

PHARMACY POLICY STATEMENT

Marketplace

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| DRUG NAME | Ingrezza (valbenazine) |
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Ingrezza, initially approved by the FDA in 2017, is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia or for chorea associated with Huntington's disease.

Tardive dyskinesia (TD) is the most common type of tardive syndrome, which primarily involves abnormal, involuntary movements of the face. It is caused by antipsychotic medications or other drugs that block dopamine receptors. Severity of TD is assessed using the Abnormal Involuntary Movement Scale (AIMS), a 12-item scale with a total score range of 0 to 28, with a higher score translating to increased severity.

Huntington's disease is a hereditary, progressive, neurodegenerative disease characterized by involuntary movements, cognitive dysfunction, and psychiatric symptoms. A prominent Huntington disease symptom is chorea, an involuntary, sudden movement that can affect any muscle and flow randomly across body regions.

Ingrezza (valbenazine) will be considered for coverage when the following criteria are met:

Tardive Dyskinesia (TD)

For initial authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist or psychiatrist; AND
3. Member has a documented diagnosis of moderate to severe neuroleptic-induced TD; AND
4. Symptoms have been present at least 3 months and impede daily activities or quality of life; AND
5. Documentation of Abnormal Involuntary Movement Scale (AIMS) score must be in chart notes; AND
6. One or more of the following approaches has been attempted with inadequate symptom control:
 - a) The drug causing TD symptoms has been stopped and a different drug has been tried and/or
 - b) The member is clinically stable on the offending drug and the lowest effective dose is being used; AND
7. Member has tried and failed Austedo or Austedo XR.
8. **Dosage allowed/Quantity limit:** Initial: 40 mg once daily. After one week, increase the dose to the recommended dose of 80 mg once daily. (QL: 30 capsules per 30 days)

If all the above requirements are met, the medication will be approved for 3 months.

For reauthorization:

1. Documentation that the member's TD symptoms have improved due to Ingrezza use as evidenced by AIMS score showing reduction of score from baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Huntington's Disease (HD)

For initial authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of Huntington's Disease, confirmed by family history or genetic testing (expanded CAG repeat in the HTT gene); AND
4. Member is experiencing bothersome symptoms of chorea associated with Huntington's Disease; AND
5. Documented consultation on risks of suicidal ideation or behavior while on Ingrezza; AND
6. Member's baseline Total Maximal Chorea Score (of the Unified Huntington's Disease Rating Scale (UHDRS)) is submitted with chart notes; AND
7. Member has tried and failed Austedo or Austedo XR.
8. **Dosage allowed/Quantity limit:** Initial: 40 mg once daily. Increase the dose in 20 mg increments every two weeks to the recommended dosage of 80 mg once daily. (QL: 30 capsules per 30 days)

If all the above requirements are met, the medication will be approved for 3 months.

For reauthorization:

1. Member must have documentation of improved Total Maximal Chorea (TMC) score compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ingrezza (valbenazine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|--|
| 08/29/2017 | New policy for Ingrezza created. |
| 12/14/2017 | Criterion revised in collaboration with Indiana Medicaid DUR Board. Criterion requirement of clinical diagnoses of Schizophrenia or Schizoaffective Disorder, or Mood Disorder for at least 3 months was removed. Length of initial authorization increased to 3 months. Criterion on guidelines recommended treatment was revised. |
| 12/28/2017 | Criterion on negative drug test revised. Substance use disorder remission length requirement changed. |
| 02/08/2018 | New provider's specialty was added: nurse practitioner within a psychiatric or neurologic practice. |
| 05/06/2019 | The guideline recommended treatment criterion changed from two to one medication to try as a trial. Criterion on negative urine drug test or positive drug test result due to current prescriptions was removed. |
| 12/21/2020 | Updated quantity limit from 60 per 30 days to 30 per 30 days because a new strength (80 mg) is now available. |
| 04/06/2022 | Transferred to new template. Updated and added references. Removed NPs from specialist and added generalized "or in consultation with." Removed trial of clonazepam or ginkgo. Added that TD must be present for at least 3 months and with impeding symptoms. Removed list of exclusions. Removed duration from substance use disorder remission. |
| 11/09/2023 | Added criteria for new Huntington's disease (HD) indication. TD: Removed psychiatric and substance abuse parts of criteria. |
| 09/19/2025 | Added step through Austedo. |

References:

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9. Bachoud-Lévi AC, Ferreira J, Massart R, et al. International Guidelines for the Treatment of Huntington's Disease. *Front Neurol*. 2019;10:710. Published 2019 Jul 3. doi:10.3389/fneur.2019.00710
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