Sample Letter of Medical Necessity

***Please Note: This letter is intended as an example for your consideration and may not include all the information necessary to support your prior authorization request. Requirements will vary based on the health plan guidelines and patient benefit design. Please note the requesting provider is entirely responsible for ensuring the accuracy, adequacy, medical necessity, and supportability of all information required. Further, the requesting provider is solely responsible for submission to and follow-up with the health plan regarding this prior authorization request. Use of this document does not guarantee coverage or reimbursement and is not intended to be a substitute for or an influence on the independent medical judgement of the physician*.**

*This template is provided by Kyowa Kirin, Inc. for informational purposes for informational purposes with the intent to support patients. Prescribers are not required to use Kyowa Kirin products in relation to or exchange for this template and should use their clinical judgement when determining patient treatment.*

[PRESCRIBER LETTERHEAD]

(Date)

(Payer Name)

ATTN: PRIOR AUTHORIZATION

(Type in Payer Name)

(Type in Payer address)

Patient: (Type in patient’s first and last name)

Subscriber ID#: (Type in insurance ID#)

Subscriber Group #: (Type in insurance group#)

Re: NOURIANZ® (istradefylline) tablets, for oral use

To whom it may concern:

I am submitting this letter to document the medical necessity of Nourianz® for my patient, [patient name] [policy number].

Nourianz is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson’s disease (PD) experiencing “off” episodes.

**Patient’s Clinical History**

[Patient’s name] is a [age] year old [male/female] who was diagnosed in [date] with Parkinson’s disease. [Patient’s name] has been treated with levodopa/carbidopa for [X] years.

The patient underwent [describe treatment to date].

* [Be sure to include diagnosis and dates]
* [Past treatments]
* [Patient's ability to manage current disease]
* [Social & family information (especially if younger patient)]

[i.e. young children or grandchildren contributes to the well-being of the family, part-time work, volunteer work]

**Treatment Rationale**

Nourianz® (istradefylline) was approved by the FDA on Aug 27, 2019, as adjunctive treatment to levodopa/carbidopa for the treatment of adult patients with Parkinson’s disease (PD) experiencing “off” episodes.

Please see the enclosed documentation demonstrating the medical necessity of Nourianz as an adjunct to levodopa/carbidopa for my patient, [Patient’s Name].

**Summary**

I believe Nourianz is appropriate and medically necessary for [Patient’s Name] and request that you provide coverage for this treatment. If you have further questions about this matter, please contact me at [Physician Phone Number] or via email at [Physician email]. Should you have any questions, please do not hesitate to call me at phone number [MD phone#]

Thank you for your time and consideration.

Sincerely,

(Physician’s name and credentials)

Full Prescribing Information

Relevant clinical/chart notes

**Indication**

NOURIANZ® (istradefylline) is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson’s disease (PD) experiencing “off” episodes.

**Important Safety Information**

**Warnings and Precautions**

**Dyskinesia:** NOURIANZ in combination with levodopa may cause dyskinesia or exacerbate pre-existing dyskinesia. In clinical trials, 1% of patients treated with either NOURIANZ 20 mg or 40 mg discontinued treatment because of dyskinesia, compared to 0% for placebo.

**Hallucinations / Psychotic Behavior:** Because of the potential risk of exacerbating psychosis, patients with a major psychotic disorder should not be treated with NOURIANZ. Consider dosage reduction or discontinuation if a patient develops hallucinations or psychotic behaviors while taking NOURIANZ.

**Impulse Control / Compulsive Behaviors:** Patients treated with NOURIANZ and one or more medication(s) for the treatment of Parkinson’s disease (including levodopa) may experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges. In clinical trials, 1 patient treated with NOURIANZ 40 mg was reported to have impulse control disorder, compared to no patient on NOURIANZ 20 mg or placebo.

**Drug Interactions**

The maximum recommended dosage in patients taking strong CYP3A4 inhibitors is 20 mg once daily. Avoid use of NOURIANZ with strong CYP3A4 inducers.

**Specific Populations**

**Pregnancy:** Based on animal data, may cause fetal harm.

**Hepatic impairment:** The maximum recommended dosage of NOURIANZ in patients with moderate hepatic impairment is 20 mg once daily. Avoid use in patients with severe hepatic impairment.

**Adverse Reactions**

The most common adverse reactions with an incidence ≥5% and occurring more frequently than with placebo were dyskinesia (15%, 17%, and 8%), dizziness (3%, 6%, and 4%), constipation (5%, 6%, and 3%), nausea (4%, 6%, and 5%), hallucination (2%, 6%, and 3%), and insomnia (1%, 6%, and 4%) for NOURIANZ 20 mg, 40 mg, and placebo, respectively.

You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at **1-844-768-3544** or FDA at
1-800-FDA-1088 or [www.fda.gov/medwatch](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

**Please see full**[**Prescribing Information**](https://www.nourianzhcp.com/assets/pdf/nourianz-full-prescribing-information.pdf)**for NOURIANZ.**