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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	October 1, 2023
<b>Subsection:</b>	Central Nervous System Drugs	<b>Original Policy Date:</b>	October 11, 2019
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**Last Review Date:** September 8, 2023

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## 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<sub>2A</sub> 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<sub>2A</sub> 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.; May 2020.

### 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

### Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.**