CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

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.
7. **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.
7. **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.

References:

1. Ingrezza [package insert]. San Diego, CA; Neurocrine Biosciences, Inc.: 2023.
2. ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2017 Jun 9 - . Identifier NCT02274558, A Phase 3 Study of NBI-98854 for the Treatment of Tardive Dyskinesia (KINECT 3); 2017 Jun 9 [cited 2017 Jul 31]. Available from: https://clinicaltrials.gov/ct2/show/NCT02736955?cond=ingrezza&rank=1.
3. American Academy of Neurology. Summary of Evidence-based Guideline for PATIENTS and their FAMILIES. Treating and managing tardive syndromes. https://www.aan.com/Guidelines/Home/GetGuidelineContent/614.
4. Hauser RA, Factor SA, Marder SR, et al. KINECT 3: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Valbenazine for Tardive Dyskinesia. *Am J Psychiatry*. 2017;174(5):476-484. doi:10.1176/appi.ajp.2017.16091037
5. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2013 Nov 26;81(22):1968]. *Neurology*. 2013;81(5):463-469. doi:10.1212/WNL.0b013e31829d86b6
6. Bhidayasiri R, Jitkritsadakul O, Friedman JH, Fahn S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. *J Neurol Sci*. 2018;389:67-75. doi:10.1016/j.jns.2018.02.010
7. Solmi M, Pigato G, Kane JM, Correll CU. Treatment of tardive dyskinesia with VMAT-2 inhibitors: a systematic review and meta-analysis of randomized controlled trials. *Drug Des Devel Ther*. 2018;12:1215-1238. Published 2018 May 14. doi:10.2147/DDDT.S133205
8. Furr Stimming E, Claassen DO, Kayson E, et al. Safety and efficacy of valbenazine for the treatment of chorea associated with Huntington's disease (KINECT-HD): a phase 3, randomised, double-blind, placebo-controlled trial [published correction appears in Lancet Neurol. 2023 Sep;22(9):e10] [published correction appears in Lancet Neurol. 2023 Sep;22(9):e10]. *Lancet Neurol*. 2023;22(6):494-504. doi:10.1016/S1474-4422(23)00127-8
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
10. Ferreira JJ, Rodrigues FB, Duarte GS, et al. An MDS Evidence-Based Review on Treatments for Huntington's Disease. *Mov Disord*. 2022;37(1):25-35. doi:10.1002/mds.28855

Effective date: 04/01/2024
Revised date: 11/09/2023