Drug Coverage Policy

Effective Date 09/01/2024
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 guidance in interpreting certain standard benefit plans administered by Cigna 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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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.**

Medical Necessity Criteria

Ingrezza or Ingrezza Sprinkle is 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, and C):
   - **A)** Patient is ≥ 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 ≥ 18 years of age; AND
   - **B)** Patient has a history of use of dopamine receptor blocking agent; AND
     Note: 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.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Ingrezza® capsules and Ingrezza® Sprinkle [prescribing information]. San Diego, CA: Neurocrine Biosciences; April 2024.

Revision Details

Type of Revision	Summary of Changes	Date
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	09/01/2024

	agent.” **Removed** the statement specifying the conditions for the medical necessity of the Ingrezza 4 week Initiation Pack.	

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

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