

Ingrezza (valbenazine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ingrezza (valbenazine)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Ingrezza (valbenazine) may be approved for individuals who meet the following criteria:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of tardive dyskinesia (TD) confirmed by the following (DSM-5):
 - A. At least 60 days of stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking drugs used in treatment of nausea and gastroparesis [such as, prochlorperazine, promethazine, metoclopramide]); **AND**
 - B. Presence of involuntary athetoid or choreiform movements lasting at least 30 days.

Requests for continuation of therapy for Ingrezza (valbenazine) may be approved for individuals who meet the following criteria:

- I. Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider.

Requests for Ingrezza (valbenazine) **may not** be approved for individuals who meet the following criteria:

- I. Individual has congenital long QT syndrome or arrhythmia associated with a prolonged QT interval; **OR**
- II. Individual is currently using a strong CYP 3A4 Inducer (examples: rifampin, carbamazepine, phenytoin, St. John's wort); **OR**
- III. Individual is currently using a monoamine oxidase inhibitor (MAOI) (examples: isocarboxazid, phenelzine, selegiline).

State Specific Mandates

State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders: DSM-5. Washington, D.C: American Psychiatric Association.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 5, 2017.

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 May 1; 174(5): 476-484.

O'Brien CF, Jimenez R, Hauser RA, et.al. NBI-98854, a selective monoamine transport inhibitor for the treatment of tardive dyskinesia: A randomized, double-blind, placebo-controlled study. Mov Disord. 2015 Oct; 30(12): 1681-7.