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 A2A 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).
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

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 in patients 18 years of age or older with Parkinson’s disease and if the conditions indicated below are met.

Nourianz is considered investigational for patients less than 18 years of age and 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
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
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 A2A 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

Policy History

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<td>October 2019</td>
<td>Addition to PA</td>
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<td>December 2019</td>
<td>Annual review. Revised regulatory status and added requirement to monitor for non-motor side effects per SME</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.