

Deutetrabenazine (AUSTEDO) and Deutetrabenazine extended-release tablets (AUSTEDO XR) Criteria for Use

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive deutetrabenazine.

- Patients is actively suicidal or has untreated or inadequately treated depression.
- Congenital long QT interval, or a QTc >450 ms for men or QTc >470 ms for women.
- History of cardiac arrhythmias (patients with a history of ventricular arrhythmias), cardiac conduction system disease (LBBB or RBBB) or cardiac device can be considered candidates with cardiology evaluation. ^1
- Concurrent use of a monoamine oxidase inhibitor (MAOI) or within 14 days of discontinuing therapy with an MAOI.
- Current or use of reserpine within the past 20 days.
- Concurrent use of another VMAT2 inhibitor (i.e., tetrabenazine, valbenazine)
- History of neuroleptic malignant syndrome (NMS)
- Current clinically significant hyperprolactinemia
- Pregnant or lactating
- Hepatic impairment

Inclusion Criteria: Treatment of Huntington Disease

The answers to ALL of the following must be fulfilled in order to meet criteria.

- When the initial prescriber is a resident, fellow or other trainee, an attending psychiatrist or neurologist has verified the diagnosis and need for deutetrabenazine.
- The patient has a diagnosis of Huntington disease documented in his/her medical record.
- The chorea is disabling or painful and interferes with the patient's functional status, including self-care and ambulation; quality of life; or creates a social stigma sufficient to cause social isolation or embarrassment.
- The prescriber has documented the specific movement(s) (e.g., facial, oral extremity, or trunk) in the patient's medical record along with how the chorea is affecting the patient's function, quality of life or socialization.

Inclusion Criteria: Treatment of Dystonia

The answers to ALL of the following must be fulfilled in order to meet criteria.

- When the initial prescriber is a resident, fellow or other trainee, an attending psychiatrist or neurologist has verified the diagnosis and need for deutetrabenazine.
- No response or intolerant to alternative agents (local botulinum toxin injections, anticholinergics, or benzodiazepines).

Inclusion Criteria: Treatment of Tardive Dyskinesia

The answers to ALL of the following must be fulfilled in order to meet criteria.

- The patient has a diagnosis of tardive dyskinesia (TD) secondary to a dopaminergic blocking agent, e.g. antipsychotic or metoclopramide.
- The patient's TD interferes with the patient's functional status, including self-care and ambulation; quality of life; or creates a social stigma sufficient to cause social isolation or embarrassment.
- The prescriber has documented the specific movement(s) (e.g., facial, oral extremity, or trunk) in the patient's medical record along with how TD is affecting the patient's function, quality of life or socialization.
- A recent Abnormal Involuntary Movement Scale (AIMS) score is recorded in the patient's medical record.
- An ECG was performed to confirm a QTc <450 ms for men or QTc <470 ms for women.
- When the initial prescriber is a resident, fellow or other trainee, an attending psychiatrist or neurologist has verified the diagnosis and need for deutetrabenazine.

Prepared: December 2017; Revised August 2019, February 2020, September 2023. Contact: Matthew A. Fuller, Pharm.D., National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12 PBM)

1. LBBB: left bundle branch block; RBBB: right bundle branch block