Pharmacy Medical Necessity Guidelines: Ingrezza (valbenazine)

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

Pharmacy Benefit:
RXUM: 617-673-0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

While the mechanism of action in the treatment of TD is unknown, it is thought that reversible inhibition of VMAT2 regulates dopamine uptake from the cytoplasm to the synaptic vesicle for storage and release. This may offset the movement-related side effects of antipsychotics and other dopamine receptor blocking agents.

COVERAGE GUIDELINES

The plan may authorize coverage of Ingrezza (valbenazine) for members when all of the following criteria are met:

1. Members are 18 years or older

AND

2. Documented diagnosis of moderate to severe tardive dyskinesia

AND

3. The member has demonstrated an inadequate response to **OR** is unable to tolerate an adequate trial with at least two of the following medications or classes of medications:
    a) benzodiazepine (e.g., clonazepam)
    b) amantadine

LIMITATIONS

None

CODES

None

REFERENCES

1. Bergman H, Walker DM, Nikolakopoulou A, Soares-Weiser K, Adams CE. Systematic review of interventions for treating or preventing antipsychotic-induced tardive dyskinesia. Health Technol Assess. 2017; 21(43):1-218.
2. Cornett EM, Novitch M, Kaye AD, et al. Medication-Induced Tardive Dyskinesia: A Review and Update. Ochsner J. 2017; 17(2):162-174.
3. Ingrezza (valbenazine) [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; July 2019.

APPROVAL HISTORY

September 12, 2017: Reviewed by Pharmacy and Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 14, 2017: Administrative update- removed quantity limitation as it was incorrectly listed.
- April 10, 2018: Effective 10/1/18, removed tetrabenazine as an option for a prerequisite trial.
- December 10, 2019: No changes
- November 10, 2020: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.