## DEUTETRABENAZINE

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| DEUTETRABENAZINE | AUSTEDO | 44192 | | |

### GUIDELINES FOR USE

1. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meet the following criterion?
   - Therapy is prescribed by or given in consultation with a neurologist or movement disorder specialist

   If yes, **approve for 12 months by GPID for all the dosage strengths with the following quantity limits:**
   - **6mg tablet (GPID 43228): #2 tablets per day**
   - **9mg tablet (GPID 43236): #4 tablets per day**
   - **12mg tablet (GPID 43237): #4 tablets per day**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe tardive dyskinesia and meet ALL of the following criteria?
   - Moderate to severe tardive dyskinesia has been present for at least 3 months
   - The patient is at least 18 years of age
   - Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
   - Patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

   If yes, **approve for 12 months by GPID for all the dosage strengths with the following quantity limits:**
   - **6mg tablet (GPID 43228): #2 tablets per day**
   - **9mg tablet (GPID 43236): #4 tablets per day**
   - **12mg tablet (GPID 43237): #4 tablets per day**

   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

**CONTINUED ON NEXT PAGE**

## DEUTETRABENAZINE

### GUIDELINES FOR USE (CONTINUED)

**DENIAL TEXT:** The guideline named **DEUTETRABENAZINE (Austedo)** requires a diagnosis of chorea (involuntary movements) associated with Huntington's disease or moderate to severe tardive dyskinesia. In addition, the following criteria must be met:

**For diagnosis of chorea (involuntary movements) associated with Huntington's disease, approval requires:**

- Therapy is prescribed by or given in consultation with a neurologist or movement disorder specialist

**For diagnosis of moderate to Severe Tardive Dyskinesia, approval requires:**

- Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
- The patient is at least 18 years of age
- Moderate to severe tardive dyskinesia has been present for at least 3 months
- Patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

---

### RATIONALE

Promote appropriate utilization of **DEUTETRABENAZINE** (Austedo) based on FDA approved indication and dosing.

### FDA APPROVED INDICATIONS

Austedo is indicated for the treatment of chorea associated with Huntington’s disease and for the treatment of adults with tardive dyskinesia.

### DOSAGE AND ADMINISTRATION

The dose of Austedo is determined individually for each patient based on reduction of chorea or tardive dyskinesia and tolerability.

***Dosing Recommendations to Initiate DEUTETRABENAZINE (Austedo) treatment***

When first prescribed to patients who are not being switched from tetrabenazine, the dosing recommendations are as follows:

- The recommended starting dose of Austedo is 6 mg administered orally once daily for patients with chorea associated with Huntington’s Disease and 12 mg orally once daily for patients with tardive dyskinesia
- The dose may be increased at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg
- Administer total daily dosages of 12 mg or above in two divided doses
- Administer Austedo with food. Swallow Austedo whole. Do not chew, crush, or break tablets

**CONTINUED ON NEXT PAGE**

## DEUTETRABENAZINE

### FDA APPROVED INDICATIONS (CONTINUED)

### DOSAGE

***Initial Dosing Recommendations for Patients Switching from Tetrabenazine to Austedo***

Discontinue tetrabenazine and initiate Austedo the following day. The recommended initial dosing regimen of Austedo in patients switching from tetrabenazine to Austedo is as follows:

| Current tetrabenazine daily dosage | Initial regimen of Austedo |
|---|---|
| 12.5 mg | 6 mg once daily |
| 25 mg | 6 mg twice daily |
| 37.5 mg | 9 mg twice daily |
| 50 mg | 12 mg twice daily |
| 62.5 mg | 15 mg twice daily |
| 75 mg | 18 mg twice daily |
| 87.5 mg | 21 mg twice daily |
| 100 mg | 24 mg twice daily |

***Dosage Adjustment with Strong CYP2D6 Inhibitors***

In patients receiving strong CYP2D6 inhibitors (e.g., quinidine, antidepressants such as paroxetine, fluoxetine, and bupropion), the total daily dosage of Austedo should not exceed 36 mg (maximum single dose of 18 mg).

***Dosage Adjustment in Poor CYP2D6 Metabolizers***

In patients who are poor CYP2D6 metabolizers, the total daily dosage of Austedo should not exceed 36 mg (maximum single dose of 18 mg).

### REFERENCES


- Austedo [Prescribing Information]. North Wales, PA. Teva Pharmaceuticals, Inc. August 2017.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 04/01/18
Created: 04/17
Client Approval: 02/18
P&T Approval: 01/18