SPECIALTY GUIDELINE MANAGEMENT

tetrabenazine tablets (generic)
XENAZINE (tetrabenazine tablets)

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
• Treatment of chorea associated with Huntington’s disease

Compendial Uses
• Chronic tics associated with Tourette’s syndrome
• Tardive dyskinesia
• Hemiballismus
• Chorea not associated with Huntington’s disease

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
• Daily dose above 50 mg: CYP2D6 metabolizing enzyme genotype results

C. EXCLUSION CRITERIA

• Active suicidal ideation
• Untreated or inadequately treated depression

D. CRITERIA FOR APPROVAL

1. Chorea
   Authorization of 12 months may be granted for the treatment of chorea.

2. Chronic tics associated with Tourette’s syndrome
   Authorization of 12 months may be granted for the treatment of chronic tics associated with Tourette’s syndrome.

3. Tardive dyskinesia
   Authorization of 12 months may be granted for the treatment of tardive dyskinesia.

4. Hemiballismus
   Authorization of 12 months may be granted for the treatment of hemiballismus.

E. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
1. Dosing Limits
The following dosing limits apply:
   a. 100 mg per day:
      • For members who are intermediate or extensive CYP2D6 metabolizers
   b. 50 mg per day:
      • For members receiving concomitant treatment with a strong CYP2D6 inhibitor (e.g., fluoxetine, paroxetine, quinidine)
      • For members who are poor CYP2D6 metabolizers

REFERENCES