Parkinson's Disease Prior Authorization Checklist

XADAGO®
(safinamide) tablets

This form provides information that is generally used to determine clinical necessity by payer. This is for reference only and does not guarantee prior authorization approval. Please verify each individual payer policy for clinical guidelines and policies.

Patient Name: _____ DOB: ____/____/____

Drug and Strength

Drug: XADAGO

Strength: ☐ 50 mg ☐ 100 mg

Diagnosis Code(s)

ICD-CM codes are provided herein for reference only. Only a patient's healthcare provider may determine the appropriate ICD-CM code.*

*ICD-CM codes are based on the World Health Organization (WHO) International Classification of Diseases, 10th edition. US WorldMeds, LLC ("US WorldMeds") assumes no liability for information contained herein. US WorldMeds claims no ownership or other interest in the ICD-CM codes.

☐ G20.0 Parkinson's disease experiencing *off* episodes

☐ Other ICD-10 code: _____

Drugs Tried/Failed

☐ Rasagiline (AZILECT®) Start Date: _____ End Date: _____

- If not checked, why is rasagiline not clinically appropriate for this patient?

_____

☐ Selegiline (ELDEPRYL®) Start Date: _____ End Date: _____

- If not checked, why is selegiline not clinically appropriate for this patient?

_____

☐ Entacapone (COMTAN®) Start Date: _____ End Date: _____

☐ Rotigotine (NEUPRO®) Start Date: _____ End Date: _____

☐ Carbidopa/levodopa Start Date: _____ End Date: _____

☐ Other: _____

Clinical History Information (check if necessary)

☐ Will be taken in combination treatment with carbidopa/levodopa therapy

☐ Patient is experiencing *off* episodes with carbidopa/levodopa therapy

☐ Continuity of care; patient has had a positive response to therapy (XADAGO)

☐ Treatment start date: _____

☐ Other important clinical details:

Does the patient have severe hepatic impairment?

☐ Yes ☐ No

Physician Signature: _____ Date: ____/____/____

Please see Important Safety Information on reverse side and accompanying full Prescribing Information and Patient Information.

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INDICATION

- XADAGO (safinamide) is indicated as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Concomitant use of other drugs in the monoamine oxidase inhibitor (MAOI) class or other drugs that are potent inhibitors of monoamine oxidase, including linezolid.
- Concomitant use of opioid drugs (e.g., meperidine and its derivatives, methadone, propoxyphene, or tramadol); serotonin-norepinephrine reuptake inhibitors (SNRIs), tri- or tetra-cyclic or triazolopyridine antidepressants; cyclobenzaprine; methylphenidate, amphetamine, and their derivatives; or St. John's wort. Concomitant use could result in life-threatening serotonin syndrome.
- Concomitant use of dextromethorphan.
- In patients with a history of a hypersensitivity to safinamide.
- In patients with severe hepatic impairment (Child-Pugh C).

WARNINGS & PRECAUTIONS

- XADAGO may cause or exacerbate hypertension. In clinical trials, the incidence of hypertension was 7%, 5%, and 4% for XADAGO 50mg, 100mg, and placebo respectively. Patients should be monitored after starting XADAGO for new-onset hypertension or hypertension that is not adequately controlled. Dietary tyramine restriction is not required during treatment with recommended doses of XADAGO. However, patients should be advised to avoid foods containing a very high amount of tyramine because of the potential for severe increases in blood pressure, also referred to as hypertensive urgency, crisis, or emergency.
- Patients treated with dopaminergic medications have reported falling asleep while engaged in activities of daily living. If a patient develops daytime sleepiness or episodes of falling asleep during activities that require full attention (e.g., driving a motor vehicle, conversations, eating), XADAGO should ordinarily be discontinued, or the patient should be advised to avoid driving and other potentially dangerous activities.
- May cause dyskinesia (or exacerbate dyskinesia).
- Patients with a major psychotic disorder should ordinarily not be treated with XADAGO because of the risk of exacerbating psychosis with an increase in central dopaminergic tone. Consider dosage reduction or discontinuation if hallucinations or psychotic-like behavior develop.
- Patients can experience impulse control/compulsive behaviors while taking XADAGO. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about new or increased abnormal behaviors.
- Withdrawal-emergent hyperpyrexia and confusion, a symptom complex resembling neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction, withdrawal of, or changes in drugs that increase central dopaminergic tone.
- Monitor periodically for visual changes in patients with a history of retinal/macular degeneration, uveitis, inherited retinal conditions, family history of hereditary retinal disease, albinism, retinitis pigmentosa, or any active retinopathy (e.g., diabetic retinopathy).

DOSING GUIDELINES & CONSIDERATIONS

- The maximum recommended dosage of XADAGO in patients with moderate hepatic impairment is 50 mg once daily. Discontinue XADAGO if patient progresses from moderate to severe hepatic impairment. XADAGO is contraindicated in patients with severe hepatic impairment.

ADVERSE REACTIONS

- In placebo-controlled studies, the most common adverse reactions associated with XADAGO treatment in which the incidence for XADAGO 100mg/day was at least 2% greater than the incidence for placebo were dyskinesia, fall, nausea, and insomnia.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Supernus Pharmaceuticals, Inc. at 1-888-492-3246 (1-888-4XADAGO). You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information and Patient Information at XADAGOhcp.com.

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