Mass General Brigham
Health Plan

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

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

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.