	ITER HEALTH®	<b>*ae</b>	etna <sup>™</sup>	
Coverage F	Policy/Guideline			
Name:	Austedo-Austedo XI	₹	Page:	1 of 2
Effective D	ate: 2/3/2025		Last Review Date:	12/17/2024
Applies	□Illinois	□Virginia	☐New Jersey	
to:	⊠Pennsylvania Kids	⊠Florida Kids	⊠Maryland	

#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Austedo under the patient's prescription drug benefit.

## **Description:**

#### **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.

## **Applicable Drug List:**

Austedo XR

## **Policy/Guideline:**

The patient unable to take the preferred formulary alternatives, Ingrezza and tetrabenazine, for the given diagnosis, due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

#### **Documentation:**

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

- A. <u>Tardive dyskinesia</u>: Chart notes or medical record documentation of clinical manifestations of disease.
- B. <u>Chorea associated with Huntington's disease</u>: Chart notes or medical record documentation of characteristic motor examination features.

### **Criteria for Initial Approval:**

#### A. Tardive dyskinesia

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

- 1. Member exhibits clinical manifestations of disease.
- 2. 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]).

#### B. 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:

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

## **Criteria for Continuation of Therapy:**

Authorization of 12 months may be granted for members with an indication of EITHER Tardive Dyskinesia OR Chorea associated with Huntington's disease, who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

## **Approval Duration and Quantity Restrictions:**

#### Approval:

Initial: 6 monthsRenewal: 12 months

## **Quantity Level Limit:**

Medication	Standard Limit	
Austedo 6mg tablet	60 per 30 days	
Austedo 9mg tablet	120 per 30 days	
Austedo 12mg tablet	120 per 30 days	
Austedo XR 6mg tablet	90 per 30 days	
Austedo XR 12mg tablet	120 per 30 days	
Austedo XR 18mg tablet	30 per 30 days	
Austedo XR 24mg tablet	60 per 30 days	
Austedo XR 30mg tablet	30 per 30 days	
Austedo XR 36mg tablet	30 per 30 days	
Austedo XR 42mg tablet	30 per 30 days	
Austedo XR 48mg tablet	30 per 30 days	
Austedo XR Titration Kit (6mg, 12mg, 24mg tablets)	1 kit (42 tablets) per 90 days	
Austedo XR Titration Kit (12mg, 18mg, 24mg, 30mg tablets)	1 kit (28 tablets) per 90 days	

#### **References:**

- 1. Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc. July 2024.
- 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