

**Xadago (safinamide)
 Inbrija (levodopa)
 Nourianz (istradefylline)
 Effective 12/01/2020**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled through a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Xadago and Nourianz do NOT require specialty pharmacy		

Overview

Parkinson disease symptoms are due to lack of striatal dopamine. Levodopa circulates in the plasma to the blood-brain-barrier (BBB), where it crosses, to be converted by striatal enzymes to dopamine. Inbrija is an oral inhalation of levodopa. 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. Nourianz (istradefylline) is an adenosine receptor antagonist indicated for patients with PD, in combination with levodopa/carbidopa, in adults experiencing “off” episodes.

Coverage Guidelines

Inbrija and Xadago

Authorization may be granted for members new to the plan who are currently receiving treatment with Xadago and Inbrija excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members with Parkinson disease experiencing “off” episodes when all the following criteria are met, and documentation is provided:

1. Member is concurrently taking carbidopa/levodopa.
2. Member is ≥ 18 years of age
3. Member is experiencing “off” symptoms with carbidopa/levodopa therapy
4. Member has had an inadequate response or adverse reaction to selegiline **AND** rasagiline

5. **For Inbrija only**, the member has an inadequate response or adverse reaction to selegiline, rasagiline **AND** Xadago

Nourianz

Authorization may be granted for members new to the plan who are currently receiving treatment with Nourianz excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Member has a diagnosis of Parkinson disease experiencing “off” episodes
2. Member is concurrently taking carbidopa/levodopa.
3. Member is ≥ 18 years of age
4. Member is experiencing “off” symptoms with carbidopa/levodopa therapy
5. Member has inadequate response or intolerance to at least two (2) of the following:
 - a. Dopamine agonist. Ex) pramipexole, ropinirole
 - b. COMT (catechol-O-methyltransferase) inhibitor. Ex) entacapone, tolcapone
 - c. MAO-B (monoamine oxidase B) inhibitor. Ex) selegiline, rasagiline

OR

6. Member has contraindication to ALL available generic agents to treat Parkinson’s disease.

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member’s condition.

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months
3. The following quantity limits apply:

Inbrija 42mg	300 capsules per 30 days
Nourianz 20 &40mg	30 tablets per 30 days

References

1. Xadago (safinamide) [prescribing information]. Louisville, KY: US WorldMeds; June 2017
2. Selegiline Hydrochloride Capsules [prescribing information]. Weston, FL: Apotex Corp; June 2014
3. Azilect (rasagiline) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA; December 2018
4. Inbrija (levodopa) [prescribing information]. Ardsley, NY: Acorda Therapeutics; December 2018
5. Lloyd KG, Davidson L, Hornykiewicz O. The neurochemistry of Parkinson's disease: effect of L-dopa therapy. *J Pharmacol Exp Ther.* 1975;195(3):453-464. [\[PubMed 489\]](#)
6. Nourianz (istradefylline) [prescribing information]. Bedminster, NJ: Kyowa Kirin, Inc.; August 2019.
7. Takahashi M, Fujita M, Asai N, et al. Safety and effectiveness of istradefylline in patients with Parkinson's disease: interim analysis of a post-marketing surveillance study in Japan. *Expert Opin Pharmacother* 2018; 19:1635
8. Trenkwalder C, Kuoppamäki M, Vahteristo M, et al. Increased dose of carbidopa with levodopa and entacapone improves "off" time in a randomized trial. *Neurology* 2019; 92:e1487
9. LeWitt PA, Hauser RA, Pahwa R, et al. Safety and efficacy of CVT-301 (levodopa inhalation powder) on motor function during off periods in patients with Parkinson's disease: a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet Neurol* 2019; 18:145



Review History

09/24/2018 – Reviewed

06/19/2019 – Added Inbrija

09/18/2019 – Reviewed

07/22/2020 – Reviewed at P&T Mtg; Added Nourianz to criteria

09/16/2020 – reviewed and updated at Sept P&T Mtg; added QL to Nourianz. Effective 12/01/2020.

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

