ConnectiCare

Commercial/Healthcare Exchange PA Criteria
Effective: May 4, 2016

Prior Authorization: Tetrabenazine

Products Affected: tetrabenazine oral tablet, Xenazine oral tablet

Medication Description:
Huntington's disease is an inherited disease that causes the progressive breakdown (degeneration) of nerve cells in the brain.

Tetrabenazine is a monoamine depletor for oral administration indicated for the treatment of chorea associated with Huntington's disease. Huntington disease (HD) is an incurable, adult-onset, autosomal dominant inherited disorder associated with cell loss within a specific subset of neurons in the basal ganglia and cortex. Huntington's disease is a progressive disorder characterized by changes in mood, cognition, chorea, rigidity, and functional capacity over time. Chorea is characterized as jerky, irregular, relatively rapid, involuntary movements that can affect the face or limbs. The exact mechanism by which tetrabenazine exerts its anti-chorea effects is unknown but is believed to be related to its effect as a reversible depletor of monoamines (such as dopamine, serotonin, norepinephrine, and histamine) from nerve terminals. Tetrabenazine reversibly inhibits the human vesicular monoamine transporter type 2 resulting in decreased uptake of monoamines into synaptic vesicles and depletion of monoamine stores.

Tetrabenazine was granted orphan drug designation by the FDA; a drug is granted orphan status if it addresses a population of fewer than 200,000 patients or if it treats conditions that affect more than 200,000 patients but where there is no reasonable expectation of profit being recovered for the drug. About 30,000 people in the United States have Huntington's disease, and another 200,000 are at risk of developing the disease, the FDA statement notes.

Covered Uses:
1. Chorea associated with Huntington's disease
2. Tardive dyskinesia
3. Tourette syndrome and related tic disorders

Exclusion Criteria:
1. Patients who are actively suicidal, or in patients with untreated or inadequately treated depression
2. Patients with hepatic impairment
3. Patients taking monoamine oxidase inhibitors (MAOIs)
4. Patients taking reserpine. (At least 20 days should elapse after stopping reserpine before starting tetrabenazine)
5. Patients taking deutetrabenazine or valbenazine

Required Medical Information:
1. Diagnosis
2. Current therapy regimen
3. Medical history

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist or psychiatrist.

Coverage Duration: 12 Months

Other Criteria:

A. Patient has a diagnosis of:
   a. Chorea associated with Huntington's disease; OR
   b. Tardive dyskinesia; OR
   c. Tourette syndrome and related tic disorders.

References:

1. Xenazine™ package insert, Ovation Pharmaceuticals, Inc, Deerfield, Illinois, Sept 2008.
2. Yero, T, Rey, J. Tetrabenazine (Xenazine), An FDA-Approved Treatment Option for Huntington's Disease-Related Chorea Pharmacy and Therapeutics 2008,33:690-694.
3. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thompson Micromedex. Updated periodically. Accessed March 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	3/21/2016
2	Update	Update policy to FDA label Removal of Non-FDA approved indications	Exclusion Criteria Other Criteria/Covered Uses	12/5/2019
3	Update	CCI adoption of EH Policy, removed from CCI VMAT Inhibitors Policy CCI P&T Review History: 5/17, 11/17, 1/18 CCI Revision Record: 11/17	All	12/17/2019