Pharmacy Medical Necessity Guidelines: Austedo® (deutetrabenazine)

Effective: June 15, 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:

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.

Huntington's disease is a rare, inherited neurological disorder affecting about 1 in 10,000 people in the United States. The disease results from genetically programmed degeneration of brain cells. The deterioration causes uncontrolled movements, loss of intellectual faculties, and emotional disturbance. Huntington's disease is passed from parent to child through a gene mutation. Each child of a parent with the disease has a 50 percent chance of inheriting the mutation.

Chorea, a primary feature of Huntington's disease, is an abnormal involuntary movement disorder caused by overactivity of the neurotransmitter dopamine in the areas of the brain that control movement. Chorea is characterized by brief, irregular contractions that are not repetitive or rhythmic, but appear to flow from one muscle to the next. Standard treatments for chorea include benzodiazepines, amantadine, and antipsychotics, and VMAT-2 inhibitors (tetrabenazine and deutetrabenazine).

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 prescribing physician is a neurologist

AND

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

Tardive Dyskinesia

1. Documentation the Member is at least 18 years of age

AND

2. Documented diagnosis of moderate to severe tardive dyskinesia

LIMITATIONS

- The following quantity limits apply:
  - 6 and 9 mg tablets: 60 tablets per 30 days
  - 12 mg tablets: 120 tablets per 30 days

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.; July 2019.
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

March 10, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
2. January 12, 2010: No changes.
3. January 11, 2011: No changes.
4. January 10, 2012: No changes.
5. January 15, 2013: No changes.
6. November 5, 2013: No changes.
7. November 4, 2014: No changes.
8. November 10, 2015: No changes.
9. January 1, 2016: Administrative change to rebranded template.
10. October 18, 2016: No changes. Effective October 18, 2016 Medical Necessity Guideline applies to Tufts Health Together.
11. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
12. August 8, 2017: Updated name of Medical Necessity Guideline to Medications for the Treatment of Huntington's Chorea. Added newly approved Austedo to the Medical Necessity Guideline.
13. April 10, 2018: Updated Guideline to include coverage criteria for the new supplemental indication of tardive dyskinesia for Austedo. Updated the quantity limitation information for Austedo 12 mg tablets based on new indication for tardive dyskinesia.
14. March 12, 2019: Effective March 18, 2019, removed generic tetrabenazine from the Medical Necessity Guideline because tetrabenazine PA program is retired. Updated the quantity limitations for Xenazine (tetrabenazine) 12.5 mg tablets to be 90 tablets per 30 days for all lines of business. For tardive dyskinesia, removed the following from the coverage criteria for Austedo: "The Member has demonstrated an inadequate response to or is unable to tolerate an adequate trial with Ingrezza." Effective July 1, 2019, removed brand Xenazine from the medical Necessity Guideline because it is non-covered for all Commercial and Medicaid formularies. For Huntington's chorea, updated the prerequisite requirements for Austedo to require an inadequate response to or inability to tolerate tetrabenazine.
15. June 9, 2020: Changed title of Medical Necessity Guideline to "Austedo® (deutetrabenazine)"

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.