Pharmacy Medical Necessity Guidelines: Austedo® (deutetrabenazine)

Effective: July 11, 2023

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0988	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Austedo (deutetrabenazine) is a vesicular monoamine transporter 2 (VMAT2) inhibitor approved for the treatment of chorea associated with Huntington's disease and tardive dyskinesia in adults.

COVERAGE GUIDELINES

The plan may authorize coverage of Austedo (deutetrabenazine) for Members, when the following criteria are met:

Huntington's Disease

1. Documented diagnosis of moderate chorea associated with Huntington's Disease

AND

2. The Member is at least 18 years of age

AND

3. The Member has demonstrated an inadequate response to or inability to tolerate tetrabenazine

Tardive Dyskinesia

Documented diagnosis of moderate to severe tardive dyskinesia

AND

The Member is at least 18 years of age

LIMITATIONS

None

CODES

None

REFERENCES

1. Armstrong, M. J., Miyasaki, J. M. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. August 2012;79(6):597–603.
2. Austedo (deutetrabenazine) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; February 2023.
3. Fasano, A., Cadeddu, F., Guidubaldi, A., et al. The long-term effect of tetrabenazine in the management of Huntington disease. *Clin Neuropharmacol,* November 2008;31:313–18.
4. Frank, S. Tetrabenazine as anti-chorea therapy in Huntington Disease: an open-label continuation study. Huntington Study Group/TETRA-HD Investigators. *BMC Neurol*. 2009 Dec 18; 9:62.
5. Frank, S., Jankovic, J. Advances in pharmacological management of Huntington's disease. Drugs. March 2012;70(5):561-71
6. Huntington Study Group. Effect of deutetrabenazine in chorea among patients with Huntington disease: a randomized clinical trial. *JAMA*. 2016; 316(1):40-50.
7. Marshall, F.J. Tetrabenazine as antichorea therapy in Huntington disease: A randomized controlled trial. *Neurology.* February 2006; 66(3):366-372.
8. National Institute of Neurological Disorders and Stroke. Huntington's disease information page. National Institutes of Health. URL: ninds.nih.gov/Disorders/All-Disorders/huntingtons-disease-Information-Page#disorders-r1. Available from Internet. Accessed 2017 April
9. Novak MJ, et al. Huntington's disease. *British Medical Journal* 2010; 340:c3109.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

1. July 11, 2023: 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.