Pharmacy Policy Bulletin: J-0602 Xadago (safinamide) – Commercial and Healthcare Reform	
Number: J-0602	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0602-012	**Original Date:** 05/10/2017
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Xadago (safinamide)
FDA-Approved Indication(s):	• Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

Background:	• Xadago is an inhibitor of monoamine oxidase type B (MAO-B) receptors mostly found in the brain. Beneficial effects are thought to be attributed to increased levels and activity of dopamine. • There are approximately one million people in the United States who have PD. "Off" episodes occur in PD patients when carbidopa/levodopa has worn off and may consist of tremor, slowness, stiffness, difficulty walking or moving, and trouble getting around. • For the treatment of motor fluctuations including "off" episodes, The International Parkinson and Movement Disorder Society (IPMDS) recommends adjusting the timing of levodopa to a shorter time interval, improving absorption by taking levodopa on an empty stomach, and treating constipation to improve gastrointestinal transit. • The guidelines also recommend addressing "off" episodes with adjunctive medications by evaluating side effect profiles and individual patient characteristics as well as cost and availability. First-line treatments are usually oral (or transdermal) agents followed by parenteral and surgical techniques for more advanced patients. All non-ergot dopamine agonists are clinically useful for reducing motor fluctuations. Enhancing levodopa duration with enzyme inhibition using catechol-O-methyl transferase (COMT) and/or MAO-B inhibition remains an effective approach for reducing motor fluctuations. • The 2018 IPMDS guidelines recommend the following drugs as clinically useful or possibly useful treatments to prevent/delay motor fluctuations: pramipexole, ropinirole, cabergoline, and bromocriptine. For treatment of motor fluctuations, the following drugs are considered clinically useful: pramipexole, ropinirole, Neupro (rotigotine), apomorphine; rasagiline, zonisamide, Xadago (safinamide), entacapone, Ongentys (opicapone) or possibly useful: bromocriptine, cabergoline, tolcapone, and Nourianz (istradefylline). While selegiline has been

	deemed investigational in the guidelines for treating motor fluctuations, it is recommended as clinically useful for early PD requiring symptomatic therapy. • Prescribing Considerations: ○ Xadago is contraindicated in patients who are using other MAO inhibitors, opioid drugs, serotonin-norepinephrine reuptake inhibitors, tricyclic or tetracyclic antidepressants, triazolopyridine antidepressants, cyclobenzaprine, methylphenidate, amphetamine, their derivatives, and dextromethorphan. ○ Xadago is contraindicated in patients with severe hepatic impairment. ○ Xadago has not been shown to be effective as monotherapy for the treatment of PD.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Xadago may be approved when all of the following criteria are met **(A. through F.)**:

A. The member is 18 years of age or older.
B. The member has a diagnosis of Parkinson's disease (ICD-10: G20).
C. The member will be using Xadago as an adjunct to levodopa/carbidopa.
D. The member is experiencing wearing off (for example "off" episodes) despite optimized levodopa/carbidopa therapy.
E. The member has experienced therapeutic failure, contraindication, or intolerance to the plan-preferred product, generic rasagiline.
F. The member has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following plan-preferred products **(1. through 4.)**:
1. selegiline
2. pramipexole
3. ropinirole
4. entacapone

II. Reauthorization

When a benefit, reauthorization of Xadago may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Xadago [package insert]. Rockville, MD: MDD US Operations, LLC; August 2021.
2. Parkinson’s Foundation. Statistics. Available at: https://www.parkinson.org/Understanding-Parkinsons/Statistics. Accessed May 05, 2025.
3. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord* 2018;33(8):1248-1266.