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**Sample Letter of Medical Necessity**

Payers vary in their requirements for determining medical necessity. See the following page for a

sample letter that providers can reference when preparing the Letter of Medical Necessity on their office letterhead. The letter of medical necessity should include the type of information that payers may require to establish medical necessity, such as:

* The patient's history, diagnosis, and current condition
* Information about prior treatments
* A summary of your clinical assessment and rationale for requesting coverage

This information herein is for informational purposes and for the healthcare provider’s convenience only. It is not intended as legal advice and is not a substitute for a provider’s independent professional judgment. This information is not a guarantee of coverage or payment (partial or full). Healthcare providers should always confirm coverage for individual patients with their insurance providers.

**Please see Indication and Important Safety Information on page 3.**

 *Physician Letterhead*

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| --- | --- |
| [Insurance Company] | Re: Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [Address Line 1] |  Policy ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [Address Line 2] |  Policy Group: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

[Date]

Attn: [Medical/Pharmacy Director], [Department]

Dear [Medical/Pharmacy Director]:

I am writing on behalf of [patient’s name], a [male/female] aged [patient’s age] years, to formally document the medical necessity for treatment with INGREZZA® (valbenazine) capsules for a diagnosis of tardive dyskinesia (G24.01). This letter provides information about the patient’s medical history, diagnosis, and treatment plan with INGREZZA. INGREZZA is the only once-daily FDA-approved treatment for adults with Tardive Dyskinesia.

**Patient’s Medical History and Treatment Rationale:**

* Patient’s medical history, diagnosis, and current condition (eg, signs, symptoms, functioning): [Provide a brief statement about the patient’s diagnosis and medical history, including any underlying health issues that affect your treatment selection]
* Prior treatments and response to those treatments: [If applicable, provide a list of current and past medications, as well as reasons for not prescribing a medication (eg, contraindications, drug interactions, lack of efficacy) and a summary of patient experience for each medication, including clinical outcome, adverse drug reactions, and length of therapy]
* [Summary as to why, based on your clinical judgment, your patient requires treatment with INGREZZA]

In summary, based on my clinical opinion, INGREZZA is medically necessary and reasonable for [patient’s name]’s medical condition. Please contact my office at [office phone number] if any additional information is required to ensure prompt approval for this course of treatment.

Sincerely,

[Physician’s name]

[List enclosures as appropriate, (eg, excerpt(s) from patient’s medical record, relevant treatment guidelines, and product Prescribing Information)]

**This page is for your reference only. Content on this page does not need to be sent to the insurance company.**

**Important Information**

**INDICATION & USAGE**

INGREZZA® (valbenazine) capsules is indicated for the treatment of adults with tardive dyskinesia.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

**WARNINGS & PRECAUTIONS**

**Somnolence**

INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

**QT Prolongation**

INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

**Parkinsonism**

INGREZZA may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

**ADVERSE REACTIONS**

The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see INGREZZA full** [**Prescribing Information**](https://www.neurocrine.com/ingrezzapi)