istradefylline (Nourianz™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO084

Description

Istradefylline (Nourianz) is an orally administered adenosine receptor antagonist.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
istradefylline (Nourianz)	20 mg tablets	Parkinson's disease	30 tablets/30 days	207954
	40 mg tablets		30 tablets/30 days	207955

Initial Evaluation

I. Istradefylline (Nourianz) may be considered medically necessary when the following criteria below are met:
   A. Prescribed by or in consultation with a neurologist; **AND**
   B. A diagnosis of **Parkinson's Disease** when the following are met:
      1. Member is currently on an oral levodopa regimen at least four times per day; **AND**
      2. Member is experiencing at least two hours of daily OFF time; **AND**
      3. Prescriber attests that member will be using istradefylline (Nourianz) in combination with carbidopa/levodopa; **AND**
      4. Treatment with one the following has been ineffective, contraindicated or not tolerated:
         i. Carbidopa/levodopa IR up to five times a day; **OR**
         ii. Carbidopa/levodopa XR; **AND**
      5. Current or previous treatment with at least TWO of the following agents used as adjunctive treatment to levodopa/carbidopa has been ineffective, contraindicated, or not tolerated:
         i. Dopamine agonist (e.g., ropinirole, pramipexole)
         ii. COMT inhibitor (e.g,. entacapone, tolcapone)
         iii. MAO-B inhibitor (e.g., rasagiline, safinamide, selegiline)

II. Istradefylline (Nourianz) is considered investigational when used for all other conditions, including but not limited to:
   A. Parkinson's disease WITHOUT documentation of motor fluctuations, "wearing off"

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Prescriber attests that member will be using istradefylline (Nourianz) in combination with carbidopa/levodopa; **AND**
IV. Documentation that member has a reduction in wearing off period from baseline

Supporting Evidence

I. The efficacy of istradefylline (Nourianz) as adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes was shown in four 12-week placebo-controlled trials that included a total of 1,143 patients. In all four studies, patients treated with istradefylline (Nourianz) experienced a statistically significant decrease from baseline in daily "off" time compared to patients receiving a placebo. In these pivotal clinical trials, patients were experiencing at least two hours of daily OFF time and were receiving the following concomitant therapies: dopamine agonists (85%), COMT inhibitors (38%), MAO-B inhibitors (40%), anticholinergics (13%), and/or amantadine (33%).
II. Levodopa, administered in oral carbidopa/levodopa formulations, is the mainstay and most effective medication for management of PD motor symptom management. Currently, motor fluctuations are managed by increasing the patient's levodopa dose, reducing intake of dietary protein with levodopa administration, using longer acting carbidopa/levodopa formulations, and adding other agents that can be clinically useful in extending "on" time (e.g., dopamine agonists, COMT inhibitors, and MAO-B inhibitors).
III. The 2018 International Parkinson and Movement Disorder Society Evidence-Based Medicine Review reported istradefylline (Nourianz) to be "likely efficacious" and "possibly useful" for clinical practice due to conflicting evidence but generally positive outcomes. Guidelines don't recommend one adjunctive therapy approach over another.

Investigational or Not Medically Necessary Uses

I. Parkinson's disease WITHOUT documentation of motor fluctuations, "wearing off"
   A. Istradefylline (Nourianz) has not been studied in patients with Parkinson's disease who aren't experiencing motor fluctuations; therefore, it would be considered investigational when requested in this setting.

References

1. Nourianz [Prescribing Information]. Kyowa Kirin Inc.: Bedminster, NJ. August 2019.
2. Fox, SH, et al. International Parkinson and Movement Disorder Society Evidence-Based Medicine Review: Update on Treatments for the Motor Symptoms of Parkinson's Disease. Movement Disorders 2018; 00:1-16. Available at: www.movementdisorders.org/MDS-Files1/Resources/PDFs/TreatmentsforMotorSymptomsofPD-2018.pdf
3. American Parkinson Disease Association (April 2017). Motor Fluctuations in Parkinson's Disease – What You Need to Know. Available at: www.aoic.net/APDA/APDA1609arc/APDA%20Motor%20Fluctuations%20Fact%20Sheet.pdf
4. UpToDate, Inc. Medical management of motor fluctuations and dyskinesia in Parkinson's disease. UpToDate [database online]. Waltham, MA. Last updated May 17, 2019 Available at: http://www.uptodate.com/home/index.html.
5. Food and Drug Administration [online press release]. FDA approves new add-on drug to treat off episodes in adults with Parkinson's disease. Available at: www.fda.gov/news-events/press-announcements/fda-approves-new-add-drug-treat-episodes-adults-parkinsons-disease. Updated August 27, 2019.
6. LeWitt PA, Guttman M, Tetrud JW, et al. Adenosine A2A receptor antagonist istradefylline (KW-6002) reduces "off" time in Parkinson's disease: a double-blind, randomized, multicenter clinical trial (6002-US-005). Ann Neurol 2008;63:295-302.
7. Hauser RA, Shulman LM, Trugman JM, et al. Study of istradefylline in patients with Parkinson's disease on levodopa with motor fluctuations. Mov Disord 2008;23:2177-2185.
8. Stacy M, Silver D, Mendis T, et al. A 12-week, placebo-controlled study (6002-US-006) of istradefylline in Parkinson disease. Neurology 2008;70:2233-2240.
9. Pourcher E, Fernandez HH, Stacy M, Mori A, Ballerini R, Chaikin P. Istradefylline for Parkinson's disease patients experiencing motor fluctuations: results of the KW-6002-US-018 study. Parkinsonism Relat Disord 2012;18:178-184.

Policy Implementation/Update:

Date Created	September 2019
Date Effective	November 2019
Last Updated	
Last Reviewed	

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Action and Summary of Changes	Date