

Foslevodopa/Foscarbidopa Continuous Subcutaneous Infusion (VYALEV) Criteria for Use March 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive foscarbidopa/foslevodopa.

- Currently taking or taken within 14 days a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine)
- Patient has not demonstrated a response to prior levodopa use

Inclusion Criteria

All of the following criteria must be met.

- Diagnosis of Idiopathic Parkinson's disease
- Patient is under the care of a VA or VA Community Care neurologist
- Motor fluctuations ("wearing off") that require dosing of dopaminergic medications at intervals every 4 hours or less
- Either combination of carbidopa/levodopa controlled-release (CR) and immediate-release (IR) tablet formulations or carbidopa/levodopa extended-release (ER) capsules throughout the day have not adequately resolved OFF periods
- Contraindication, intolerance, or inadequate therapeutic response to at least one agent from two of the following classes: dopamine agonist, catechol-O methyl transferase [COMT] inhibitor, monoamine oxidase type B [MAO B] inhibitor
- Discussion with the patient/caregiver/family regarding realistic efficacy expectations, device management, and potential device-related complications should be documented in the patient's medical record.

Supplemental Information

- Refer to product's prescribing information to determine the recommended dosing based on the patient's current carbidopa/levodopa dose and other PD therapies (e.g., COMT inhibitors).

Prepared: March 2025. Contact: N. Antonovich, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
