VYALEV™ COMPLETE

Enrollment and Prescription Form

VAP-073124-A07

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.

Fax the following to 1-888-953-2762:

- ☐ *Fully completed form*
- ☐ *Patient's insurance cards (both front and back)*
- ☐ *Patient's medical documentation*

Patient Information

Patient Name: _____ _____
First Last

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

Prescriber Contact Information

Name: _____

Phone #: _____

MEDICAL DOCUMENTATION THAT MUST BE SUBMITTED WITH THIS FORM

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. Submit copies of the following records—each box must be checked by the prescriber to indicate the documentation was submitted:

- ☐ 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

This form cannot be processed unless you complete this section and 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.

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**; **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
Injection for subcutaneous use
12 mg/240 mg per mL

abbvie

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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

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

Gender: ○Male ○Female

Address: _____

City/State/ZIP: _____

Phone #: _____

Email: _____

☐ Check here if patient is a veteran

☐ Check here if an interpreter is needed

Language: _____

Authorized Caregiver Contact Information:

Name: _____

Relationship to patient: _____

Phone #: _____

Email: _____

Facility Information:

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

Name of Facility: _____

Facility Contact Name: _____

Facility Phone #: _____

☐ **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://abbv.ie/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

Signature: _____ _____ /_____ /_____
Month Date 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. 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 pharmacy preference below:

○Acaria Health ○Accredo ○CVS ○No preference

4. Prescriber Information

Prescriber Name: _____

Specialty: _____

Clinic Name: _____

Address: _____

City/State/ZIP: _____

NPI #: _____

Office Contact Name: _____

Office Contact Phone #: _____

Office Contact Email: _____

Office Fax #: _____

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

VYALEV™ foscarbidopa/foslevodopa Injection for subcutaneous use

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FOR PRESCRIBER USE ONLY

5. Diagnosis and Prescription Information

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

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

Patient Diagnosis (checkbox is required to confirm diagnosis for aPD): ☐ Advanced Parkinson's Disease ICD-10 Code: _____

☐ No Known Allergies Drug Allergies: _____

Prescriber Name: _____ NPI: _____

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

○ **Unprogrammed**
(Prescriber will program)

○ **Programmed** (Specialty Pharmacy will program) PIN requested (XXXX): _____
(Please remember the PIN requested—you will need this PIN to unlock the pump for dose or feature adjustments. To ensure patient safety, the patient should **NOT** have visibility or access to the PIN requested on this form.)

FLOW RATES FOR CONTINUOUS INFUSION

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.

	Base Rate (X.XX mL/h)	High Rate (Y.YY mL/h)	Low Rate (Z.ZZ mL/h)
Pump Settings:			
Patient Dose Settings:	____.____ ____ mL/h	____.____ ____ mL/h	____.____ ____ mL/h

Other dosing options (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 ○ None
Lockout Time: _____ hours _____ minutes (Value: 1-24; Value: 00, 15, 30, or 45)

Loading Dose: ____.____ ____ mL (Increments of 0.1; Range: 0.1 mL to 3.0 mL)
Lockout Time: _____ hours (Range: 3-8)

IMPORTANT: To ensure the pharmacy calculates the correct number of vials needed for the prescription, all intended Continuous Infusion Rates, other dosing options and Lockout Times must be completed.

VYALEV solution cartons 7 vials per carton: 120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL (12 mg foscarbidopa and 240 mg foslevodopa per mL). *# of cartons:* To be determined by pharmacist *Days Supply:* 28 *Refills:* 12 *SIG:* Change solution at least every 24 hours or sooner, as indicated by pump

SUPPLIES

☑ Braun Omnifix® Syringe 10 mL Luer Lock — *Qty:* Equal to total # of vials above with 7 more in case of waste *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; cannot be split) — *Qty:* 2 cartons (56 units) *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 6 mm cannula will be sent) — *Qty:* 3 cartons (30 units) *Refills:* 12 *SIG:* Change cannula at least once every 3 days or more often as directed by your doctor

PATIENT DELIVERY SYSTEM TRAINING

☐ I request optional supplemental VYALEV delivery system training according to USPI, if needed, for this patient by an AbbVie-offered and contracted third-party home health nurse that 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 below (see "PRESCRIBER CONSENT"), and may be canceled by me at any time.

PRESCRIBER ACKNOWLEDGEMENT: If the "Programmed" option above is selected, I acknowledge and agree that I am responsible for the accuracy of all information necessary for programming of the pump, including information provided in the section entitled "Flow Rates for Continuous Infusion." In addition, I am responsible for providing the Specialty Pharmacy with any additional instruction or information for such programming, as necessary, including prescription changes. If the "Unprogrammed" option above is selected, I acknowledge and agree that I am responsible for the programming of the pump. I agree to provide information in the section entitled: "Flow Rates for Continuous Infusion." My signature below certifies that I agree to the Prescriber Consent on page 4.

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**.

PRESCRIBER SIGNATURE AND DATE – STAMP SIGNATURE NOT ALLOWED

_____ ○ Dispense as written/Do not substitute — ____ (Month) / ____ (Date) / ____ (Year)

_____ ○ Substitution permitted/Brand exchange permitted — ____ (Month) / ____ (Date) / ____ (Year)

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

VYALEV™ foscarbidopa/foslevodopa Injection for subcutaneous use

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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. If I requested HHN Training (see above), 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 payor for HHN Training; and (iv) at any time, I can separately order and direct a home health nurse of my choosing that 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; (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. 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 full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

VYALEV™
foscarbidopa/foslevodopa
Injection for subcutaneous use

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Important Safety Information[1]

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.

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 ≥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 (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.

Reference: 1. VYALEV [package insert]. North Chicago, IL: AbbVie Inc.

VYALEV™ foscarbidopa/foslevodopa Injection for subcutaneous use

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