Drug Coverage Policy

Effective Date.....07/01/2024
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 guidance 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 and have discretion in making individual coverage determinations. 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 guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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
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.

Medical Necessity Criteria

Coverage for istradefylline (Nourianz) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

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, and D):
   - **A)** Patient is currently taking carbidopa/levodopa; AND
   - **B)** Patient is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND
   - **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 (istradefylline tablets)	**ONE** of the following: 1. Failure, contraindication, or intolerance to **ONE** of the following: A. cabergoline B. entacapone C. Kynmobi [may require prior authorization] D. pramipexole E. rasagiline F. ropinirole G. selegiline H. tolcapone 2. Currently receiving Nourianz

Individual and Family Plans:

Product	Criteria
Nourianz (istradefylline tablets)	**ONE** of the following: 1. Failure, contraindication, or intolerance to **ONE** of the following: A. cabergoline B. entacapone C. Kynmobi [may require prior authorization] D. pramipexole E. rasagiline F. ropinirole G. selegiline H. tolcapone 2. Currently receiving 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.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (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

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