

Drug and Biologic Coverage Policy



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Coverage Policy Number IP0080

Valbenazine

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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. 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

This policy supports medical necessity review for Ingrezza™ (valbenazine).

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

Medical Necessity Criteria

Valbenazine (Ingrezza) is considered medically necessary when **ONE** the following is met:

1. **Chorea Associated with Huntington's Disease.** Individual meets **ALL** of the following criteria:
 - A. Age 18 years or older
 - B. Diagnosis of Huntington's Disease confirmed by documentation of genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36)
 - C. The medication is prescribed by, or in consultation with, a neurologist

2. **Tardive Dyskinesia.** Individual meets **ALL** of the following criteria:

- A. Age 18 years or older
- B. Documented diagnosis of tardive dyskinesia
- C. Individual has a history of treatment with a dopamine receptor blocking agent (for example, antipsychotics, metoclopramide, prochlorperazine)
- D. The medication is prescribed by, or in consultation with, a neurologist or a psychiatrist

In addition to the criteria above, the Ingrezza 4 week Initiation Pack is considered medically necessary ONLY when used for treatment initiation in a valbenazine naïve individual.

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.

Reauthorization Criteria

Ingrezza (valbenazine) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval and reauthorization duration: 12 months

Conditions Not Covered

Ingrezza (valbenazine) is considered experimental, investigational or unproven for ANY other use.

Background

OVERVIEW

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

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

References

1. Ingrezza[®] capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences; August 2023.

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