Drug Coverage Policy

Effective Date 9/1/2024
Coverage Policy Number..........IP0079
Policy Title..............................Austedo

Vesicular Monoamine Transporter Type 2 Inhibitors – Austedo

- Austedo® (deutetrabenazine tablets – Teva)
- Austedo® XR (deutetrabenazine extended-release tablets – Teva)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

Austedo and Austedo XR, vesicular monoamine transporter type 2 inhibitors, are indicated in adults for the following uses:[1]

- **Chorea associated with Huntington's disease**.
- **Tardive dyskinesia**.

Medical Necessity Criteria

Austedo/Austedo XR are considered medically necessary when ONE of the following is met (1 or 2):

FDA-Approved Indications

1. **Chorea Associated with Huntington's Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36); AND
   - **C)** The medication is prescribed by or in consultation with a neurologist.

2. **Tardive dyskinesia.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has a history of use of dopamine receptor blocking agent;
     Note: Examples of dopamine receptor blocking agents include dopamine agonists (e.g., pramipexole, ropinirole), antipsychotics, metoclopramide, prochlorperazine.
   - **C)** The medication is prescribed by or in consultation with a neurologist or psychiatrist.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Austedo® tablets/Austedo® XR extended-release tablets [prescribing information]. North Wales, PA: Teva; September 2023.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	**Tardive Dyskinesia.** Updated "Individual has a history of treatment with a dopamine receptor blocking agent (for example, antipsychotics, metoclopramide, prochlorperazine)" to now be "Patient has a history of use of dopamine receptor blocking agent" with the examples moved to a Note. Updated title from Deutetrabenazine.	9/1/2024

The policy effective date is in force until updated or retired.

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