

BILLING and CODING

Your guide to understanding
the billing and coding principles
for VYALEV™



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

INDICATION

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

SAFETY CONSIDERATIONS

VYALEV is **contraindicated** in patients who currently take or have taken (within 2 weeks) a nonselective monoamine oxidase [MAO] inhibitor, as concurrent use can cause hypertension. VYALEV may cause **sudden falling asleep** during daily activities and somnolence; **hallucinations/psychosis**; compulsive behavior or **lack of impulse control**; **infusion site reactions and infections**; **withdrawal-emergent hyperpyrexia** and confusion; **dyskinesia**; **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.

This is for informational purposes only and is not intended to provide reimbursement or legal advice. The information presented here does not guarantee payment or coverage.

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

Please click here for full VYALEV™ [Prescribing Information](#).

CODING: DIAGNOSIS AND ADMINISTRATION

Diagnosis codes for Parkinson's disease¹

ICD-10-CM code	Diagnosis
G20.A2	Parkinson's disease without dyskinesia, with fluctuations
G20.B1	Parkinson's disease with dyskinesia, without mention of fluctuations*
G20.B2	Parkinson's disease with dyskinesia, with fluctuations

JC Reach out to your VYALEV™ Complete Access Specialist if you need J-code information.

Office administrative codes for services²

CPT code	Description	Instructions
96369[†]	Subcutaneous infusion for therapy or prophylaxis initial (≤ 1 hour)	<ul style="list-style-type: none"> • Specify substance or drug • Include pump setup and establishment of subcutaneous infusion site(s)
+96370[†]	Subcutaneous infusion for therapy or prophylaxis (> 1 hour) [‡]	<ul style="list-style-type: none"> • Specify substance or drug • Each additional hour • List separately in addition to code for primary procedure • Report in conjunction with 96369

*ICD-10-CM code aligns with the Prescribing Information but may not align with all payer policies.

[†]Not intended to be reported by a physician in the facility setting.

[‡]Use 96370 for infusion intervals of greater than 30 minutes beyond 1-hour increments.

It's important to remember that the CPT coding system offers you a uniform process to streamline the reporting of medical services and procedures, so make sure to use CPT procedure codes to confirm medical necessity.

Codes are for informational purposes only and are not intended to suggest the use of any drug that is inconsistent with FDA approval, or to function as reimbursement or legal advice. Providers should verify codes with third-party payers.

The codes shown are only suggestions. The codes you may need can vary by patient.

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CODING: EVALUATION AND MANAGEMENT

Evaluation codes²

Represent services by health care professionals in which the provider is evaluating the health of the patient

CPT code	Procedure
64999	Unlisted procedure, nervous system
95999	Unlisted neurological or neuromuscular diagnostic procedure
99199	Unlisted special service, procedure, or report

Management office codes²

Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination

CPT code	Description	Instructions
99212	Straightforward medical decision-making	10-19 minutes of total time is spent on the date of the encounter
99213	Low-level medical decision-making	20-29 minutes of total time is spent on the date of the encounter
99214	Moderate-level medical decision-making	30-39 minutes of total time is spent on the date of the encounter
99215	High-level medical decision-making	40-54 minutes of total time is spent on the date of the encounter



Keep in mind: Incorrect medical coding can result in a payment getting denied, delayed, or partially paid, which can impact the practice and the patient's treatment journey.

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CODING: PROLONGED SERVICE

CPT codes for prolonged clinical staff services²

Prolonged clinical staff service (the service beyond the highest time in the range of total time of the service) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision

CPT code	Description	Instructions
99415	First hour	<ul style="list-style-type: none"> • List separately in addition to code for outpatient evaluation and management service • Use in conjunction with CPT codes 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215 • Do not use in conjunction with CPT codes 99354, 99355, 99417
99416	Each additional 30 minutes	<ul style="list-style-type: none"> • List separately in addition to CPT code for prolonged service • Use in conjunction with CPT code 99415 • Do not use in conjunction with CPT codes 99354, 99355, 99417



For questions about billing and coding, call your VYALEV™ Complete Access Specialist.

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CODING: PROLONGED SERVICE (continued)


CPT codes for prolonged office or outpatient evaluation and management services ^{2,3}

Commercial: Prolonged office or other outpatient evaluation and management service(s) beyond the minimum required time of the primary procedure that has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service

CPT code	Description	Instructions
99417	Each 15 minutes of total time	<ul style="list-style-type: none"> • List separately in addition to CPT code 99215 for office or other outpatient evaluation and management services • Use in conjunction with CPT codes 99205, 99215 • Do not use in conjunction with CPT codes 99354, 99355, 99358, 99359, 99415, 99416 • Do not report for any time < 15 minutes

Medicare: Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure that has been selected using total time on the date of the primary service

CPT code	Description	Instructions
G2212	Each additional 15 minutes by the physician or qualified health care professional, with or without direct patient contact	<ul style="list-style-type: none"> • List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services • Do not use in conjunction with CPT codes 99354, 99355, 99358, 99359, 99415, 99416 • Do not report for any time < 15 minutes

 For more coding and billing support, reach out to your VYALEV™ Complete Access Specialist—they can answer any questions you may have.

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INDICATION AND IMPORTANT SAFETY INFORMATION FOR VYALEV™ (foscariidopa/foslevodopa)

INDICATION

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

IMPORTANT SAFETY INFORMATION

VYALEV™ (foscariidopa/foslevodopa) is **contraindicated** in patients who are currently taking or have taken (within 2 weeks) a **nonspecific 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.

Please see additional Important Safety Information for VYALEV™ on page 7.
Please click [here](#) for full VYALEV™ **Prescribing Information**.



IMPORTANT SAFETY INFORMATION (continued) FOR VYALEV™ (foscarnidopa/foslevodopa)

IMPORTANT SAFETY INFORMATION (continued)

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

References:

1. ICD-10-CM/PCS MS-DRG v41.0 Definitions Manual. Centers for Medicare and Medicaid Services website. Accessed March 26, 2024. https://www.cms.gov/icd10m/fy2024-nprmversion41.0-fullcode-cms/fullcode_cms/P2500.html.
2. American Medical Association. Current Procedural Terminology: CPT® 2023; Professional Edition. AMA Press; 2022.
3. HCPCS Quarterly Update. Centers for Medicare and Medicaid Services website. Accessed October 13, 2023. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>.

Please click here for full VYALEV™ [Prescribing Information](#).



SUPPORT AND HELP WHEN NEEDED WITH VYALEV™ COMPLETE

HELPING SUPPORT TIMELY ACCESS TO VYALEV™ TREATMENT

VYALEV™ Complete Access Specialists have expertise in insurance policies and processes. They will partner with you to help navigate insurance coverage and authorizations.

Your VYALEV™ Complete Access Specialist provides:

- Medical policy education for Medicare, Medicare Advantage, and local and national commercial plans
- Help with individual patients' unique insurance situation and authorization requirements
- Expertise in the coding and billing process
- Specialty Pharmacy fulfillment updates

HELPING PATIENTS WITH PERSONALIZED SUPPORT

Once patients are prescribed VYALEV™ and enrolled in VYALEV™ Complete, they will be assigned a dedicated Nurse Ambassador* as a single point of contact. This Ambassador will get to know the best ways to support your patient and their care partner throughout their VYALEV™ treatment journey.

The Nurse Ambassador provides patients with:

- Help navigating the insurance and Specialty Pharmacy process
- Help organizing and preparing for their infusion initiation in your office
- Consultation in the comfort of their home to help them practice self-administration



Contact your VYALEV™ Complete Access Specialist for questions about billing and coding at 1-866-4VYALEV (1-866-489-2538).

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

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

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Injection for subcutaneous use