

Drug Coverage Policy

Effective Date	.06/15/2025
Coverage Policy Number.	IP0080
Policy Title	Ingrezza

Vesicular Monoamine Transporter Type 2 Inhibitors – Ingrezza Products

- Ingrezza[®] (valbenazine capsules Neurocrine Biosciences)
- Ingrezza[®] Sprinkle (valbenazine capsules Neurocrine Biosciences)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide auidance in interpreting certain standard benefit plans administered by Ciana Companies, Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Ingrezza and Ingrezza Sprinkle, a vesicular monoamine transporter type 2 inhibitor, are indicated in adults for the treatment of the following uses:¹

- Chorea associated with Huntington's disease.
- Tardive dyskinesia.

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Policy Statement

Prior Authorization is required for prescription benefit coverage of Ingrezza or Ingrezza Sprinkle. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ingrezza or Ingrezza Sprinkle as well as the monitoring required for adverse events and long-term efficacy, approval requires Ingrezza or Ingrezza Sprinkle to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Ingrezza/Ingrezza Sprinkle are considered medically necessary when the following criteria are met:

FDA-Approved Indications

- **1. Chorea Associated with Huntington's Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, <u>and</u> C):
 - A) Patient is \geq 18 years of age; AND
 - **B)** Diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36); AND
 - **C)** The medication is prescribed by or in consultation with a neurologist.
- **2. Tardive Dyskinesia.** Approve for 1 year if the patient meets BOTH of the following (A, B, and C):
 - A) Patient is \geq 18 years of age; AND
 - B) Patient has a history of use of dopamine receptor blocking agent; AND <u>Note:</u> Examples of dopamine receptor blocking agents include dopamine agonists (e.g., pramipexole, ropinirole), antipsychotics, metoclopramide, prochlorperazine
 - **C)** The medication is prescribed by or in consultation with a neurologist or psychiatrist.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Ingrezza/Ingrezza Sprinkle for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Ingrezza[®] capsules and Ingrezza[®] Sprinkle [prescribing information]. San Diego, CA: Neurocrine Biosciences; February 2025.

Revision Details

Type of RevisionSummary of ChangesDate	
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Annual Revision	 Policy Name Change: Updated Policy Name from "Valbenazine" to "Vesicular Monoamine Transporter Type 2 Inhibitors – Ingrezza Products." Added Ingrezza Sprinkle to the policy with the same criteria applied as for Ingrezza. Tardive Dyskinesia: Removed the requirement for a documented diagnosis of tardive dyskinesia. Updated the statement from "individual has a history of treatment with a dopamine receptor blocking agent" to now specifically say "patient has a history of use of dopamine receptor blocking agent." Removed the statement specifying the conditions for the medical necessity of the Ingrezza 4 week Initiation Pack. 	09/01/2024
Annual Revision	The Conditions Not Covered statement was reworded.	06/15/2025

The policy effective date is in force until updated or retired.

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