|                           | TTER HEALTH®<br>Policy/Guideline | <b>*ae</b>    | etna <sup>™</sup> |           |
|---------------------------|----------------------------------|---------------|-------------------|-----------|
| Name:                     | Austedo-Austedo X                | R             | Page:             | 1 of 2    |
| Effective Date: 8/19/2024 |                                  |               | Last Review Date: | 7/18/2024 |
| 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:**

### **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:

- 1. Member demonstrates characteristic motor examination features
- 2. Member meets ONE of the following conditions:

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- 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

# **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