

5.60.039

Section:	Prescription Drugs	Effective Date:	January 1, 2024
Subsection:	Central Nervous System Drugs	Original Policy Date:	October 11, 2019
Subject:	Nourianz	Page:	1 of 4

Last Review Date: December 8, 2023

Nourianz

Description

Nourianz (istradefylline)

Background

Nourianz (istradefylline) is an adenosine receptor antagonist. The precise mechanism by which it exerts its effect in Parkinson's disease is unknown. Studies have demonstrated that Nourianz is adenosine A_{2A} receptor antagonist (1).

Regulatory Status

FDA-approved indications: Nourianz is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes (1).

Nourianz in combination with levodopa may cause dyskinesia or exacerbate pre-existing dyskinesia (1).

In patients on Nourianz who develop hallucinations or psychotic behaviors, dosage reductions or discontinuation should be considered (1).

Patients treated with Nourianz and one or more medication(s) for the treatment of Parkinson's disease (including levodopa) may experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges. Dose reduction or discontinuation of Nourianz should be considered if the patient develops such urges (1).

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Use of Nourianz during pregnancy is not recommended. Women of childbearing potential should be advised to use contraception during treatment with Nourianz (1).

The recommended dosage of Nourianz in patients who use tobacco in amounts of 20 or more cigarettes per day (or the equivalent of another tobacco product) is 40 mg once daily (1).

The safety and effectiveness of Nourianz in pediatric patients less than 18 years of age have not been established (1).

Related policies

Inbrija, Nuplazid, Tasmar

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nourianz may be considered **medically necessary** if the conditions indicated below are met.

Nourianz may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Parkinson's disease experiencing OFF episodes

AND ALL of the following:

1. Used in combination with carbidopa/levodopa
2. Inadequate control of Parkinson's symptoms on maximum tolerated doses of oral carbidopa/levodopa therapy
3. Prescriber agrees to monitor for dyskinesia

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4. Prescriber agrees to monitor for non-motor side effects (such as hallucinations, delusions, confusion, somnolence, and impulse control disorder)
5. Prescriber agrees to monitor tobacco smokers and adjust Nourianz dose if necessary

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Parkinson's disease experiencing OFF episodes

AND ALL of the following:

1. Improvement in Parkinson's symptoms
2. Used in combination with carbidopa/levodopa
3. Prescriber agrees to monitor for dyskinesia
4. Prescriber agrees to monitor for non-motor side effects (such as hallucinations, delusions, confusion, somnolence, and impulse control disorder)
5. Prescriber agrees to monitor tobacco smokers and adjust Nourianz dose if necessary

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 6 months

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Prior – Approval *Renewal* Limits

Quantity 90 tablets per 90 days

Duration 12 months

Rationale

Summary

Nourianz (istradefylline) is an adenosine receptor antagonist. The precise mechanism by which it exerts its effect in Parkinson's disease is unknown. Studies have demonstrated that Nourianz is adenosine A_{2A} receptor antagonist. The safety and effectiveness of Nourianz in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Nourianz while maintaining optimal therapeutic outcomes.

References

1. Nourianz [package Insert]. Bedminster, NJ: Kyowa Kirin, Inc.; March 2023.

Policy History

Date	Action
October 2019	Addition to PA
December 2019	Annual review. Revised regulatory status and added requirement to monitor for non-motor side effects per SME
December 2020	Annual review and reference update
September 2021	Annual review
September 2022	Annual review
September 2023	Annual review
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.