

## PHARMACY POLICY STATEMENT

### Georgia 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) 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:

1. Member is 18 years of age and older and medication is prescribed by neurologist or psychiatrist or nurse practitioner within a psychiatric or neurologic practice; AND
2. Member has clinical diagnosis of moderate to severe neuroleptic-induced TD as determined by clinical observation and documented in chart notes; AND
3. Member must try and fail at least 2 other guideline recommended treatments (e.g., clonazepam, ginkgo biloba); AND
4. Chart notes confirming that member does **not** have risk for suicidal or violent behavior and has stable psychiatric symptoms; AND
5. Member has a negative urine drug test for **all** of the following: amphetamines, barbiturates, benzodiazepine, phencyclidine, cocaine, opioids, and cannabinoids OR if member has a positive drug test, chart notes or pharmacy claims must be submitted confirming that a positive drug test result is due to current prescriptions; AND
6. If member has a history of substance use disorder, chart notes confirming that member is in remission for **at least** 3 months must be provided; AND
7. Member's The Abnormal Involuntary Movement Scale (AIMS) score is documented in chart notes; AND
8. Member does **not** have ANY of the following:
  - a) History of neuroleptic malignant syndrome;
  - b) History of long QT syndrome or cardiac arrhythmia;
  - c) Allergy, hypersensitivity, or intolerance to tetrabenazine.
9. **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 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 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.
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.

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, Knesevich 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.

Effective date: 02/21/2018

Revised date: 02/08/2018