

| Market Applicability/Effective Date | | | | | | | | | | | | | | | |
|-------------------------------------|----|----------|--------|--------|----|-----|----|----|----|----|----|----|-----|-----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | NA |

*FHK- Florida Healthy Kids

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).

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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| Applicable | X | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | X |

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

Key References:

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

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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.

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