



PRIOR AUTHORIZATION POLICY

- POLICY:** Vesicular Monoamine Transporter Type 2 Inhibitors – Ingrezza Products Prior Authorization Policy
- Ingrezza® (valbenazine capsules – Neurocrine Biosciences)
 - Ingrezza® Sprinkle (valbenazine capsules – Neurocrine Biosciences)

REVIEW DATE: 4/10/2024; selected revision 05/15/2024

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 NATIONAL FORMULARY COVERAGE:

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.**

POLICY STATEMENT

Prior Authorization is recommended 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® (valbenazine capsules – Neurocrine Biosciences)**
- **Ingrezza® Sprinkle (valbenazine capsules – Neurocrine Biosciences)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 and B):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** The medication is prescribed by or in consultation with a neurologist or psychiatrist.

CONDITIONS NOT COVERED

- **Ingrezza® (valbenazine capsules – Neurocrine Biosciences)**
 - **Ingrezza® Sprinkle (valbenazine capsules – Neurocrine Biosciences)**
- is(are) considered experimental, investigational or unproven for ANY other use(s); 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/07/2023
Selected Revision	Chorea Associated with Huntington’s Disease: This condition and criteria for approval was added to the policy.	08/30/2023
Annual Revision	No criteria changes.	04/10/2024
Selected Revision	Ingrezza Sprinkle was added to the policy with the same criteria applied as for Ingrezza. There were no other changes to the criteria. Policy name changed from Vesicular Monoamine Transporter Type 2 Inhibitors – Ingrezza Prior Authorization Policy to Vesicular Monoamine Transporter Type 2 Inhibitors – Ingrezza Products Prior Authorization Policy.	5/15/2024

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