

Commercial/Healthcare Exchange PA Criteria

Effective: May, 2017

Prior Authorization: Ingrezza

Products Affected: Ingrezza (valbenazine)

Medication Description:

Ingrezza (valbenazine) is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia (TD).

The mechanism of action of valbenazine in the treatment of tardive dyskinesia is unknown, but is thought to be mediated through the reversible inhibition of vesicular monoamine transporter 2 (VMAT2), a transporter that regulates monoamine uptake from the cytoplasm to the synaptic vesicle for storage and release.

Covered Uses:

Treatment of adults with tardive dyskinesia

Exclusion Criteria:

Ingrezza has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances.

1. Patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval
2. Patients with a hypersensitivity to Ingrezza (valbenazine) or any component of its formulation

Required Medical Information:

1. Dose and frequency
2. Medication history

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by or in consultation with a neurologist or psychiatrist.

Coverage Duration: 12 months

Other Criteria:

Approve Ingrezza if the patient meets **ALL** of the following criteria:

- A. Patient is 18 years of age or older; **AND**
- B. Patient has a diagnosis of moderate to severe tardive dyskinesia; **AND**
- C. Patient has a history of current or former chronic use of an antipsychotic or other dopamine antagonist; **AND**
- D. One of the following:

- i. Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

- ii. Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

References:

1. Ingrezza [package insert]. San Diego, CA; Neurocrine Biosciences; April 2017.
2. 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 Psych.* 2017; 174(5): 476-484. DOI: 10.1176/appi.ajp.2017.16091037
3. National Guideline Clearinghouse (NGC). Guideline summary: Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality. Available at: <https://www.guideline.gov/summaries/summary/47021/evidencebased-guideline-treatment-of-tardive-syndromes-report-of-the-guideline-development-subcommittee-of-the-american-academy-of-neurology>.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/16/17
2	Update	Updated to new template & adopted EmblemHealth criteria	All	4/27/2020

