Pharmacy Medical Necessity Guidelines: Xadago® (safinamide)

Effective: March 10, 2026

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
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

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.

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

The plan may authorize coverage of **Xadago (safinamide)** when the following criteria are met and limitations do not apply:

1. Diagnosis of Parkinson's Disease and member is experiencing "off" time on levodopa/carbidopa

AND

2. Xadago is prescribed in combination with levodopa/carbidopa

AND

3. Member had an inadequate response, adverse reaction, or contraindication to ALL of the following preferred generic alternatives:
    a. rasagiline
    b. selegiline

LIMITATIONS

None

CODES

None

REFERENCES

1. Azilect (rasigiline) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; June 2020.
2. Borgohain R, Szasz J, Stanzione P et al. Randomized tiral of safinamide add-on to levodopa in Parkinson's disease with motor functions. *Mov Disord*. 2017; 29(2):229-37.
3. Center for Disease Control and Prevention. Deaths: final data for 2013. National vital statistics reports. 2016; 64(2): 1-119. cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf Available from Internet. Accessed 2017 November.
4. Center for Medicare and Medicaid Services, MDS 3.0 Frequency Report: First Quarter 2017. URL:cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/Minimum-Data-Set-3-0-Frequency-Report.html Available from Internet. Accessed 2017 November.
5. Connolly BS. Lang AE. Pharmacological treatment of Parkinson's disease. Review. *JAMA.* 2014; 311(16), S1670-1683.
6. Hauser RA, Rascol O, Korzyn AD, et al. Ten-year follow-up of Parkinson's Disease. Review. *JAMA.* 2014l 311(16), S1670-1683.
7. Hoehn M and Yahr MD. Parkinsonism: Onset, Progression, and Mortality. Neurology. 1967; 17(5), 427-442.
8. Katzenschlager, R. Head J, Schrag Al, et al. Fourteen-year Final Report of the Randomized PDRG-UK trial comparing three intitial treatments in PD. Neurology.2008; 71, 474-80.
9. Liang TW, Tarsy D. Medical management of motor fluctuations and dyskinesia in Parkinson disease. UpToDate. Available at: www.uptodate.com. Accessed 30 May 2023.

10. Miyasaki, J.M.; W.; Suchowersky, O.; Weiner, W.J.; Lang, A.E. Practice parameter: initiation of treatment for Parkinson's disease: an evidence-based review: report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 58:11-7; 2002. URL: http://n.neurology.org/content/58/1/11 Available from Internet. Accessed 2017 November.
11. National Institue for Health and Care Excellence. Parkinson's Disease; National Clinical Guidelines for Diagnosis and Mangement in Primary and Secondary Care. 2006.
12. Pahwa R., Factor S.A., Lyons K. E., et al. Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). *Neurology.* April 2006; 66:983-995.
13. Parkinson Study Group. A Randomized Placebo-Controlled Trial of Rasagiline in Levodopa-Treatment Patients with Parkinson Disease and Motor Fluctuations: The PRESTO Study. Arch Neurol. 2005; 62(2):241-248.
14. PerezLioret S, Negre-Pages L, Damier P, et al. Prevalence, determinants, and effect of quality of life of freezing of gain in Parkinson disease. *JAMA Neurol.* 2014; 71, 884-890.
15. Schapira AH, Fox SH, Hauser RA et al. Assessment of safety and efficacy of safinamide as an adjunct to levodopa in patients with Parkinson's disease and motor fluctuations (LARGO, Lasting effect in Adjunct therapy with Rasagiline Given Once daily, study): a randomized, double-blind, parallel-group trial. Lancet. 2005; 365(9463):947-954.
16. Xadago (safinamide) [prescribing information]. Rockville, MD: MDD US World Operations, LLC; October 2024.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: Effective September 1, 2023, updated criteria to remove requirement that current levodopa/carbidopa use is monotherapy, and updated language for previous use of rasagiline and selegiline.
2. March 12, 2024: Effective April 1, 2024, updated RxUM fax number.
3. March 11, 2025: No changes
4. March 10, 2026: No changes.

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.

Provider Services