

SPECIALTY GUIDELINE MANAGEMENT

AUSTEDO (deutetrabenazine)

POLICY

I. 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

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

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

II. DOCUMENTATION

Submission of the following information is necessary for both initial approval and continuation of therapy prior authorization reviews: Documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS) for tardive dyskinesia.

III. CRITERIA FOR INITIAL APPROVAL

A. Chorea associated with Huntington's disease

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

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

B. Tardive dyskinesia

Authorization of 6 months may be granted for treatment of tardive dyskinesia when the baseline AIMS score for items 1 to 7 is obtained.

IV. CONTINUATION OF THERAPY

A. Tardive Dyskinesia

Authorization of 12 months may be granted for treatment of tardive dyskinesia when the member's tardive dyskinesia symptoms have improved as indicated by a decreased AIMS score (items 1 to 7) from baseline.

B. Other Indications

Reference number(s)
1746-A

Authorization of 12 months may be granted for treatment of chorea associated with Huntington's disease when the disease has improved or stabilized.

V. REFERENCES

1. Austedo [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. December 2020.
2. Frank S, Testa CM, Stamler D, et al. Effect of deutetrabenazine on chorea among patients with Huntington disease: A randomized clinical trial. Huntington Study Group. *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.