

Istradefylline (NOURIANZ)

Criteria for Use

March 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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 PBM-MAP-VPE 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 istradefylline.

- Patient is taking a strong CYP3A4 inducer
- Severe hepatic impairment (Child-Pugh Class C)
- End-stage renal disease (CrCl less than 15 mL/min) or hemodialysis
- Pregnancy

Inclusion Criteria

All of the following criteria must be met.

- Patient is under the care of a VA or VA Community Care neurologist or locally designated expert
- Diagnosis of Parkinson's disease (PD) with at least 2 hours of OFF time per day
- Patient is receiving carbidopa/levodopa at least four times daily. Dose has been stable at least 4 weeks prior to request.
- Attempts to reduce dosing intervals of carbidopa/levodopa have not adequately resolved OFF periods
- Use of carbidopa/levodopa extended-release (ER) capsule formulation (RYTARY) or controlled-release (CR) tablet formulation 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

Additional Inclusion Criteria

Select if applicable.

- For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy

Prepared: March 2024. Contact: N. Antonovich, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
