Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Xenazine (Tetrabenazine) & Austedo (deutetrabenazine)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Xenazine (tetrabenazine) and Austedo (deutetrabenazine).

Xenazine (Tetrabenazine) is indicated for the treatment of chorea associated with Huntinton's disease.

Austedo (deutetrabenazine) is indicated for the treatment of chorea associated with Huntinton's disease and tardive dyskinesia in adults.

DEFINITIONS

Chorea – a rapid, involuntary, nonrepetitive movement involving the face, trunk, and limbs.

Huntington's Disease – an inherited progressive neurodegenerative disorder characterized by chorea, psychiatric problems, and dementia.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs, Xenazine (Tetrabenazine) and Austedo (deutetrabenazine).are subject to the prior authorization process.

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PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. All rrequests:
    - Must be prescribed by a neurologist
    - Must be age 18 years or older
    - Must not be actively suicidal or have uncontrolled depression
        - Members with a history of depression and/or suicidal ideation must have an evaluation by a neurologist or behavioral health provider prior to starting therapy. These members must also be followed concurrently with a behavioral health provider while on therapy. Chart documentation must be provided.
    - Must currently not be using a monoamine oxidase inhibitor (MAOI) or reserpine
    - Must not use Austedo and Xenazine as combination therapy
    - Must not have hepatic impairment

2. For Chorea Associated with Huntington's Disease:
    - Must have chart documentation of a diagnosis of chorea associated with Huntington's Disease confirmed by a neurologist with expertise in Huntington's Disease and ONE of the following:
        - Confirmation of diagnosis by Huntington Disease Mutation Analysis. Documentation of laboratory result indicating an expanded CAG repeat (≥ 36) in the huntington gene (HTT) (also known as HD gene) must be submitted.
        - A positive family history of Huntington's Disease, with autosomal dominant inheritance pattern
    - Must have clinical signs of Huntington's Disease. Chart documentation of clinical work-up must be submitted indicating that the member has one or more of the following clinical signs:
        - Motor (e.g. finger tapping, rigidity)
        - Oculomotor
        - Bulbar (e.g. dysarthria, dysphagia)
        - Affective (e.g. depression)
        - Cognitive

3. Tardive Dyskinesia (Austedo only)
    - Must have a diagnosis of tardive dyskinesia

Requests for doses above Xenazine (tetrabenazine) 50mg/day:

- Must meet one of the following criteria:
    - Must have an adequate trial of 50 mg per day dosing with an inadequate response. Chart documentation of trial and inadequate response is required.
    - Must be a CYP 2D6 intermediate or extensive metabolizer. Documentation of CYP 2D6 genotyping results are required.
- Documentation of slow titration of tetrabenazine dose with close monitoring of side effects
- The maximum dose that can be approved is 100mg daily.

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorizations may be extended at one-year intervals based upon the following:

- Documentation from the provider that the member's condition has stabilized or improved based upon the prescriber's assessment while on therapy
- For members with a history of depression and/or suicidal thoughts or behaviors or for members with a current treatment for depression and/or suicidal thoughts or behaviors, chart documentation must be provided to show current evaluation by a neurologist or behavioral health provider and that the patient is not experiencing suicidal thoughts or behaviors
- For Xenazine (tetrabenazine) requests for doses above 50mg/day:
    - Documentation must be provided showing inadequate efficacy of lower doses and slow titration of Xenazine dose with close monitoring of side effects

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16/, 02/17, 02/18*
Addition of Austedo	*07/17*
New Indication	*01/18*