Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky 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 **NOT** MEDICALLY NECESSARY	Click Here

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; 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 first: clonazepam, ginkgo biloba, amantadine, or tetrabenazine; AND
4. 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
5. Chart notes confirming that member does **not** have risk for suicidal or violent behavior and has stable psychiatric symptoms; AND
6. Member has a negative urine drug screen for **all** of the following: amphetamines, barbiturates, benzodiazepine, phencyclidine, cocaine, opiates, and cannabinoids; AND
7. 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
8. Member's The Abnormal Involuntary Movement Scale (AIMS) score is documented in chart notes; AND
9. 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.
10. **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**:

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.

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.

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