UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2138-8
Program	Prior Authorization/Medical Necessity
Medication	Austedo® (deutetrabenazine), Austedo® XR (deutetrabenazine)
P&T Approval Date	11/2017, 11/2018, 11/2019, 11/2020, 2/2022, 2/2023, 4/2023, 4/2024
Effective Date	7/1/2024

1. Background

Austedo and Austedo XR are vesicular monoamine transporter 2 (VMAT2) inhibitors indicated in adults for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia.

2. Coverage Criteria[a]:

A. Tardive Dyskinesia

1. **Initial Authorization**

a. **Austedo** or **Austedo XR** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe tardive dyskinesia

-AND-

(2) **One** of the following:

(a) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

-OR-

(b) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

-AND-

(3) Prescribed by or in consultation with **one** of the following:

(a) Neurologist
(b) Psychiatrist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

B. Chorea associated with Huntington's disease

1. **Initial Authorization**

   a. **Austedo** or **Austedo XR** will be approved based on **both** of the following criteria:

      (1) Diagnosis of chorea associated with Huntington's disease

      -AND-

      (2) Prescribed by or in consultation with **one** of the following:

         (a) Neurologist
         (b) Psychiatrist

   Authorization will be issued for 12 months.

2. **Reauthorization**

   a. Documentation of positive clinical response to therapy

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Austedo – Austedo XR [package insert]. Parsippany, NJ: Teva Pharmaceuticals Inc.; September 2023.
2. Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2012 August.
3. Claassen DO, Carroll B, De Boer LM, et al. Indirect tolerability comparison of deutetrabenazine and tetrabenazine for Huntington disease. J Clin Mov Disord. 2017. 4:3.
4. Geschwind MD, Paras N. Deutetrabenazine for treatment of chorea in Huntington disease. JAMA. 316(1):33-34.
5. Huntington Study Group. Effect of deutetrabenazine on chorea among patients with Huntington disease. JAMA. 2016; 316(1):40-50
6. Keepers GA, Fochtmann LJ, Anzia JM, et al. The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia. Focus (Am Psychiatr Publ). 2020;18(4):493-497. doi:10.1176/appi.focus.18402

7. Bachoud-Lévi AC, Ferreira J, Massart R, et al. International Guidelines for the Treatment of Huntington's Disease. Front Neurol. 2019;10:710. Published 2019 Jul 3. doi:10.3389/fneur.2019.00710

Program	Prior Authorization/Medical Necessity - Austedo (deutetrabenazine)
Change Control	
11/2017	New program
11/2018	Annual review. No changes to clinical coverage criteria.
11/2019	Annual review. No changes to clinical coverage criteria. Updated reference.
11/2020	Annual review. Updated references.
2/2022	Annual review with no change to clinical criteria.
2/2023	Annual review. Updated background per package insert and updated references.
4/2023	Added coverage criteria for Austedo XR formulation per prescribing information. Updated background and references.
4/2024	Annual review with no change to clinical criteria. Reference updated.