Pharmacy Policy Bulletin: J-0228 Nourianz (istradefylline) – Commercial and Healthcare Reform	
Number: J-0228	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0228-010	**Original Date:** 11/06/2019
Effective Date: 10/28/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• Nourianz (istradefylline)
FDA-Approved Indication(s):	• Adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes

Background:	• Nourianz (istradefylline) is an adenosine A_{2A} receptor antagonist. The precise mechanism of action in Parkinson's disease is unknown. • There are approximately one million people in the U.S who have Parkinson's disease. • "Off" episodes occur when carbidopa/levodopa has worn off and may consist of tremor, slowness, stiffness, difficulty walking or moving, and trouble getting around. • For the treatment of motor fluctuations including "off" episodes, the International Parkinson and Movement Disorder Society (IPMDS) recommends adjusting the timing of levodopa to a shorter time interval, improving absorption by taking levodopa on an empty stomach, and treating constipation to improve gastrointestinal transit. The guidelines also recommend addressing "off" episodes with adjunctive medications. • IPMDS guidelines state that using dopamine agonists, COMT inhibitors, or MAO-B inhibitors as adjunct therapy to levodopa is an effective approach. Comtan (entacapone) is a clinically useful COMT inhibitor and Azilect (rasagiline) is a clinically useful MAO-B inhibitor. Ropinirole and pramipexole are considered clinically useful dopamine agonists according to the guidelines. The role of selegiline formulations remains investigational due to low quality studies. First-line treatments for motor fluctuations as an adjunct to oral levodopa should be oral or transdermal agents followed by parenteral and surgical techniques for more advanced patients. • Prescribing Considerations: ○ The recommended dose in tobacco smokers who smoke 20 or more cigarettes per day is 40 mg once daily.

	○ Nourianz has warnings or precautions for dyskinesia, hallucinations, psychotic behavior, impulse control, and compulsive behaviors.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Nourianz may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member has a diagnosis of Parkinson's disease (ICD-10: G20) and is experiencing "off" episodes.

B. The member is using Nourianz as an adjunct to levodopa/carbidopa.

C. The member has experienced therapeutic failure, contraindication, or intolerance to three (3) of the following plan-preferred generic products **(1. through 5.)**:

1. selegiline
2. rasagiline
3. pramipexole
4. ropinirole
5. entacapone

II. Reauthorization

When a benefit, reauthorization of Nourianz may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Nourianz [package insert]. Bedminster, NJ: Kyowa Kirin; August 2019.
2. Parkinson's Foundation. Statistics. Available at: https://www.parkinson.org/Understanding-Parkinsons/Statistics. Accessed August 27, 2024.
3. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord*. 2018;33(8):1248-1266.