

Drug Policy

Policy:	Nourianz (istradefylline)	Annual Review Date: 10/19/2023
		Last Revised Date: 10/19/2023

OVERVIEW

Nourianz is a first-in-class, selective adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's Disease (PD) experiencing "off" episodes.

POLICY STATEMENT

This policy involves the use of Nourianz. Prior authorization is recommended for pharmacy benefit coverage of Nourianz. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Nourianz as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Nourianz be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nourianz is recommended in those who meet the following criteria:

1. **Parkinson's Disease (PD), initial therapy**

Criteria. *Patient must meet the following criteria*

- A. The patient is 18 years of age or older; AND
- B. The patient is experiencing "off" episodes related to end-of-dose wearing off of levodopa/carbidopa totaling an average of at least 2 hours daily; AND
- C. Nourianz is prescribed by or in consultation with a neurologist; AND
- D. The patient has been treated with levodopa/carbidopa for a minimum of 1 year and has been using a stable dose for at least 4 weeks; AND
- E. Nourianz will be used in combination with levodopa/carbidopa; AND
- F. The patient is in stage 2-4 of disease as assessed by the Modified Hoehn and Yahr Scale

2. **Parkinson's Disease (PD), continuation of therapy**

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Criteria. *Patient must meet the following criteria*

- A. The patient has been using Nourianz for at least 3 months; AND
- B. The patient has responded to Nourianz therapy, as evidenced by a decrease in “off” time AND an increase in “on” time without troublesome dyskinesia; AND
- C. Nourianz will continue to be used in combination with levodopa/carbidopa; AND
- D. Nourianz is prescribed by or in consultation with a neurologist

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 1 year
- B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Nourianz has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Nourianz [prescribing information]. Kyowa Kirin, Inc. Bedminster, NJ: August 2019.
2. Istradefylline. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 4 October 2019. Accessed on 13 October 2019.