

Ingrezza (Valbenazine) Drug Use Criteria

Created: 4/9/2025

Reviewed: 4/9/2025

Includes:

Ingrezza® (*valbenazine*)

GUIDELINE FOR USE:

Initial Request:

1. Is the patient 18 years of age or older?
 - a. If yes, go to 2
 - b. If no, deny as not meeting criteria. Ingrezza is FDA- approved only for use in adults.
2. Has the member been diagnosed with MODERATE or SEVERE Tardive dyskinesia (TD)?
 - a. If yes, go to 3
 - b. If no, deny as not meeting criteria.
3. Have TD symptoms been present for at least 3 months?
 - a. If yes, go to 4
 - b. If no, deny as not meeting criteria. TD must be established and persistent for 3 or more months
4. Is the TD associated with either chronic dopamine receptor-blocking agent use OR chorea secondary to Huntington's disease?
 - a. If associated with dopamine receptor blocking agent use, go to 5
 - b. If associated with chorea from Huntington's disease, go to 9
 - c. If no, deny as not meeting criteria.
5. Are there no other diagnosed movement disorders other than TD (e.g., Parkinson's disease, acute dystonia)?
 - a. If yes, go to 6
 - b. If no, deny as not meeting criteria. Symptoms may be attributable to another movement disorder.
6. Is the member currently taking monoamine oxidase inhibitors (MAOIs)?
 - a. If yes, deny as not meeting criteria. Concurrent use of MAOIs is contraindicated
 - b. If no, go to 7
7. Has laboratory data been provided to confirm that member has adequate hepatic function (no severe hepatic impairment)?
 - a. If yes, go to 8
 - b. If no, deny as not meeting criteria. Severe hepatic impairment is a contraindication

8. Has there been an attempt to reduce or discontinue the causative agent (dopamine-blocking agent)?
 - a. If yes, go to 9
 - b. If no, deny as not meeting criteria. Please adjust the member's treatment regimen to prevent adverse reaction to causative agent.
9. Has the member had an adequate trial (8 or more weeks) with tetrabenazine without clinical benefit or with documented intolerance?
 - a. If yes, go to 10
 - b. If no, deny as not meeting criteria. Must trial tetrabenazine for 8 weeks without benefit before Ingrezza
10. Has patient assessment concluded absence of uncontrolled depression or risk of violent or suicidal behavior?
 - a. If yes, approve for 3 months
 - b. If no, deny as not meeting criteria

Renewal Request:

1. Has the member shown clinical benefit (e.g., reduced TD movements, improved function)?
 - a. If yes, go to 2
 - b. If no, deny as not meeting criteria
2. Are there any significant adverse effects or safety concerns?
 - a. If yes, deny as not meeting criteria
 - b. If no, go to 3
3. Is there documentation of ongoing medical necessity for treatment?
 - a. If yes, approve for 6 months. Please provide updated labs and chart notes with the next request.
 - b. If no, deny as not meeting criteria.

Rationale: To define a process for covering agents used in the treatment of tardive dyskinesia that is consistent with clinical practice guidelines and medical evidence while ensuring that less costly formulary options are trialed first.

FDA Approved Indications: Ingrezza (valbenazine) is FDA-approved for treating adults with tardive dyskinesia and chorea associated with Huntington's disease

Mechanism of Action: Ingrezza (valbenazine) is a selective vesicular monoamine transporter 2 (VMAT2) inhibitor. It works by regulating dopamine release through inhibition of VMAT2, leading to decreased uptake of monoamines (such as dopamine) into synaptic vesicles. This helps reduce the excessive dopamine signaling that contributes to the involuntary movements seen in tardive dyskinesia.

References:

-
1. Neurocrine Biosciences, Inc. Ingrezza (valbenazine) [prescribing information]. San Diego, CA; 2023.
 2. Jankovic J. Treatment of Tardive Dyskinesia With VMAT2 Inhibitors. *Movement Disorders*. 2021;36(4):789–805. doi:10.1002/mds.28424.
 3. Citrome L, Isaacson S. Valbenazine in Tardive Dyskinesia: A Systematic Review. *Neuropsychiatric Disease and Treatment*. 2017;13:2241–2250. doi:10.2147/NDT.S118097.
 4. U.S. Food and Drug Administration. FDA Drug Database. Available at: <https://www.accessdata.fda.gov>. Accessed April 2025.