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 Important Safety Information starting on page 3 and accompanying**

**full** [**Prescribing Information**](https://www.neurocrine.com/assets/2024/04/INGREZZA-Full-Prescribing-Information_PI_Approved.pdf)**, including Boxed Warning.**

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| --- | --- |
|  | [*Physician Letterhead*] |
| [Insurance Company] [Address Line 1][Address Line 2] | Re: | Patient Name: Policy ID: 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 or INGREZZA® SPRINKLE (valbenazine) capsules] a diagnosis of [tardive dyskinesia (G24.01) or Huntington’s chorea (G10)]. This letter provides information about the patient’s medical history, diagnosis, and treatment plan with INGREZZA.

INGREZZA® (valbenazine) capsules or INGREZZA® SPRINKLE (valbenazine) capsules are prescription medicines used to treat adults with:

* movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).
* involuntary movements (chorea) of Huntington’s disease. INGREZZA or INGREZZA SPRINKLE do not cure the cause of involuntary movements, and do not treat other symptoms of Huntington’s disease, such as problems with thinking or emotions.

**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, hepatic impairment, 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 and INGREZZA® SPRINKLE (valbenazine) capsules are indicated in adults for the treatment of tardive dyskinesia and for the treatment of chorea associated with Huntington’s disease.

**IMPORTANT SAFETY INFORMATION**

**Depression and Suicidality in Patients with Huntington’s Disease: VMAT2 inhibitors, including INGREZZA and INGREZZA SPRINKLE, can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington’s disease. Balance the risks of**

**depression and suicidality with the clinical need for treatment of chorea. Closely monitor patients for the emergence or worsening of depression, suicidal ideation, or unusual changes in behavior. Inform patients, their caregivers, and families of the risk of depression and suicidal ideation and behavior and instruct them to report behaviors of concern promptly to the treating physician.**

**Exercise caution when treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in patients with Huntington’s disease.**

**CONTRAINDICATIONS**

INGREZZA and INGREZZA SPRINKLE are contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA or INGREZZA SPRINKLE.

**WARNINGS & PRECAUTIONS**

**Hypersensitivity Reactions**

Hypersensitivity reactions, including cases of angioedema involving the larynx, glottis, lips, and eyelids, have been reported in patients after taking the first or subsequent doses of INGREZZA. Angioedema associated with laryngeal edema can be fatal. If any of these reactions occur, discontinue INGREZZA or INGREZZA SPRINKLE.

**Somnolence and Sedation**

INGREZZA and INGREZZA SPRINKLE can cause somnolence and sedation. 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 or INGREZZA SPRINKLE.

**QT Prolongation**

INGREZZA and INGREZZA SPRINKLE may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing.

INGREZZA and INGREZZA SPRINKLE 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.

**Neuroleptic Malignant Syndrome**

A potentially fatal symptom complex referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with drugs that reduce dopaminergic transmission, including INGREZZA. The management of NMS should include immediate discontinuation of INGREZZA or INGREZZA SPRINKLE, intensive symptomatic treatment and medical monitoring, and treatment of any concomitant serious medical problems. If treatment with INGREZZA or INGREZZA SPRINKLE is needed after recovery from NMS, patients should be monitored for signs of recurrence.

**Parkinsonism**

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

**IMPORTANT SAFETY INFORMATION (continued)**

**ADVERSE REACTIONS**

The most common adverse reaction in patients with tardive dyskinesia (≥5% and twice the rate of placebo) is somnolence.

The most common adverse reactions in patients with chorea associated with Huntington’s disease (≥5% and twice the rate of placebo) are somnolence/lethargy/sedation, urticaria, rash, and insomnia.

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**.

**Dosage Forms and Strengths:** INGREZZA and INGREZZA SPRINKLE are available in 40 mg, 60 mg, and 80 mg capsules.

**Please see accompanying full** [**Prescribing Information**](https://www.neurocrine.com/assets/2024/04/INGREZZA-Full-Prescribing-Information_PI_Approved.pdf)**, including Boxed Warning.**