SPECIALTY GUIDELINE MANAGEMENT

XENAZINE (tetrabenazine)

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 (HD)

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

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
  o Genotype testing results to determine if members are intermediate or extensive metabolizers of CYP2D6

C. EXCLUSION
• Members who are actively suicidal or have untreated or inadequately treated depression

D. CRITERIA FOR APPROVAL
1. Chorea
   a. Authorization of 12 months may be granted for members prescribed Xenazine for the treatment of chorea.

2. Chronic ticks associated with Tourette’s syndrome
   a. Authorization of 12 months may be granted for members prescribed Xenazine for the treatment of chronic ticks associated with Tourette’s syndrome.

3. Tardive dyskinesia
   a. Authorization of 12 months may be granted for members prescribed Xenazine for the treatment of tardive dyskinesia.

4. Hemiballismus
   a. Authorization of 12 months may be granted for members prescribed Xenazine for the treatment of tardive dyskinesia.

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:
   - 100 mg per day
     - For a daily dose above 50 mg: genotype must be provided to determine if members are intermediate or extensive metabolizers of CYP2D6.

REFERENCES