

**Xadago (safinamide)  
Inbrija (levodopa)  
Nourianz (istradefylline)  
Effective 09/01/2020**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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 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  $\geq$  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 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  $\geq 18$  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
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### **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. Effective 09/01/20

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