

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

Diagnosis	<input type="checkbox"/> Chorea secondary to Huntington's disease <input type="checkbox"/> Movement disorder secondary to another condition (please state): _____ _____
Exclusion criteria	Check if any of the following apply to the patient: <input type="checkbox"/> Hepatic dysfunction <input type="checkbox"/> Uncontrolled depression <input type="checkbox"/> Actively suicidal <input type="checkbox"/> Reserpine use within the past 20 days
Physician Specialty	<input type="checkbox"/> Neurology <input type="checkbox"/> Other (please state): _____
Supporting documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):
	Please attach a copy of the prescription or provide ALL of the information below: Xenazine® (tetrabenazine) * Doses exceeding 50mg daily will be reviewed for medical necessity Strength _____ Sig _____ Qty _____ Refills _____
	Please attach all relevant medical records and test results We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP
4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/05/11

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Xenazine (tetrabenazine)

CLASSIFICATION

- Central nervous system agent (benzoquinolizine, monoamine depletory)

DESCRIPTION

- Tetrabenazine is designated an orphan product for use in the treatment of Huntington's disease.
- Tetrabenazine is a benzoquinolizine derivative used for the treatment of dyskinesic disorders. The drug was initially developed as a neuroleptic agent.
- Tetrabenazine is a monoamine depletor whose exact mechanism is unknown, but is thought to resemble that of reserpine, although there are some differences. The duration of action of tetrabenazine is shorter, possibly related to reversible monoamine depletion (compared to irreversible depletion with reserpine). Clinically, tetrabenazine has displayed a more rapid onset of action and appears to be associated with a lower incidence of depression and postural hypotension than reserpine. It depletes monoamine such as dopamine, serotonin, norepinephrine, and histamine from nerve terminals. Tetrabenazine reversibly inhibits the human vesicular monoamine transporter type 2 which results in decreased uptake of monoamines into synaptic vesicles and depletion of monoamine stores. In vitro, tetrabenazine exhibits weak binding affinity at the dopamine D2 receptor and antagonist activity.
- The safety and efficacy of tetrabenazine for this indication were established primarily in a randomized, double-blind, placebo-controlled trial. Serious side effects such as depression and suicidal thoughts and actions have been reported with the use of tetrabenazine, therefore, the risk versus benefit of treatment must be carefully considered prior to initiation of therapy.
- Tetrabenazine has also been studied for the treatment of tardive dyskinesia, either as initial therapy or in patients who have responded poorly to other agents (eg, reserpine, bromocriptine, clozapine). Indirect comparisons suggest tetrabenazine may be the most effective agent available for this disorder, although further studies assessing long-term benefit and the propensity of the drug to aggravate the tardive dyskinesia are needed.
- In addition to tardive dyskinesia, tetrabenazine has been studied for the treatment of spontaneous and drug-induced dyskinesias. The drug may be useful in selected patients with Tourette syndrome refractory to haloperidol and idiopathic dystonia unresponsive to anticholinergics, although efficacy has tended to be lower in these disorders. Combined use with pimozide and trihexyphenidyl may benefit some patients with severe dystonia. Again, further studies are needed to establish the place in therapy of tetrabenazine for these disorders.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T4
Commercial Formulary:	T4
Medicare Part D coverage:	T5 (Specialty)

COVERAGE CRITERIA

Xenazine (tetrabenazine) meets the definition of **medical necessity** for the following:

- Chorea associated with Huntington's disease

Xenazine (tetrabenazine) is considered **experimental** for the following:

- Any movement disorder not associated with Huntington's disease. Examples include: Drug-induced dyskinesia (ie. levodopa adverse reaction), spontaneous dyskinesia, Gilles de la Tourette's syndrome, Tardive dyskinesia

Required Provider Specialty:

- Approval is limited to Neurology

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy have not been established in pediatric patients):

- Chorea - Huntington's disease: initial, 12.5 mg ORALLY once daily in the morning; after 1 week, increase to 12.5 mg ORALLY twice daily; if necessary, titrate by 12.5 mg at weekly intervals to a dose of 37.5 mg to 50 mg/day ORALLY in divided doses 3 times a day; MAX single dose, 25 mg; MAX daily dose, 100 mg; genotype patients for CYP2D6 if requiring greater than 50 mg/day
 - Daily doses above 50 mg should not be administered without CYP2D6 genotyping
- Chorea - Huntington's disease: CYP2D6 extensive and intermediate metabolizers, at doses greater than 50 mg/day, titrate at weekly intervals by 12.5 mg and give in divided doses 3 times a day; MAX single dose, 37.5 mg; MAX daily dose, 100 mg
- Chorea - Huntington's disease: CYP2D6 poor metabolizers, titrate doses at weekly intervals by 12.5 mg; MAX single dose, 25 mg; MAX daily dose, 50 mg
- Chorea - Huntington's disease: treatment interruption of greater than 5 days, re-titrate dose; interruption for less than 5 days, resume tetrabenazine at the previous maintenance dose

Dosing adjustments

- Addition of a strong CYP2D6 inhibitor to established tetrabenazine therapy, cut daily dose of tetrabenazine in half
- Addition of tetrabenazine to established strong CYP2D6 inhibitor therapy, titrate tetrabenazine up at weekly intervals by 12.5 mg; maximum recommended single dose is 25 mg and the maximum recommended daily dose is 50 mg

PRECAUTIONS:

- Black Box Warning
 - Tetrabenazine can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Anyone considering the use of tetrabenazine must balance the risks of depression and suicidality with the clinical need for control of choreiform movements. Close observation of patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior should accompany therapy. Patients, their caregivers, and families should be informed of the risk of depression and suicidality and should be instructed to report behaviors of concern promptly to the treating physician.

- Particular caution should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in Huntington’s disease. Tetrabenazine is contraindicated in patients who are actively suicidal, and patients with untreated or inadequately treated depression.
- Contraindications include any patient who is actively suicidal, on concomitant use of an MAOI, on concomitant use of reserpine (or within 20 days of discontinuation), has untreated or inadequately-treated depression, or has impaired hepatic function
- For other precautions, please consult full product prescribing information

Billing/Coding information

- n/a

COST

- AWP (September 2010) – Xenazine 25mg tablets (30): \$2,393.70

COMMITTEE APPROVAL:

- September 22, 2010

GUIDELINE UPDATE INFORMATION:

Sept 2010	Policy created

REFERENCES:

- DRUGDEX®, accessed 09/14/2010
- Product Information: XENAZINE(R) oral tablets, tetrabenazine oral tablets. Prestwick Pharmaceuticals, Inc, Washington, DC, 2008.