Ingrezza (valbenazine)

Override(s)	Approval Duration
Prior Authorization	Initial approval: 3 months
Quantity Limit	Subsequent approval: 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. Documentation is provided that individual has a diagnosis of chorea associated with Huntington's disease;

OR

- III. Individual is 18 years of age or older; AND
- IV. Individual has a diagnosis of tardive dyskinesia (TD) confirmed by the following (DSM-5):
 - A. Documentation is provided that 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. Documentation is provided that individual has experienced an improvement in symptoms deemed to be clinically significant by the provider based on stabilization or improvement in Abnormal Involuntary Movement Scale (AIMS) score (for TD) or total maximal chorea score (for Huntington's disease).

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); **OR**
- IV. Individual is currently using deutetrabenazine or tetrabenazine.

Key References:

- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 29, 2023.
- 2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.
- American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders: DSM-5. Washington, D.C: American Psychiatric Association.
- 5. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the guideline development subcommittee of the American Academy of Neurology. *Neurology*. 2013;81:463-9. Available at https://www.aan.com/Guidelines/. Accessed on July 6, 2023.
- 6. Bhidayasiri R, Jikritsadakul O, Friedman JH, Fahn S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. *J Neurol Sci.* 2018 Jun 15; 389:67-75. Accessed on July 6, 2023.
- Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease. Report
 of the guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2012; 79:597-603.
 Accessed on July 6, 2023.
- 8. Huntington Study Group. Effect of deutetrabenazine on chorea among patients with Huntington disease: A randomized clinical trial. *JAMA*. 2016; 316(1):40-50.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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