice:** For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit <https://abbvie.com/PrivacyPatient>.

**Consent to Process My Sensitive Information:** Through my submission of the enrollment form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the "How We May Disclose Personal Data" section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting "Your Privacy Choices" on AbbVie's website.

**HIPAA Consent:** My signature below certifies that I agree to the HIPAA Authorization on page 4.

Indicate relationship:  Patient  Authorized Caregiver

Patient Signature: John Doe Today's Date: 8 / 15 / 25  
Month Date Year

#### Authorized Caregiver Contact Information:

Name: Sarah Doe  
First Last

Relationship to patient: Spouse

Phone #: 555-912-3435

Email: sarah.doe@email.com

#### Facility Information:

Patient Resides in a Facility (e.g., nursing home, hospital)  Yes  No

Name of Facility: ABC Medical Center

Facility Contact Name: Susan Barber

Facility Phone #: 555-917-7262

Provide the authorized caregiver's information to allow them to communicate with the support program on behalf of the patient.

The patient should check this box if they want to receive communications related to AbbVie's products, clinical trial(s), research opportunities, and other services.

If they do not opt-in, the patient will still receive communications specific to VYALEV.

The patient or authorized caregiver's handwritten signature and date is required. A stamp, digital signature, or note that verbal confirmation was received will not be accepted.

Patient or authorized caregiver handwritten signature is required to complete enrollment in VYALEV Complete, and critically important to allow communication with the patient to ensure coordination of the initial prescription shipment and refills with the specialty pharmacy.

Check one of the boxes to identify the patient's pharmacy preference.

#### FOR PRESCRIBER USE ONLY

#### 2. Insurance Information

Patient benefits cannot be accessed without all current insurance information provided. **Please fax a copy of all insurance cards, front and back (prescription and medical insurance as needed), with this form to the fax number indicated in the top right corner of this form.**

#### 4. Prescriber Information

Prescriber Name: Andrew Johnson

Specialty: Neurology

Clinic Name: ABC Medical Center

#### 3. Specialty Pharmacy Preference

VYALEV may only be filled at one of the below pharmacies. Patient insurance pharmacy mandates will take precedence for filling pharmacy; however, if no mandate is required by insurance, please select patient's pharmacy preference below:

Acaria Health  Accredo  CVS  No preference

If not selected, no preference would be assumed.

Office Contact Name: Susan Barber

Office Contact Phone #: 555-917-7262

Office Contact Email: susan.barber@email.com

Office Fax #: 555-917-5650

Please see additional Important Safety Information on page 5.

Please see full Prescribing Information or visit [https://www.rxabbvie.com/pdf/vyalev\\_pi.pdf](https://www.rxabbvie.com/pdf/vyalev_pi.pdf).



2 of 5

Please fax a copy of both sides of the insurance cards. Be sure to include secondary and tertiary insurance information (photocopies and/or electronic health record demographic pages are acceptable).

Prescriber information is required to coordinate care.



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foscarnidopa/foslevodopa  
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### Page 3: Section 5(A) Diagnosis and Prescription Information

**VYALEV™ COMPLETE**  
**Enrollment and Prescription Form** VAP-090825-A09

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Call with questions: 1-866-489-2538

**Section 5** **FOR PRESCRIBER USE ONLY**  
FILL OUT ALL SECTIONS BELOW – A, B, & C

**5(A) Diagnosis and Prescription Information**

Patient Name: John Doe Date of Birth: April / 17 / 1964  
First Last Month Date Year

Patient Address: 123 Main Drive City/State/ZIP: Anytown, IL 12345

⚠ Patient Diagnosis (MUST SPECIFY ICD-10 CODE to confirm diagnosis for aPD):  G20.A2  G20.B1  G20.B2

No Known Allergies Drug Allergies: \_\_\_\_\_

Prescriber Name: Dr. Andrew Johnson NPI: 1234567891

Prescriber Address: 25 Townline Road City/State/ZIP: Anytown, IL 54321

**PUMP** Route of administration via pump *Phillips-Medisize portable infusion pump and pump carry case*

⚠ **MUST SELECT** either Unprogrammed or Programmed. Please see the "PRESCRIBER ACKNOWLEDGEMENT" below.

Unprogrammed (Prescriber will program)  Programmed (Specialty Pharmacy will program) PIN requested (XXXX): 0951

(Please remember the PIN requested. PIN must be 4 digits AND cannot be consecutive digits [e.g., 2345] or the same 4 digits [e.g., 2222]. The patient should NOT have visibility or access to the PIN requested on this form.) If seeking a Programmed Pump and no PIN is provided, default will be 0951.

*(The rest of the form content is blurred in the sample image)*

\_\_\_\_\_  
Dr. Andrew Johnson

ICD-10 code is required for form completion.

**Programming Options:**

**Select "Programmed":** The Specialty Pharmacy will program the pump using the settings specified below and send it ready for use.

**Select "Unprogrammed":** The Specialty Pharmacy will send an unprogrammed pump that the HCP must program before patient use.

4-digit PIN is required.

Warning:

- Use a PIN HCP will remember or keep it on file.
- Do not share the pump's PIN with the patient.
- Programming the pump at a delivery rate other than what is prescribed will cause over- or under-delivery of medication.
- If PIN is lost or forgotten, contact VYALEV Complete at 866-489-2538, Option 2 for support.

Page 3 sample continues on next page.



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### Page 3: Sections 5(B) Dosing and 5(C) Supplies

VYALEV™ Enrollment and Prescription Form

Section 5(B) Dosing:

**Continuous Infusion Flow Rates** Flow rates can be set in increments of 0.01 mL/h with a range of 0.15 mL/hr to 1.25 mL/hr. If High Rate or Low Rate are left blank, it is assumed that those rates are intended to be the same as the Base Rate.

**MUST SELECT** Dosing will be administered over  
 24 hours or  Other \_\_\_\_\_

**Pump Settings:** Base Rate (X.XX mL/h) High Rate (YYY mL/h) Low Rate (Z.ZZ mL/h)  
 Patient Dose Settings: 0.50 mL/h 0.55 mL/h 0.45 mL/h

**Optional Dosing Features: Extra Dose and Load Dose** If left blank, these doses will be assumed to be 0.00.

• **Extra Dose** mL (check one):  0.10  0.15  0.20  0.25  0.30

Number of times a day (check one):  2  Other \_\_\_\_\_

Lockout time: 1 hour(s) 0 minute(s) (Range: 1–24 hours [15 min increments])

• **Loading Dose:**  Once daily  Other 2

Lockout time: 3 hour(s) (Range: 3–8 hours [1 hr increments])

**Lockout Time:** The minimum amount of time that must elapse between doses before the next dose can be administered.  
 Extra Dose Minimum: 1 hour  
 Loading Dose Minimum: 3 hours

**Minimum Vial Count Methodology:** See page 4.

**5(C) SUPPLIES**

Braun Omnifix® Syringe 10 mL Luer Lock Qty: To be determined by pharmacist Refills: 12 SIG: Change syringe at least every 24 hours or sooner, as indicated by pump

West Vented Vial Adapter™ (Carton size of 28 vial adapters) Qty: To be determined by pharmacist Refills: 12 SIG: Use one per vial

Neria™ Guard Infusion Set:  6 mm  9 mm

**Choose cannula length** (If cannula length is left blank, the default 9 mm cannula will be sent)

1st Fill Qty: 3 cartons (30 units) Refills: 0 SIG: Change cannula at least once every 3 days or more often as directed by your doctor

Refill Qty: To be determined by pharmacist Refills: 11 SIG: Change cannula at least once every 3 days or more often as directed by your doctor

Minimum # of vials: 44 Days Supply: 28 Refills: 12 SIG: Change solution at least once every 24 hours; change during waking hours only

This is the anticipated number of extra doses for a 24-hour period for dispensing purposes. The pump will not prevent a patient from administering more than the number listed. If 2 or more extra doses are taken by the patient during a 24-hour/day treatment period, a revision of the base continuous infusion rate should be considered.

Lockout times are used to prevent patients from administering another extra dose until a set time has passed. The extra dose feature is limited to no more than 1 extra dose per hour, and can be set in 15 min increments.

The optional loading dose is used when VYALEV therapy is being initiated in an "Off" state or when the patient has not been receiving their base continuous infusion for more than 3 hours. This is the anticipated number of loading doses for a 24-hour period for dispensing purposes. The pump will not prevent a patient from administering more than the number listed.

Lockout times are used to prevent patients from administering another loading dose until a set time has passed. The loading dose feature is limited to no more than 1 loading dose every 3 hours and can be set in 1 hour increments between 3–8 hours.

Use the dosing calculator at [VyalevCalculator.com](http://VyalevCalculator.com) to calculate:

- Pump settings
  - base rate
  - high rate
  - low rate
  - optional extra dose
  - optional loading dose
- Vials
  - minimum number of vials

### Safety Considerations<sup>1</sup>

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**; **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 page 8**.

Please see full **Prescribing Information** or visit [https://www.rxabbvie.com/pdf/vyalev\\_pi.pdf](https://www.rxabbvie.com/pdf/vyalev_pi.pdf).



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VYALEV™ COMPLETE

### Page 3: Training Option and Prescriber Acknowledgment

**PATIENT DELIVERY SYSTEM TRAINING OPTION:**

I request optional supplemental VYALEV delivery system training according to the USPI, if needed, for this patient by an AbbVie-offered and contracted third-party home health nurse who would provide limited training upon request made by the patient to AbbVie ("HHN Training"). My order requesting this training is valid for up to one year, is subject to the terms and conditions listed in the "PRESCRIBER CONSENT" on page 4, and may be canceled by me at any time.

**PRESCRIBER ACKNOWLEDGEMENT:** By my signature below, I submit this prescription for the above-named patient and I certify the following:

(1) If the "Programmed" option in Section 5(A) above is selected, I acknowledge and agree that I am responsible for the accuracy of all information necessary for programming the pump, including the dosing settings I have specified in the "Continuous Infusion Flow Rates" subsection of Section 5(B) above, and any additional information or instruction required by the Specialty Pharmacy for pump programming, including prescription changes OR if the "Unprogrammed" option in Section 5(A) above is selected, I acknowledge and agree that I am directly responsible for programming the pump, and for the accuracy of the dosing settings I have specified in the "Continuous Infusion Flow Rates" subsection of Section 5(B) above; and,  
(2) I confirm that I have read, acknowledge, and agree with the "PRESCRIBER CONSENT" on page 4.

**PRESCRIBER SIGNATURE AND DATE - STAMP SIGNATURE NOT ALLOWED**

*Dr. Andrew Johnson* Today's Date: 08 / 15 / 25 Today's Date: \_\_\_\_\_  
 Dispense as written/Do not substitute Month / Date / Year  Substitution permitted/Brand exchange permitted Month / Date / Year

In states not permitting dual prescriptions or specific prescription requirements, please fax a separate prescription.

**Prescriber Privacy Notice:** For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit <https://abbvie.com/PrivacyHCP>.

Please see additional **Important Safety Information** on page 5.

Please see full **Prescribing Information** or visit [https://www.rxabbvie.com/pdf/vyalev\\_pi.pdf](https://www.rxabbvie.com/pdf/vyalev_pi.pdf).

3 of 5

Select this option to avoid additional outreach if the patient is deemed to need home health nursing support. Home health nurses are specially trained to support patients with product education, cannula placement, and questions. If not selected and it is later determined a patient requires additional support, the HCP office will be contacted for direction and orders.

Prescriber's **handwritten** signature is required (stamp or digital signature will not be accepted).



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### Enrollment and Prescription Form

VAP-090825-A09

Fax: 1-888-953-2762

Call with questions: 1-866-489-2538

**MINIMUM VIAL COUNT METHODOLOGY:** The minimum number of vials is based on the highest continuous infusion rate of the dosage administered over a 24-hour period. It serves as an estimate to assist prescribers to determine the number of vials necessary per 28 days based on calculated doses. This takes into consideration appropriate timing of syringe changes during waking hours (16 hours).<sup>2</sup>

**METHODOLOGY:** The calculation for the number of vials needed per 28 days is based on the highest continuous infusion rate (mL/hr) maintained over a 24-hour period with waking hour changes only (assuming a 16-hour waking day). The methodology estimates the total volume of medication required daily, which is then extrapolated with an estimated timing of syringe changes to determine the minimum number of vials needed per 28 days. This approach incorporates real-world infusion practices to inform effective medication supply planning. It is important to note that these calculations are derived from mathematical estimates and not from clinical trial results. The goal of this calculation is to provide a practical estimate for the minimum number of vials needed per 28 days. In clinical trials, syringes were changed on a schedule during waking hours only.<sup>2</sup>

The maximum recommended daily dosage of VYALEV is 3525 mg of the foslevodopa component (equivalent to approximately 2500 mg levodopa). Prescribing a backup oral carbidopa and levodopa product is recommended in the event that delivery of VYALEV is interrupted, which may result in underdosing.<sup>1</sup>

**PRESCRIBER CONSENT:** I authorize VYALEV Complete to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan, and obtaining patient benefit information and the necessary prior authorization forms when dealing with the Health Plan and Pharmacy Benefits Managers (PBMs), if the Plan or PBM requires such authorization. I understand that a representative from the specialty pharmacy will contact the patient to obtain authorization prior to shipping the prescription. Further, if I checked the PATIENT DELIVERY SYSTEM TRAINING OPTION box at the bottom of page 3, I acknowledge and agree that: (i) HHN Training is optional and offered at no charge for benefit of the patient and is not required for the patient to receive the prescribed product; (ii) HHN Training is limited to education based on the approved product labeling and the prescription as written, physical assistance by the home health nurse with placement of the infusion set if the patient requests assistance and adverse event reporting, but no other services and with no reports provided to me by the nurse; (iii) HHN Training is not eligible for reimbursement and I will not seek reimbursement from the patient or any third party payee for HHN Training; and (iv) at any time, I can separately order and direct a home health nurse of my choosing who would not be associated with the HHN Training, AbbVie or any of its contracted vendors.

### HIPAA Authorization

Please read the following, then date and sign where indicated on page 2, section 1.

#### This page must be included when faxed. ●

I authorize my health care providers and staff, health plan, and pharmacies (collectively, my "Healthcare Providers") to disclose individually identifiable information about me, my health or condition(s), treatment and care that I have received, my insurance coverage, my payment information, and my medication history and prescriptions (collectively, "Protected Health Information") to AbbVie Inc. and/or its designated affiliates, agents, representatives, and service providers (collectively, "AbbVie") in order for AbbVie to (i) enroll me in, provide, operate and administer the VYALEV Complete Program ("Program"); (ii) provide me with information concerning the Program; and (iii) develop, evaluate, and improve products, services, materials, and programs related to my condition or treatment. I understand that Protected Health Information disclosed to AbbVie under this Authorization will no longer be protected by HIPAA and may be subject to redisclosure by AbbVie. I also understand that my Healthcare Providers/Pharmacies may receive benefits, which may include compensation, for my participation in the Program and the disclosure of my Protected Health Information. I understand that I am not required to sign this Authorization and that my Healthcare Providers will not otherwise condition my treatment, payment, health insurance enrollment, or eligibility for health care benefits to which I am otherwise entitled on whether I sign this Authorization. However, I understand that if I do not sign this Authorization, I cannot take part in the Program. I understand that this Authorization will expire once I am no longer participating in the Program, unless I cancel it sooner. I understand that I may cancel this Authorization at any time by making a data subject rights request at <https://abbviemetadata.my.site.com/AbbvieDSRM> or by writing to [privacydsr@abbvie.com](mailto:privacydsr@abbvie.com). However, I understand that if I cancel this Authorization, it will end my enrollment in the Program. I understand that cancelling this Authorization will not affect any use or disclosure of my Protected Health Information that has already taken place in reliance on this Authorization.

Note: You have a right to receive a copy of this Authorization. You may print a copy of or save this Authorization and retain a copy for your records.

Please see additional **Important Safety Information** on page 5.

Please see full **Prescribing Information** or visit [https://www.rxabbvie.com/pdf/vyalev\\_pi.pdf](https://www.rxabbvie.com/pdf/vyalev_pi.pdf).



**VYALEV™**  
foscarnidopa/foslevodopa  
Injection for subcutaneous use

**THIS PAGE MUST BE FAXED**  
with pages 1–4 of the VYALEV  
Enrollment and Prescription form  
as well as the minimum medical  
documentation.

## Indication<sup>1</sup>

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

## Important Safety Information<sup>1</sup>

VYALEV™ (foscariidopa/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.

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.

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.

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.

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.

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

**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.

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

**Drug Interactions:** The use of **nonselective MAO inhibitors** is contraindicated. **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**.

The most common adverse reactions for VYALEV that occurred in  $\geq 3\%$  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.

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

Please see full **Prescribing Information** or visit [https://www.rxabbvie.com/pdf/vyalev\\_pi.pdf](https://www.rxabbvie.com/pdf/vyalev_pi.pdf).

Reference: 1. VYALEV [package insert]. North Chicago, IL: AbbVie Inc. 2. Data on file. AbbVie Inc.