Effective Date: 06/01/2021
Reviewed: 03/2021, 4/2022 Scope: Medicaid

Austedo (deutetrabenazine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Treatment of chorea associated with Huntington's disease
2. Treatment of tardive dyskinesia in adults

All other indications are considered experimental/investigational and not medically necessary.

II. INITIAL CRITERIA

A. Patient will not use Austedo concomitantly with monoamine oxidase inhibitors (MAOIs), reserpine or Tetrabenazine.
B. Patient is not using an additional vesicular monoamine transporter 2 (VMAT2) while taking Austedo.
C. Dose does not exceed 48mg/day.

Huntington's Disease

i. For use in Huntington's disease, Austedo must be prescribed by or in consultation with a neurologist.
ii. The patient is not suicidal, or has untreated/inadequately treated depression (a score of greater than or equal to 11 on the depression subscale of the Hospital Anxiety and Depression scale (HADS).
iii. Authorization 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:
        a. Laboratory results indicate an expanded *HTT* CAG repeat sequence of at least 36
        b. Member has a positive family history for Huntington's disease; OR

Tardive Dyskinesia

i. For use in tardive dyskinesia, Austedo must be prescribed by or in consultation with a neurologist or psychiatrist.
ii. Diagnosis of tardive dyskinesia secondary to a centrally acting dopamine receptor-blocking agent (DRBA).
iii. Baseline documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS) with a total score of $\geq$ 6.

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III. CONTINUATION OF THERAPY

A. Patient is tolerating treatment; AND
B. Patient will not use Austedo concomitantly with monoamine oxidase inhibitors (MAOIs), reserpine or Tetrabenazine; AND
C. Patient is not using an additional vesicular monoamine transporter 2 (VMAT2) while taking Austedo; AND
D. For the treatment of chorea associated with Huntington's disease, the chorea symptoms have improved or stabilized from baseline and patient is not suicidal, or has untreated/inadequately treated depression (a score of greater than or equal to 11 on the depression subscale of the Hospital Anxiety and Depression scale (HADS); OR
E. For the treatment of tardive dyskinesia, the patient has written documentation of a positive clinical response by a decrease of at least 3 points in total AIMS score (items 1 to 7) compared to baseline score for tardive dyskinesia.

IV. QUANTITY LIMIT

Austedo 6mg and 9mg tablets: 2 tablets/day
Austedo 12mg tablet: 4 tablets/day

V. COVERAGE DURATION

- Initial: 6 months
- Renewal: 12 months