Pharmacy Medical Necessity Guidelines: Nourianz (istradefylline)

Effective: January 12, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Nourianz (istradefylline) is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes. Patients enrolled in clinical trials had a mean duration of Parkinson's disease of 9 years that were Hoehn and Yahr Stage II to IV, were experiencing at least two hours of "off" time per day and were treated with levodopa for at least one year, with stable dosage for at least four weeks before screening. During the trials patients continued levodopa treatment with or without concomitant PD medications, including dopamine agonists, COMT inhibitors, MAO-B inhibitors, anticholinergics, and/or amantadine, provided the medications were stable for at least four weeks before screening and throughout the study period. Compared to placebo, patients treated with Nourianz experienced an additional increase in baseline in "on" time without troublesome dyskinesias.

The recommended dosage for Nourianz is 20 mg orally once daily. The dosage may be increased to a maximum of 40 mg once daily. Patients with moderate hepatic impairment should limit their dose to 20 mg once daily and Nourianz should be avoided altogether in patients with severe hepatic impairment. The recommended dosage for patients who smoke 20 or more cigarettes per day (or the equivalent of another tobacco product) is 40 mg once daily.

COVERAGE GUIDELINES

The plan may authorize coverage of Nourianz (istradefylline) for Members, when **all** of the following criteria are met:

1. The Member has a documented diagnosis of Parkinson's disease

AND

2. The Member has been treated with levodopa/carbidopa

AND

3. The Member has had an inadequate response or intolerance to at least two additional generic agents used for the treatment of Parkinson's disease, or the Member has a contraindication to all available generic agents used for the treatment of Parkinson's disease

AND

4. The Member will be taking Nourianz in conjunction with levodopa/carbidopa.

LIMITATIONS

1. Nourianz (istradefylline) will be limited to a 30 tablets per 30 days.

CODES

None

REFERENCES

1. Nourianz (istradefylline) [prescribing information]. Bedminster, NJ: Kyowa Kirin, Inc.; May 2-2-.

APPROVAL HISTORY

January 14, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. January 12, 2021: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.