ROCKY MOUNTAIN HEALTH PLANS®
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UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Xenazine® (tetrabenazine)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Xenazine® (tetrabenazine)

Diagnosis (documentation supportive of diagnosis is required)

☐ Chorea secondary to Huntington's disease
☐ Other (please state): _____

Clinical Consideration (check if any of the following apply to the patient):

☐ Hepatic dysfunction
☐ Depression, untreated or inadequately-treated
☐ Actively suicidal
☐ Use of tetrabenazine within 20 days of reserpine discontinuation
☐ Concomitant use of an MAOI

Physician Specialty

☐ Neurology
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐ Physician Office		Other:
Prescriber or Authorized Signature:		Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

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 dyskinetic 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 week binding affinity at the dopamine D2 receptor mine-receptor 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 (e.g., 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:	Tier 4
Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5 (Specialty)

COVERAGE CRITERIA

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

- Chorea associated with Huntington's disease (documentation supporting diagnosis from the patient's medical record is required).
- Doses exceeding 50mg daily will be reviewed for medical necessity.
- Xenazine is not covered if one or more of the following apply:
  - Hepatic dysfunction
  - Depression, untreated or inadequately-treated
  - Actively suicidal
  - Use of tetrabenazine within 20 days of reserpine discontinuation
  - Concomitant use of an MAOI

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

- Any movement disorder not associated with Huntington's disease. Examples include: Drug-induced dyskinesia (i.e. 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:

- Recommended starting dose: 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
- 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 is 100 mg
- CYP2D6 poor metabolizers, titrate doses at weekly intervals by 12.5 mg; MAX single dose, 25 mg; MAX daily dose is 50 mg
- 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:

- 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.

Precautions:

- Diseases, treatments, or conditions that can cause depression or increased suicidality have increased risk of suicidal behavior.
- History of depression, suicidal ideation or suicide attempts have increased risk of suicidal behavior (see black box warning).
- Bradycardia may increase risk of torsade de pointes and/or sudden death.
- Increased risk of QT prolongation in patients with history of cardiac arrhythmias.
- Avoid concomitant use of other drugs that are known to prolong QTc, including antipsychotic medications (e.g., chlorpromazine, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), class 1A (e.g., quinidine, procainamide) and class III (e.g., amiodarone, sotalol) antiarrhythmics, or any other medications known to prolong the QTc interval.
- Dose adjustment recommended when concomitant use of strong CYP2D6 inhibitors (e.g., fluoxetine, paroxetine, quinidine)
- Patients with congenital long QT syndrome have increased risk of QT prolongation with tetrabenazine use.
- Adjust dose for CYP2D6 poor metabolizers due to increased drug exposure.
- CYP2D6 genetic testing should be administered prior to institution if daily dose greater than 50 mg required.
- New development or exacerbation of preexisting depression may occur; dose reduction or antidepressant therapy may be necessary.
- Hypokalemia and hypomagnesemia may increase risk of torsade de pointes and/or sudden death.
- Irreversible tardive dyskinesia may develop; discontinue if occurs.
- Neuroleptic malignant syndrome, potentially fatal, has been reported; discontinue if occurs.

Billing/Coding information

HCPCS Coding:

J 8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

COST

- AWP (September 2010) – Xenazine 25mg tablets (30): $2,394
- AWP (April 2014) – Xenazine 25mg tablets (30): $4,043

COMMITTEE APPROVAL:

- September 22, 2010

GUIDELINE UPDATE INFORMATION:

Sept 2010	Policy created
April 2014	Policy created for Medicare Part D

REFERENCES:

- DRUGDEX®, accessed 09/14/2010, 04/12/2014
- Product Information: XENAZINE® oral tablets, tetrabenazine oral tablets. Prestwick Pharmaceuticals, Inc., Washington, DC, 2008.