

Clinical Policy: Tetrabenazine (Xenazine)

Reference Number: CP.PHAR.92

Effective Date: 12.01.11

Last Review Date: 05.19

Line of Business: HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Tetrabenazine (Xenazine[®]) is a vesicular monoamine transporter 2 (VMAT) inhibitor.

FDA Approved Indication(s)

Xenazine is indicated for the treatment of chorea associated with Huntington's disease.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Xenazine is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Huntington's Disease (must meet all):

1. Diagnosis of chorea associated with Huntington's disease;
2. Prescribed by or in consultation with a neurologist;
3. Age \geq 18 years;
4. At the time of request, deutetrabenazine or valbenazine is not prescribed concurrently;
5. Dose does not exceed 50 mg per day (*100 mg per day if genotype testing confirms extensive or intermediate CYP2D6 metabolizer status*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Huntington's Disease (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Deutetrabenazine or valbenazine is not prescribed concurrently;

4. If request is for a dose increase, new dose does not exceed 50 mg per day (*100 mg per day if genotype testing confirms extensive or intermediate CYP2D6 metabolizer status*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

MAOI: monoamine oxidase inhibitors

VMAT2: vesicular monoamine transporter 2

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Actively suicidal, or who have depression which is untreated or undertreated
 - Hepatic impairment
 - Taking monoamine oxidase inhibitors (MAOIs) or reserpine
 - Taking deutetrabenazine or valbenazine
- Boxed warning(s):
 - Depression and suicidality

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Chorea associated with Huntington's disease	12.5 mg PO QD for first week, then 12.5 mg PO BID for second week, then titrate by 12.5 mg weekly thereafter to tolerated dose that reduces chorea; doses of 37.5 mg and up to 50 mg/day	50 mg/day (max single dose of 25 mg) Extensive or intermediate CYP2D6 metabolizer: 100

Indication	Dosing Regimen	Maximum Dose
	should be administered in 3 divided doses per day	mg/day (max single dose of 37.5 mg)

VI. Product Availability

Tablets: 12.5 mg, 25 mg

VII. References

1. Xenazine Prescribing Information. Deerfield, IL: Lundbeck; September 2018. Available at: <http://www.xenazineusa.com>. Accessed February 26, 2019.
2. Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2012; 79(6): 597-603. doi: 10.1212/WNL.0b013e318263c443.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added safety and efficacy information to Background	01.15	02.15
Policy converted to new template. Criteria: Neurologist and age requirement added. Renamed to Tetrabenazine	01.16	01.16
Policy converted to new template. Age removed; max dose added. Definition of hepatic impairment is added as Child-Pugh A, B or C.	12.16	01.17
Policy converted to new template. Added age limit as safety and efficacy has not been established in pediatric populations. Removed the following contraindications: actively suicidal or untreated/inadequately treated depression (cannot be objectively confirmed) and hepatic impairment (requires clinical judgment; adverse reaction is not predictable per PI [safety and efficacy of increased exposure to Xenazine is unknown]). Modified DDI contraindication to include acceptable time of last use (MAOI > 14 days ago, reserpine > 20 days ago). Removed reasons to discontinue per new safety strategy. Increased approval durations from 3/6 months to 6/12 months.	06.28.17	11.17
2Q 2018 annual review: no significant changes; added HIM line of business; Removed DDI requirements from Section I (information added to Appendix C); added caution to prevent duplicate therapy with similar agents references reviewed and updated.	02.05.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy; HIM.PA.103.

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