Ingrezza (valbenazine)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Treatment of adults with tardive dyskinesia

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   - Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s), or contraindication(s) to Austedo
   - Submission of chart notes documenting baseline Abnormal Involuntary Movement Scale (AIMS) score.

B. Continuation requests:
   - Chart notes documenting a positive clinical response to therapy (improvement in signs and symptoms of tardive dyskinesia).
   - Submission of chart notes documenting improvement in Abnormal Involuntary Movement Scale (AIMS) score.

Criteria for Initial Approval

A) Tardive dyskinesia

Ingrezza (valbenazine) may be considered **medically necessary** for the treatment of moderate to severe tardive dyskinesia related to drug use when ALL of the following criteria are met:

1. Member is 18 years of age or older
2. Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider)
3. Member has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication
   OR
   Member is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication
4. Documentiation of baseline Abnormal Involuntary Movement Scale (AIMS) score has been provided.
5. Member meets at least ONE of the following critieria:
   a. Member has had an inadequate response to a minimum of three months of therapy with Austedo (deutetrabenazine)
   b. Member has experienced an intolerable adverse event attributed to Austedo
   c. Member has at least one of the following contraindications for use with Austedo:
      i.) Huntington's disease and is suicidal or has untreated or inadequately treated depression
      ii.) Hepatic impairment
      iii.) Taking reserpine
      iv.) Taking a monoamine oxidase inhibitor (MAOI)
      v.) Taking tetrabenazine

Approval will be for **3 months**

Continuation of Therapy

Ingrezza (valbenazine) may be considered **medically necessary** for the continued treatment of moderate to severe tardive dyskinesia when there is documentation of a positive clinical response to therapy as defined by an improvement in member's Abnormal Involuntary Movement Scale (AIMS) score.

Approval will be for **12 months**

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply:

- Ingrezza 30 capsules/30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Ingrezza [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2021.
- Austedo [package insert]. North Wales, PA: TEVA Pharmaceuticals USA, Inc.; May 2021.
- Hauser, Robert, et al. KINECT-3: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Velbenazine for Tardive Dyskinesia. American Journal of Psychiatry. 2017 Mar 21: 1-9.

- Solmi M, Pigato G, Kane JM, et al. Treatment of tardive dyskinesia with VMAT-2 inhibitors: a systematic review and meta-analysis of randomized controlled trials. Drug Des Devel Ther. 2018; 14(12):1215-1238.
- Marder SR, Singer C, Lindenmayer JP et al. A Phase 3, 1-Year, Open-Label Trial of Valbenazine in Adults With Tardive Dyskinesia. *J Clin Psychopharmacol*. 2019;39(6):620-627.
- Bhidayasiri R, Jitkritsadakul O, Friedman JH et al. Updating the Recommendations for Treatment of Tardive Syndromes: A Systematic Review of New Evidence and Practical Treatment Algorithm. *J Neurol Sci*. 2018;389:67-75.

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POLICY HISTORY

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