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| Coverage Policy Number | IP0524 |

Istradefylline

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Related Coverage Resources

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. 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.

Overview

This policy supports medical necessity review for istradefylline (Nourianz®).

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.

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

Medical Necessity Criteria

Istradefylline (Nourianz) is considered medically necessary when the following are met:

Parkinson's Disease. Individual meets ALL of the following criteria:

- 1. Age 18 years of age or older
- 2. Experiencing "off" episodes

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- 3. Currently receiving levodopa-based treatment
- 4. Medication is prescribed by, or in consultation with, a neurologist
- 5. Where preferred products required, documentation of **ONE** of the following:
 - a. Failure, contraindication, or intolerance to **ONE** of the following: cabergoline, entacapone, Kynmobi [prior authorization may apply], pramipexole, rasagiline, ropinirole, selegiline, or tolcapone
 - b. 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.

Reauthorization Criteria

Continuation of istradefylline (Nourianz) is considered medically necessary for Parkinson's Disease when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

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.

References

- 1. Nourianz® tablets [prescribing information]. Bedminster, NJ: Kyowa Kirin; November 2020.
- 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

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