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

Instruction Guide for VYALEV Complete Enrollment and Prescription Form

VYALEV® COMPLETE

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
- ☐ If patient resides in a facility, please provide the facility's information (e.g., name, 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
- ☐ 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

Please see additional Important Safety Information on page 8.
Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

VYALEV®
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Injection for subcutaneous use

Sample

VYALEV® COMPLETE

VYALEV Enrollment and Prescription Form

VYALEV® COMPLETE

Enrollment and Prescription Form

VAP-061526-A04

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

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 health care provider** 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

→ **Failure to include will delay enrollment and treatment start**

Fax these documents to 1-888-953-2762

For New Patients:

→ **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 are documented with "off" periods for a minimum of 2.5 hours/day despite current medical therapy, with "off" hours documented vs percent of day or other terminology

For dose adjustments to existing scripts, please fax page 3 only to 1-888-953-2762.

Review and provide your patient the "Treatment Start Day Instruction Guide" to help them prepare for starting VYALEV.

Indication[1]

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

Safety Considerations[1]

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 page 5.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

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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.

Notes providing guidance on requirements for dose adjustments vs requirements for a new patient.

Reminder for HCP to complete and review the "HCP Treatment Start Day Instruction Guide" form with patients to help ensure they have the clinical information needed for a successful treatment start.

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

Sample

VYALEV® COMPLETE

VYALEV Enrollment and Prescription Form

VYALEV® COMPLETE

Enrollment and Prescription Form

VAP-061526-A04

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 (First) Doe (Last)
Date of Birth: April (Month) / 17 (Date) / 1964 (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: _____

Authorized Caregiver Contact Information:
Name: Sarah (First) Doe (Last)
Relationship to patient: Spouse
Phone #: 555-912-3435
Best Time to Call (Monday–Friday):
☐ Anytime ☑ Morning ☐ Afternoon ☑ Evening
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

By enrolling in VYALEV Complete, you may receive your own Nurse Ambassador provided by AbbVie. Nurse Ambassadors do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct you to your HCP for treatment-related advice, including further referrals.

☑ **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 the AbbVie "**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.

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://www.abbvie.com/privacy-inquiry.html**.

Consent to Process My Sensitive Information: Through my submission of this 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

Written signature required by Patient or Authorized Caregiver to complete enrollment. Verbal, electronic, or stamp signature not permitted.

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

▼ 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.

3. Prescriber Information Provide prescriber information to ensure any documentation questions can be quickly addressed.

Prescriber Name: Andrew Johnson
Clinic Name: ABC Medical Center
Prescriber Address: 123 Road City, State Zip
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 Important Safety Information on page 5.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

VYALEV® foscarbidopa/foslevodopa Injection for subcutaneous use

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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.

Prescriber information is required to coordinate care.

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).

Page 3: Section 4(A) Diagnosis and Prescription Information

VYALEV® COMPLETE

Enrollment and Prescription Form VAP-061526-A04

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

Section 4 ▼ FOR PRESCRIBER USE ONLY ▼

FILL OUT ALL SECTIONS BELOW – A, B, & C

4(A). Diagnosis and Prescription Information

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

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

Patient Diagnosis (MUST SPECIFY ICD-10 CODE to confirm diagnosis for aPD):

- ☐ G20.A2 (PD without dyskinesia, with fluctuations)
- ☑ G20.B1 (PD with dyskinesia, without mention of fluctuations)
- ☐ G20.B2 (PD with dyskinesia, with fluctuations)

☑ 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): 0 9 5 1

(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.

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.

VYALEV®
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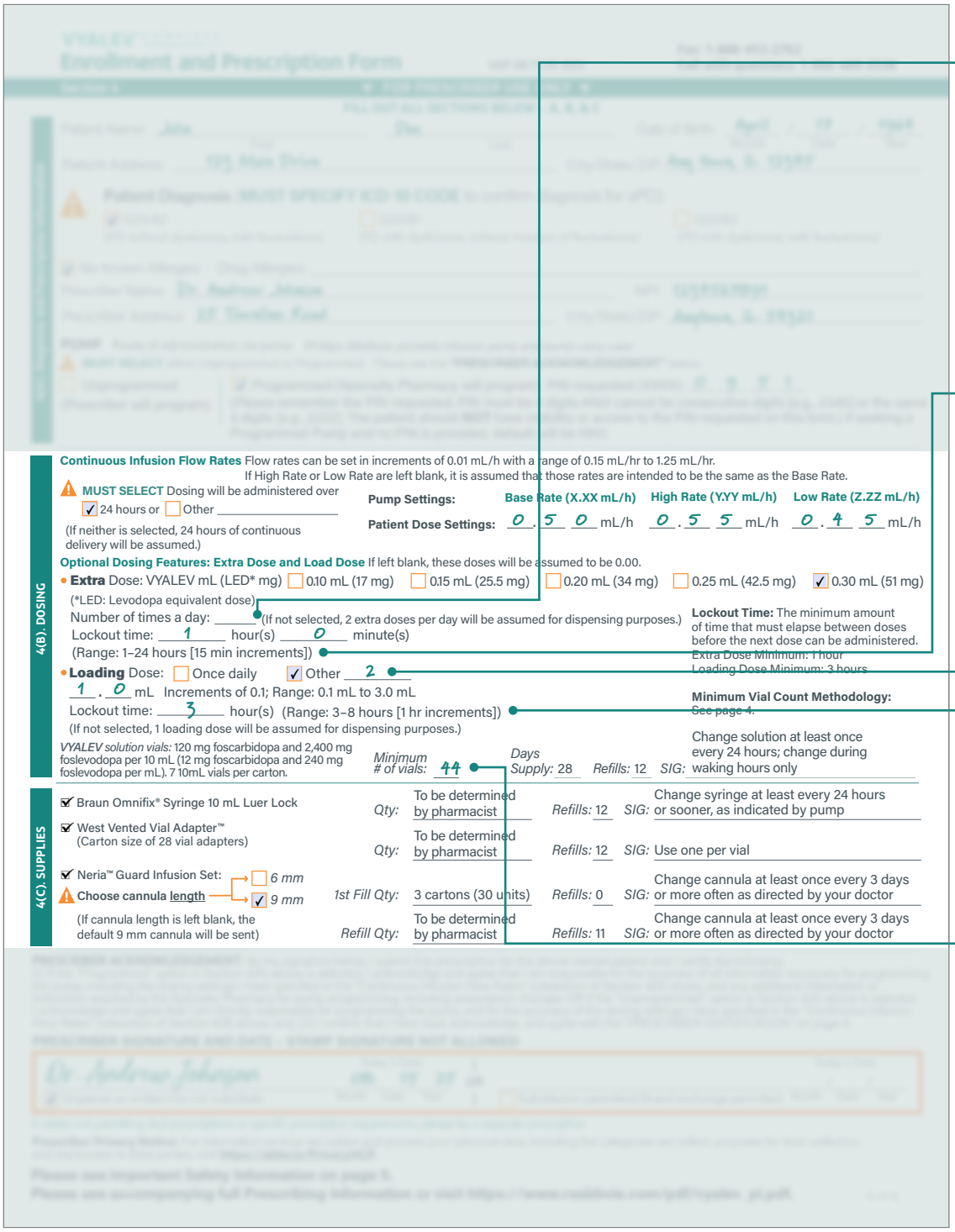
Injection for subcutaneous use

Sample

VYALEV Enrollment and Prescription Form

VYALEV® COMPLETE

Page 3: Sections 4(B) Dosing and 4(C) Supplies



4(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 _____
(If neither is selected, 24 hours of continuous delivery will be assumed.)

Pump Settings:	Base Rate (X.XX mL/h)	High Rate (Y.YY 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: VYALEV mL (LED* mg) ☐ 0.10 mL (17 mg) ☐ 0.15 mL (25.5 mg) ☐ 0.20 mL (34 mg) ☐ 0.25 mL (42.5 mg) ☑ 0.30 mL (51 mg)
  (*LED: Levodopa equivalent dose)
  Number of times a day: _____ (If not selected, 2 extra doses per day will be assumed for dispensing purposes.)
  Lockout time: 1 hour(s) 0 minute(s)
  (Range: 1–24 hours [15 min increments])
- **Loading** Dose: ☐ Once daily ☑ Other 2
  1.0 mL Increments of 0.1; Range: 0.1 mL to 3.0 mL
  Lockout time: 3 hour(s) (Range: 3–8 hours [1 hr increments])
  (If not selected, 1 loading dose will be assumed for dispensing purposes.)

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.

VYALEV solution vials: 120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL (12 mg foscarbidopa and 240 mg foslevodopa per mL). 7 10mL vials per carton.

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

4(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

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 to calculate:

Pump settings
- base rate
- high rate
- low rate
- optional extra dose
- optional loading dose

Vials
- minimum number of vials

Safety Considerations[1]

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 page 8.
Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

VYALEV Enrollment and Prescription Form

Page 3: Training Option and Prescriber Acknowledgment

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 4(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 4(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 4(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 4(B) above; and, (2) I confirm that I have read, acknowledge, and agree with the "PRESCRIBER CERTIFICATION" on page 4.

PRESCRIBER SIGNATURE AND DATE – STAMP SIGNATURE NOT ALLOWED

Dr. Andrew Johnson — Today's Date: 08 / 15 / 25 (Month / Date / Year) | OR | Today's Date: ___ / ___ / ___ (Month / Date / Year)

☑ Dispense as written/Do not substitute ☐ Substitution permitted/Brand exchange permitted

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://abbv.ie/PrivacyHCP**.

Please see Important Safety Information on page 5.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

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

VYALEV® COMPLETE

Enrollment and Prescription Form

VAP-061526-A04

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).[2]

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.[2]

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.[1]

PRESCRIBER CERTIFICATION: 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's Health 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 Health 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. I understand that VYALEV Complete may provide no-charge product to support patients who are experiencing an insurance access challenge for VYALEV until coverage is obtained, and I confirm that, if applicable, I will support the above-identified patient in seeking to secure such coverage as I deem appropriate. I certify that I will not seek reimbursement from any third party payor for any no-charge product dispensed to a patient by an AbbVie authorized pharmacy.

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://www.abbvie.com/privacy-inquiry.html** or by writing to 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 Important Safety Information on page 5.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

VYALEV® foscarbidopa/foslevodopa Injection for subcutaneous use

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

Indication[1]

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

Important Safety Information[1]

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.

Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

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

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