VYALEV® COMPLETE

Enrollment and Prescription Form for VA Patients

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

Steps to complete the VA Enrollment and Prescription Form. Follow in the order noted below:

MDS/Neuro medical provider fills out VA Enrollment and Prescription Form → MDS/Neuro sends Form to VA Pharmacy → VA Pharmacy fills out Sections 3 & 4 and sends Form to Vyalev Complete HUB → HUB sends Form to CVS → HUB confirms that CVS has received the Form

Fax these documents to 1-888-953-2762

The below checklist is intended to help you complete and provide the necessary documentation required
Be sure to provide ALL required information listed below. Incomplete submissions may cause delays in your patients starting on VYALEV.

Complete the VYALEV VA Enrollment and Prescription Form

- ☐ Patient name, address, phone, email, including authorized caregiver's name and phone number
- ☐ Provide the Veteran's Last 4 Digits of SSN
- ☐ VA Pharmacy to complete:
  - ☐ Purchase Order #—if there are separate PO #s for the medication and ancillary supplies vs the pump, provide both PO #s
  - ☐ VA Facility location, address, and VA Facility #, and Shipment Delivery Location
- ☐ Ensure the patient or authorized caregiver signs and dates the consent.
- ☐ 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
- ☐ Provide all prescription details, including:
  - ☐ Checkbox to select programmed or unprogrammed pump
  - ☐ ICD-10 Code
  - ☐ All pharmacy instructions (i.e., SIG lines)
  - ☐ Pump dose settings (base rate, high rate, low rate) and optional dose settings (extra dose and loading dose)
  - ☐ Minimum No. of vials per month
  - ☐ Pump lockout times
  - ☐ Preferred Cannula length (6mm vs 9mm)
  - ☐ Separate or alternative prescription, per state laws
- ☐ Hand-written patient or authorized caregiver and prescriber signatures (stamp and digital signatures are not allowed)

If you have specific questions, you may contact CVS, the Specialty Pharmacy working with the VA using the following automated phone sequence or VA direct email address:

- CVS Specialty can be reached at 877-437-8469
- Select option 2 "no" and then option 7 "other"
- The VA pharmacy contact will be directed to "say the medication you are calling about" and should state "Vyalev"
- Alternatively for patient prescription status updates, CVS Specialty can be e-mailed at: srx_psrneurospoc@cvshealth.com

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

VYALEV®
foscarbidopa/foslevodopa

Enrollment and Prescription Form for VA Patients

VAPV-061526-A04

Forward this completed form to the VA pharmacy. The VA pharmacy will fax the document to VYALEV Complete. 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: _____ (First) _____ (Last)

Veteran Last 4 of SSN: _____

Date of Birth: _____ (Month) / _____ (Date) / _____ (Year)

Sex: ☐ Male ☐ Female

Address: _____

City/State/ZIP: _____

Phone #: _____

Email: _____

☐ Check here if an interpreter is needed.
Language: _____

Authorized Caregiver Contact Information:

Name: _____

Relationship to Patient: _____

Phone #: _____

Email: _____

Best Time to Call (Monday–Friday):

☐ Anytime ☐ Morning ☐ Afternoon ☐ Evening

Facility Information:

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

Facility Name: _____

Facility Contact Name: _____

Facility Phone #: _____

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 _____ **Today's Date:** _____ (Month) _____ (Date) _____ (Year)

▼ FOR PRESCRIBER USE ONLY ▼

2. Prescriber Information

For questions, contact CVS at: **1-877-437-8469**

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

Prescriber Name: _____ Clinic Name: _____ Prescriber Address: _____

City/State/ZIP: _____ NPI #: _____ Office Contact Name: _____

Office Contact Phone #: _____ Office Contact Email: _____ Office Fax #: _____

▼ FOR VA USE ONLY ▼

3. VA Pharmacy Information

Primary Purchasing Contact: Phone #: _____
Email: _____ Fax #: _____

Secondary Purchasing Contact: Phone #: _____
Email: _____ Fax #: _____

Primary Clinical Contact: Phone #: _____
Email: _____ Fax #: _____

Secondary Clinical Contact: Phone #: _____
Email: _____ Fax #: _____

Payment Method ☐ Credit Card ☐ E-Invoice Tungsten Network Purchase Order # _____

4. VA Pharmacy Location Information

VA Facility #: _____ VA Facility Name: _____

VA Pharmacy Address: _____

VYALEV Shipments to Be Delivered to:
(Ship to patient's home is the preferred option)

1st Fill Ship to: ☐ Home ☐ VA Pharmacy

Refill Ship to: ☐ Home ☐ VA Pharmacy

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

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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: _____ (First) _____ (Last) Date of Birth: ____ / ____ / ____ (Month / Date / Year)

Patient Address: _____ City/State/ZIP: _____

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: _____ NPI: _____

Prescriber Address: _____ City/State/ZIP: _____

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): ____ ____ ____ ____
(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.

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 _____
(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:	____.____ mL/h	____.____ mL/h	____.____ 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: _____ hour(s) _____ minute(s)
  (Range: 1–24 hours [15 min increments])
- **Loading** Dose: ☐ Once daily ☐ Other _____
  ____.____ mL Increments of 0.1; Range: 0.1 mL to 3.0 mL
  Lockout time: _____ 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: ____ *Days Supply:* 28 *Refills:* 12 *SIG:* Change solution at least once every 24 hours; change during waking hours only

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: **Choose cannula length** → ☐ *6 mm* ☐ *9 mm* (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

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 CERTIFICATION" on page 4.

PRESCRIBER SIGNATURE AND DATE – STAMP SIGNATURE NOT ALLOWED

_____ Today's Date: ____ / ____ / ____ (Month / Date / Year)
☐ Dispense as written/Do not substitute

OR

_____ Today's Date: ____ / ____ / ____ (Month / Date / Year)
☐ 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 full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

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 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.

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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US-VYAL-260104 April 2026

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Injection for subcutaneous use