

## PHARMACY POLICY STATEMENT

### Indiana Medicaid

DRUG NAME	Ingrezza (valbenazine)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include clonazepam, ginkgo biloba, amantadine, and tetrabenazine QUANTITY LIMIT – 60 caps per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Ingrezza (valbenazine) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### TARDIVE DYSKINESIA (TD)

For **initial** authorization:

- Member is 18 years of age and older and medication is prescribed by neurologist or psychiatrist; AND
- Member has clinical diagnosis of moderate to severe neuroleptic-induced TD as determined by clinical observation and documented in chart notes; AND
- Member must try and fail at least 2 other guideline recommended treatments first: clonazepam, ginkgo biloba, amantadine, or tetrabenazine; AND
- Member has **one** of the following clinical diagnoses for at least 3 months documented in chart notes: Schizophrenia or Schizoaffective Disorder, or Mood Disorder; AND
- Chart notes confirming that member does **not** have risk for suicidal or violent behavior and has stable psychiatric symptoms; AND
- Member has a negative urine drug screen for **all** of the following: amphetamines, barbiturates, benzodiazepine, phencyclidine, cocaine, opiates, and cannabinoids; AND
- If member has a history of substance dependence, substance (drug) or alcohol abuse, chart notes confirming that member is in sustained remission for **at least** 12 months must be provided; AND
- Member's The Abnormal Involuntary Movement Scale (AIMS) score is documented in chart notes; AND
- Member does not have ANY of the following:
  - History of neuroleptic malignant syndrome;
  - History of long QT syndrome or cardiac arrhythmia;
  - Allergy, hypersensitivity, or intolerance to tetrabenazine.
- Dosage allowed:** 40 mg once daily. After one week, increase the dose to the recommended dose of 80 mg once daily.

***If member meets all the requirements listed above, the medication will be approved for 2 months.***

For **reauthorization**:

- 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

**CareSource considers Ingrezza (valbenazine) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Treatment of Huntington disease, Chorea - Huntington's disease
- Treatment of Tourette syndrome

DATE	ACTION/DESCRIPTION
08/29/2017	New policy for Ingrezza created.

References:

1. Ingrezza [package insert]. San Diego, CA; Neurocrine Biosciences, Inc.: April, 2017.
2. Kang N-R, Kim M-D. Tardive Dyskinesia: Treatment with Aripiprazole. *Clinical Psychopharmacology and Neuroscience*. 2011;9(1):1-8. doi:10.9758/cpn.2011.9.1.1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3568649/>.
3. 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>.
4. 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>.
5. Hauser RA, Factor SA, Marder SR, Kneesevich MA, et al. KINECT 3: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Valbenazine for Tardive Dyskinesia. *American Journal of Psychiatry* 2017 174:5, 476-484.

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