

Pharmacy Medical Necessity Guidelines: Medications for the Management of Parkinson’s Disease

Effective: February 15, 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
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>RXUM: 617.673.0988</p>	

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

OVERVIEW

Inbrija (levodopa) is an aromatic amino acid indicated for the intermittent treatment of “off” episodes in patients with Parkinson’s disease treated with carbidopa/levodopa.

Inbrija (levodopa) capsules contain levodopa inhalation powder and are for oral inhalation only. Inbrija must be used with Inbrija inhaler.

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.

Xadago (safinamide) is a monoamine oxidase inhibitor type-B (MAOI-B) indicated for the adjunctive treatment of patients with Parkinson’s Disease (PD) who are experiencing “off” episodes. Xadago has not been shown to be effective as monotherapy for the treatment of PD.

Ongentys (opicapone) is a catechol-O-methyltransferase (COMT) inhibitors indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease (PD) experiencing “off” episodes.

An “off” episode is a time when a patient’s medications are not working well, causing an increase in Parkinson disease symptoms, such as tremor and difficulty walking.

COVERAGE GUIDELINES

Inbrija (levodopa)

The plan may authorize coverage of **Inbrija (levodopa)** when all of the following criteria are met:

1. The member has a diagnosis of Parkinson’s disease
- AND**
2. One of the following:
 - a. The member is currently taking a controlled or extended release formulation of carbidopa/levodopa
 - b. The member is currently taking an immediate release formulation of carbidopa/levodopa and there is documentation of inadequate response, contraindication, or inability to tolerate a long acting formulation (e.g. extended release, controlled release) of carbidopa/levodopa

AND

3. The member is experiencing intermittent “off” episodes of more than 2 hours daily, related to Parkinson’s Disease

AND

4. The member has had previous treatment with or has a contraindication or intolerance to one agent from two out of three therapeutic classes listed below:
 - i. A dopamine agonist (e.g. pramipexole IR, ropinirole IR)

- ii. A monoamine oxidase-B (MAO-B) inhibitor (e.g. selegiline),
- iii. A catechol-O-methyltransferase (COMT) inhibitor (e.g. entacapone)

AND

5. Carbidopa/levodopa therapy will be continued concomitantly with Inbrija

Nourianz (istradefylline)

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

- 1. The member has a diagnosis of Parkinson’s Disease
- AND**
- 2. The member has been treated with carbidopa/levodopa
- 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 is experiencing intermittent “off” episodes of more than 2 hours daily, related to Parkinson's Disease
- AND**
- 5. Carbidopa/levodopa therapy will be continued concomitantly with Nourianz

Ongentys (opicapone)

The plan may authorize coverage of Ongentys for Members when **all** of the following criteria are met and limitations do not apply:

- 1. The Member is diagnosed with Parkinson’s disease
- AND**
- 2. The member has been treated with carbidopa/levodopa
- AND**
- 3. The Member tried and failed therapy with entacapone or tolcapone
- AND**
- 4. Carbidopa/levodopa therapy will be continued concomitantly with Ongentys

Xadago (safinamide)

The plan may authorize coverage of **Xadago (safinamide)** when all of the following criteria are met:

- 1. Diagnosis of Parkinson’s Disease and member is experiencing “off” time on levodopa/carbidopa monotherapy
- AND**
- 2. Xadago is prescribed in combination with levodopa/carbidopa
- AND**
- 3. Member tried and could not tolerate treatment due to adverse effects or there was inadequate response with ALL of the following preferred generic alternatives:
 - a. rasagiline
 - b. entacapone

LIMITATIONS

- 1. Nourianz (istradefylline) will be limited to a 30 tablets per 30 days
- 2. The quantity of Ongentys is limited to one tablet per day.

CODES

None

REFERENCES

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APPROVAL HISTORY

Xadago: December 12, 2017: Reviewed by Pharmacy & Therapeutics Committee.
 Inbrija: July 09, 2019: Reviewed by Pharmacy & Therapeutics Committee.
 Nourianz: January 14, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 13, 2018: No changes.
- November 12, 2019: Administrative update to add description of "off-episodes" to the overview section.
- April 14, 2020: Effective April 14, 2020 consolidated Xadago (ID: 6043131) and Inbrija (ID: 6528715) criteria with Nourianz (ID: 6546248) to create a class MNG. MNG retitled: Medications for the Management of Parkinson's Disease. Existing Xadago and Inbrija MNGs apply to MA and RITogether plans only.
- February 9, 2021: Added criteria and quantity limitations for Ongentys (opicapone) to the MNG. Administrative update to correct a misspelling for generic name of Nourianz.

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.

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