Reference number(s)
1746-A

Specialty Guideline Management Austedo-Austedo XR

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Austedo	deutetrabenazine
Austedo XR	deutetrabenazine extended release

Indications

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

FDA-Approved Indications[1]

- Treatment of chorea associated with Huntington's disease in adults
- Treatment of tardive dyskinesia in adults

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests:

- Chorea associated with Huntington's disease: Chart notes or medical record documentation of characteristic motor examination features.

- Tardive dyskinesia: Chart notes or medical record documentation of clinical manifestations of disease.

Coverage Criteria

Chorea associated with Huntington's disease[1,2]

Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:

- Member demonstrates characteristic motor examination features.
- Member meets one of the following conditions:
  - Laboratory results indicate an expanded HTT CAG repeat sequence of at least 36
  - Member has a positive family history for Huntington's disease

Tardive dyskinesia[1,3-5]

Authorization of 6 months may be granted for treatment of tardive dyskinesia when both of the following criteria are met:

- Member exhibits clinical manifestations of disease.
- Member's tardive dyskinesia has been assessed through clinical examination or with a structured evaluative tool (e.g., Abnormal Involuntary Movement Scale [AIMS], Dyskinesia Identification System: Condensed User Scale [DISCUS]).

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

References

1. Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc. February 2025.
2. Frank S, Testa CM, Stamler D, et al. Effect of deutetrabenazine on chorea among patients with Huntington disease: a randomized clinical trial. JAMA. 2016;316(1):40-50.
3. Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: the ARM-TD study. Neurology. 2017;88:2003-10.

4. Anderson KE, Stamler D, Davis MD, et al. Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia (AIM-TD): a double-blind, randomized, placebo-controlled, phase 3 trial. Lancet Psychiatry. 2017;4:595-604.
5. American Psychiatric Association. (2021). Practice Guideline for the Treatment of Patients With Schizophrenia, third edition. https://doi.org/10.1176/appi.books.9780890424841.