

Drug Coverage Policy

Effective Date	6/15/2025
Coverage Policy Number	IP0524
Policy Title	Nourianz

Parkinson's Disease - Nourianz

• Nourianz® (istradefylline tablets – Kyowa Kirin)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide quidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment quidelines. In certain markets, delegated vendor quidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Nourianz, an adenosine receptor antagonist, is indicated as adjunctive treatment to carbidopa/levodopa in adults with **Parkinson's disease** experiencing "off" episodes.¹

Guidelines

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The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018).² The review categorically divides treatment recommendations by Parkinson's disease characteristics. Nourianz is noted to be likely efficacious and possibly useful for treatment of motor fluctuations.

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POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Nourianz. All approvals are provided for the duration noted below. 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, approval requires Nourianz to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Nourianz is considered medically necessary when the following criteria are met:

FDA-Approved Indication

- **1. Parkinson's Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, C, <u>and</u> D):
 - A) Patient is currently taking carbidopa/levodopa; AND
 - **B)** Patient is experiencing "off" episodes; AND Note: Examples of "off" episodes include muscle stiffness, slow movements, or difficulty starting movements.
 - C) The medication is prescribed by or in consultation with a neurologist; AND
 - **D)** Preferred product criteria is met for the product as listed in the below table.

Employer Plans:

Product	Criteria
Nourianz	ONE of the following:
(istradefylline tablets)	 Tried ONE of the following: cabergoline, entacapone, pramipexole, rasagiline, ropinirole, selegiline, tolcapone, apomorphine Patients already started on Nourianz

Individual and Family Plans:

Product	Criteria
Nourianz (istradefylline tablets)	ONE of the following: 1. Tried ONE of the following: cabergoline, entacapone, pramipexole, rasagiline, ropinirole, selegiline, tolcapone, apomorphine 2. Patients already started on Nourianz

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

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Nourianz for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

- 1. Nourianz® tablets [prescribing information]. Bedminster, NJ: Kyowa Kirin; March 2024.
- 2. 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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Policy Name Change: Updated Policy Name from "Istradefylline" to "Parkinson's Disease – Nourianz." Parkinson's Disease: Removed the age requirement of 18 years or older for Parkinson's disease treatment. Updated criterion from "currently receiving levodopa-based treatment" to "currently taking carbidopa/levodopa." Moved preferred product requirement criteria to preferred product table.	07/01/2024
Annual Revision	Parkinson's Disease: Examples of evidence of "off" episodes were moved to a Note. Preferencing Table. Updated from "Currently receiving Nourianz" to "Patients already started on Nourianz" Updated from "Failure, contraindication, or intolerance" to "Tried" Added apomorphine as an alternative Removed Kynmobi as an alternative	6/15/2025

The policy effective date is in force until updated or retired.

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