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. The information required for a letter of medical necessity may vary based on the health plan guidelines and patient benefit design. Please note the requesting provider is entirely responsible for ensuring the accuracy and completeness of all information submitted, as well as any and all medical judgments reflected in that information (e.g., medical necessity, etc.) 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.

[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].

On August 27, 2019, the FDA approved Nourianz (istradefylline) as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "OFF" episodes.

Patients treated with Nourianz experienced significant improvement in OFF time compared to placebo in 4 randomized trials. Patients taking Nourianz also experienced an improvement in ON time without troublesome dyskinesia. The most common adverse reactions (at least 5% and more frequent than placebo) were dyskinesia, dizziness, constipation, nausea, hallucination, and insomnia. The prescribing information for Nourianz reflects warnings and precautions for dyskinesia, hallucinations/psychotic behavior and impulse control/compulsive behavior.

Please see the enclosed documentation demonstrating the medical necessity of Nourianz as an adjunct to levodopa/carbidopa for my patient, [Patient's Name], who has Parkinson's disease and is experiencing "OFF" episodes. I would appreciate prompt review of this information for authorization of Nourianz.

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. Patients with Parkinson's disease who are on levodopa/carbidopa and other concomitant anti-parkinson medications experiencing "OFF" episodes, have limited treatment options.

[He/She] 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. This approval was based on results from 4, 12-week registrational trials that demonstrated that patients with istradefylline plus levodopa/carbidopa experienced a greater reduction in OFF time compared with patients treated with placebo plus levodopa/carbidopa.

Nourianz is the only adenosine receptor antagonist indicated to reduce OFF episodes thus providing an alternate MOA to potentially address this patient's medical need.

Summary
In summary, Nourianz is medically necessary and reasonable for [Patient's Name]. Please contact me if any additional information is required to ensure the prompt approval of this course of treatment. 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)

Suggested Enclosures

USPI

Relevant clinical/chart notes