



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 7/16/15
LAST REVIEW DATE: 3/15/18
LAST CRITERIA REVISION DATE: 3/15/18
ARCHIVE DATE:

AUSTEDO™ (deutetrabenazine) oral tablet
INGREZZA™ (valbenazine) oral capsule
XENAZINE® (tetrabenazine) oral tablet
Tetrabenazine oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602)

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864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Description:

Austedo (deutetrabenazine) and Xenazine (tetrabenazine) are indicated for the treatment of chorea associated with Huntington's disease (HD). The mechanism of the anti-chorea action is unknown but it is believed to be related to depletion of monoamines from nerve terminals. Ingrezza (valbenazine) is indicated for the treatment of adults with tardive dyskinesia (TD). The mechanism of action of valbenazine in the treatment of TD is unknown but is thought to be due to regulation of monoamine uptake from the cytoplasm into the synaptic vesicle for storage and release.

Deutetrabenazine, tetrabenazine, and valbenazine are reversible inhibitors of the vesicle monoamine transporter type 2 (VMAT-2). They inhibit uptake of the neurotransmitters serotonin, norepinephrine, histamine, and, especially, dopamine into the granular vesicles of presynaptic neurons and ultimately lead to depletion of monoamine stores. Dopamine is a chemical that communicates between certain nerve cells in the brain. In patients with HD, this system is overactive and results in the abnormal movements of chorea. Austedo (deutetrabenazine) and Xenazine (tetrabenazine) decrease the amount of dopamine available to interact with certain nerve cells, thereby decreasing the involuntary movements. Tetrabenazine also exhibits weak binding affinity at the dopamine 2 (D2) receptor. The pathophysiology of TD remains poorly understood, but it is believed to be the result of chronic blockade of dopamine receptors, particularly D2 and possibly D3, by dopamine receptor blocking agents (DRBA). In addition to dopamine, other neurotransmitter receptors may be important, especially 5-hydroxytryptamine 2 (5-HT2) receptors that modulate motor activity. One of the most prominent theories about TD pathogenesis is that chronic exposure to the neuroleptics results in D2 receptor upregulation with postsynaptic dopamine receptor supersensitivity.

HD is a rare, inherited neurological disorder affecting about 1 in 10,000 people in the United States. The disease results from degeneration and deterioration of brain cells. The deterioration causes uncontrolled movements (chorea), cognitive decline, and psychiatric/behavioral changes. Cognitive symptoms include confusion on time and place, loss of judgment, memory loss, and personality changes. Movement problems include restless leg, fidgeting, facial movements, head turning to shift eye position, jerking of arms, legs, face and other body parts, speech problems, slow uncontrolled movements, swallowing problems, and unsteady gait. As chorea worsens the individual is at risk for falls. Due to swallowing difficulties, HD individuals also have difficulty in maintaining nutrition leading to further declines in functional capacity.

Chorea is an abnormal involuntary movement caused by overactivity of the neurotransmitter dopamine in the areas of the brain that control movement. It is characterized by brief, irregular contractions that are not repetitive or rhythmic, but appear to flow from one muscle to the next. The full spectrum of motor impairment in HD includes eye movement abnormalities, Parkinsonian features and dystonia, myoclonus, tics, ataxia, dysarthria, dysphagia, spasticity with hyperreflexia and extensor plantar responses.

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The underlying pathology and neurochemical bases of HD are complex and not fully understood. It is thought that dopamine and glutamate transmission and their interaction with receptors at various sites in the brain are affected.

A recent guideline on the treatment of HD published in 2012 from the American Academy of Neurology (AAN) stated that amantadine, tetrabenazine, or riluzole (although its effect is dose dependent) may be used for chorea. Nabilone may have a weak or a slight effect on chorea but long-term information is lacking. Data on use of clozapine, other neuroleptics, or donepezil were not sufficient to make a recommendation for or against their use in the management of chorea.

Tardive dyskinesia (TD) is one of the most well-known types of tardive syndromes (TDS). TD is estimated to affect 500,000 people in the United States. TDS are movement disorders that affect voluntary muscles. In TDS, abnormal body movements occur and these movements cannot be controlled voluntarily. Classic TD usually involves random rhythmic involuntary movements of the face; affecting the tongue, lips, or jaw where abnormal movement of the jaw is seen as a chewing motion and facial grimacing. Other affected body parts include the hands, arms, legs, fingers, toes, or hips. TDS includes other types of abnormal movements besides TD and includes: tardive akathisia, tardive dystonia, tardive myoclonus, tardive tremor, and tardive tics (also known as tardive tourettism).

TD results from chronic (three or more months) exposure to DRBA, some neuroleptics or antipsychotics (typical and atypical agents), tricyclic antidepressants (amoxapine), and antiemetics or other medications used for gastrointestinal disorders (promethazine and metoclopramide). Not all individuals who are using DRBA go on to develop TD. Factors that may contribute to the development of TD include duration of treatment, type of DRBA used, age, alcohol use or use of other substances of abuse, HIV/AIDS, and female gender. The diagnosis of TD is based on the patient's history of exposure to DRBA, characteristic clinical presentation, and exclusion or other conditions such as includes Huntington's disease.

In 2013 the American Academy of Neurology evidence-based guideline on the treatment of TDS stated that clonazepam or ginkgo biloba probably improves TDS and both should be considered as treatment. The guideline also stated that amantadine and tetrabenazine might be considered as treatment for TDS.

The Gilles de la Tourette syndrome (TS) is a chronic inherited neurological disorder characterized by involuntary motor and phonic tics that wax and wane. Tics are sudden, brief, intermittent movements (motor tics) or utterances (vocal or phonic tics). Tics have been considered involuntary, but tics can temporarily be voluntarily suppressed. The onset of TS is typically between 2-15 years of age. Many individuals with TS also have a variety of comorbid conditions such as obsessive compulsive disorder (OCD), attention deficit hyperactivity disorder (ADHD), learning difficulties, and sleep abnormalities. Tics often decline during adolescence and resolve by age 18 in about one-half of children, although some tics may persist into adulthood but their severity gradually diminishes over time in another 40-45% of cases.

TS is thought to result from a complex interaction between social and environmental factors and multiple genetic abnormalities. The diagnosis of TS is based on a set of criteria using clinical features of the disease, particularly

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the presence of multiple motor and vocal tics, with onset before age 18 or 21, the presence of vocal tics, and a family history of similar symptoms.

Treatment is indicated when symptoms of TS interfere with social interactions, school or job performance, activities of daily living, or cause subjective discomfort, pain, or injury. Specific treatment should take into account the need to treat the most troublesome symptoms and presence of comorbid conditions such as ADHD, OCD, behavioral problems, and mood disorders. However there are no well-designed and well-powered clinical studies available to guide treatment selection; the literature provides low level evidence and drugs are often selected by use of expert experience, opinion, and preference.

In 2011 a clinical guideline by the European Society for the Study of Tourette syndrome was published. After reviewing the literature, the evidence supported the use of haloperidol, pimozide, ziprasidone, risperidone (when TS is seen with disruptive behavior disorder), or olanzapine (when TS is seen with obsessive-compulsive behavior). Other antipsychotics have been used in TS and include aripiprazole, fluphenazine, and quetiapine. When TS is seen with ADHD, the evidence supported the use of clonidine or guanfacine. Tetrabenazine was concluded as an alternative to an antipsychotic. Retrospective non-randomized trials of its use in TS showed moderate to marked improvement in function and TS-related symptoms, these results were viewed as encouraging and pointed to a need for further studies.

Austedo (deutetrabenazine)

Medication class:

- Psychotherapeutic and Neurological Agents, Movement Disorder Drug Therapy

FDA-approved indication(s):

- Chorea associated with Huntington's disease
- Tardive dyskinesia in adults

Recommended Dose:

Chorea associated with Huntington's disease:

- Initial Dose: 6 mg/day
- Recommended Dose: 6 mg – 48 mg/day
- Maximum Dose: 48 mg/day

Tardive dyskinesia in adults:

- Initial Dose: 12 mg/day
- Recommended Dose: 12 mg – 48 mg/day
- Maximum Dose: 48 mg/day

Available Dosage Forms:

- Tablet: 6 mg, 9 mg, and 12 mg

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Warnings and Precautions:

- Depression and suicidality in patients with Huntington's disease. See full prescribing information for complete boxed warning.
 - QT Prolongation: May cause an increase in QT interval. Avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval.
 - Neuroleptic Malignant Syndrome (NMS): Discontinue if this occurs.
 - Akathisia, agitation, restlessness, and parkinsonism: Reduce dose or discontinue if this occurs.
 - Sedation/somnolence: May impair the patient's ability to drive or operate complex machinery.
-

Criteria:

Austedo (deutetrabenazine)

- **Criteria for initial therapy:** Austedo (deutetrabenazine) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a Psychiatrist or Neurologist
2. Individual is 18 years of age or older
3. A confirmed diagnosis of **ONE** of the following:
 - Chorea associated with Huntington's disease
 - Tardive dyskinesia in adults
4. **For Huntington's disease:** Individual has failure, contraindication or intolerance to amantadine **OR**
For Tardive dyskinesia:
 - Discontinuation of the offending drug
 - Switching from a first to a second generation antipsychotic drug when appropriate
 - Failure, contraindication or intolerance to clonazepam
 - For localized forms of severe tardive dystonia, failure, contraindication or intolerance botulinum toxin injections
 - Failure, contraindication or intolerance to Ingrezza or tetrabenazine (generic)
5. There are **NO** contraindications.
 - Contraindications include:
 - Suicidal, or untreated/inadequately treated depression in patients with Huntington's disease
 - Hepatic impairment
 - Taking reserpine, MAOIs, tetrabenazine (Xenazine), or valbenazine

Initial approval duration: Approve for 4-6 weeks only

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Tetrabenazine oral tablet (cont.)

- **Criteria for continuation of coverage (renewal request):** Austedo (deutetrabenazine) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a Psychiatrist or a Neurologist
 2. Individual's condition has not worsened while on therapy
 - Worsening is defined as:
 - Protruding and twisting movements of the tongue
 - Pouting, puckering, or smacking movements of the lips
 - Retraction of the corners of the mouth
 - Bulging of the cheeks
 - Chewing movements
 - Blepharospasm
 - Twisting, spreading, and "piano-playing" finger movements
 - Tapping foot movements
 - Dystonic extensor postures of the toes
 3. The indication for use is one that requires a longer duration than the usual 6 weeks such as use for tardive dyskinesia
 4. Individual has been adherent with the medication
 5. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - Contraindications as listed in the criteria for initial therapy section
 - Significant adverse effect such as:
 - Neuroleptic malignant syndrome
 - Akathisia, agitation, restlessness and parkinsonism that does not resolve with dose adjustment
 6. There are no significant interacting drugs

Renewal duration: 6 months

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Tetrabenazine oral tablet (cont.)

Ingrezza (valbenzaine)

Medication class:

- Psychotherapeutic and Neurological Agents, Movement Disorder Drug Therapy

FDA-approved indication(s):

- Tardive dyskinesia

Recommended Dose:

- The initial dose is 40 mg once daily. After one week, increase the dose to the recommended dose of 80 mg once daily.
- Can be taken with or without food.
- The recommended dose for patients with moderate or severe hepatic impairment is 40 mg once daily.
- Consider dose reduction based on tolerability in known CYP2D6 poor metabolizers.

Available Dosage Forms:

- Capsule: 40 mg and 80 mg

Warnings and Precautions:

- Somnolence: May impair patient's ability to drive or operate hazardous machinery.
 - QT Prolongation: May cause an increase in QT interval. Avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval.
-

Criteria:

Ingrezza (valbenzaine)

- **Criteria for initial therapy:** Ingrezza (valbenzaine) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
 1. Prescriber is a Psychiatrist or Neurologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of tardive dyskinesia and **ALL** of the following:
 - Discontinuation of the offending drug
 - Switching from a first to a second generation antipsychotic drug when appropriate
 - Failure, contraindication or intolerance to clonazepam
 - For localized forms of severe tardive dystonia, failure, contraindication or intolerance botulinum toxin injections
 - Failure, contraindication or intolerance to Ingrezza or tetrabenazine (generic)

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Tetrabenazine oral tablet (cont.)

4. Individual has failure, contraindication or intolerance to clonazepam OR amantadine

Initial approval duration: 3 months

- **Criteria for continuation of coverage (renewal request):** Ingrezza (valbenzaine) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a Psychiatrist or Neurologist
2. Individual's condition has not worsened while on therapy
 - Worsening is defined as:
 - Protruding and twisting movements of the tongue
 - Pouting, puckering, or smacking movements of the lips
 - Retraction of the corners of the mouth
 - Bulging of the cheeks
 - Chewing movements
 - Blepharospasm
 - Twisting, spreading, and "piano-playing" finger movements
 - Tapping foot movements
 - Dystonic extensor postures of the toes
3. The indication for use is one that requires a longer duration than the usual 3 months such as use for tardive dyskinesia
4. Individual has been adherent with the medication
5. There are no significant interacting drugs

Renewal duration: 6 months

Xenazine (tetrabenazine)
Tetrabenazine, generic

Medication class:

- Psychotherapeutic and Neurological Agents, Movement Disorder Drug Therapy

FDA-approved indication(s):

- Chorea associated with Huntington's disease

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XENAZINE® (tetrabenazine) oral tablet
Tetrabenazine oral tablet (cont.)

Recommended Dose:

- Individualization of dose with careful weekly titration is required. The 1 week's starting dose is 12.5 mg daily; 2nd week, 25 mg (12.5 mg twice daily); then slowly titrate at weekly intervals by 12.5 mg to a tolerated dose that reduces chorea.
- Doses of 37.5 mg and up to 50 mg/day should be administered in three divided doses per day with a maximum recommended single dose not to exceed 25 mg.
- Patients requiring doses above 50 mg/day should be genotyped for the drug metabolizing enzyme CYP2D6 to determine if the patient is a poor metabolizer (PM) or an extensive metabolizer (EM).
- Maximum daily dose in PMs: 50 mg with a maximum single dose of 25 mg.
- Maximum daily dose in EMs and intermediate metabolizers (IMs): 100 mg with a maximum single dose of 37.5 mg.
- If serious adverse reactions occur, titration should be stopped and the dose should be reduced. If the adverse reaction(s) do not resolve, consider withdrawal of Xenazine.

Available Dosage Forms:

- Tablet: 12.5 mg non-scored and 25 mg scored

Warnings and Precautions:

- Depression and suicidality. See full prescribing information for complete boxed warning.
- Periodically reevaluate the benefit and potential for adverse effects such as worsening mood, cognition, rigidity, and functional capacity.
- Do not exceed 50 mg/day and the maximum single dose should not exceed 25 mg if administered in conjunction with a strong CYP2D6 inhibitor (e.g., fluoxetine, paroxetine).
- Neuroleptic Malignant Syndrome (NMS): Discontinue if this occurs.
- Restlessness, agitation, akathisia and parkinsonism: Reduce dose or discontinue if occurs.
- Sedation/Somnolence: May impair patient's ability to drive or operate complex machinery.
- QTc prolongation: Not recommended in combination with other drugs that prolong QTc.

Criteria:

Xenazine (tetrabenazine) and tetrabenazine

- **Criteria for initial therapy:** Xenazine (tetrabenazine) and tetrabenazine is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a Psychiatrist or Neurologist
 2. A confirmed diagnosis of **ONE** of the following:
 - Individual is 18 years of age or older diagnosed with chorea associated with Huntington's disease **AND** the following:
 - Individual has failure, contraindication or intolerance to amantadine

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- Individual is 14 years of age or older diagnosed with Tics due to Tourette's syndrome **AND** the following:
 - Individual has failure, contraindication or intolerance to **ALL** of the following:
 - Aripiprazole, fluphenazine, haloperidol, olanzapine, pimozide, quetiapine, risperidone, and ziprasidone
 - Individual with concurrent ADHD has failure, contraindication or intolerance to the use of both clonidine and guanfacine
- 3. **For brand Xenazine:** Individual has failure, contraindication or intolerance generic tetrabenazine
- 4. There are **NO** contraindications.
 - Contraindications include:
 - Actively suicidal, or who have depression which is untreated or undertreated
 - Hepatic impairment
 - Taking monoamine oxidase inhibitors (MAOIs) or reserpine
 - Taking deutetrabenazine or valbenazine

Initial approval duration: 6 months

➤ **Criteria for continuation of coverage (renewal request):** Xenazine (tetrabenazine) and tetrabenazine is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a Psychiatrist or Neurologist
2. Individual's condition is stable or has not worsened while on therapy
3. Individual has been adherent with the medication
4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - Contraindications as listed in the criteria for initial therapy section
 - Significant adverse effect such as:
 - Neuroleptic malignant syndrome
 - Akathisia, agitation, restlessness and parkinsonism that does not resolve with dose adjustment
5. There are no significant interacting drugs

Renewal duration: 12 months

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Tetrabenazine oral tablet (cont.)**

Resources:

Xenazine. Package Insert. Revised by manufacturer 9/20/17. Reviewed on 02-21-2018.

Ingrezza package insert. Revised by the manufacturer 10/2017. Reviewed on 02-21-2018.

Austedo package insert. Revised by manufacturer 9/2017. Reviewed on 02-21-2018.

Xenazine. Package Insert. Revised by manufacturer 6/2015. Reviewed 06-05-2017.

Ingrezza package insert. Revised by the manufacturer 4/2017. Reviewed on 06-03-2017.

Austedo package insert. Revised by manufacturer 4/2017. Reviewed 04-18-2017.

Roessner V, Plessen KJ, Rotherberger A, et al.: European clinical guidelines for Tourette syndrome and other tic disorders. Part II: pharmacologic treatment. *Eur Child Adolesc Psychiatry* 2011; 20:173-196

De Nadai AS, Storch EA, McGuire JF, et al.: Evidence-based Pharmacotherapy for Pediatric Obsessive-Compulsive Disorder and Chronic Tic Disorders. *J Central Nervous Syst Dis* 2011; 3:125-142

Eddy CM, Rickards HE, Cavanna AE. Treatment strategies for tic in Tourette syndrome. *Ther Adv Neurol Disord* 2011; 4(1):25-45

Xenazine. Package Insert. Revised by manufacturer September 2012. Accessed 06-02-2015. Reviewed on 06-22-2015

Armstrong MJ and 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 Aug 7; 79: 597-603

Bhidayasiri R, Fahn S, Weiner W, et al.: Evidence-based guideline: Treatment of tardive syndromes. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology* 2013; 81 July 30:463-469

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: _____ Date: _____

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.