

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Xenazine (tetrabenazine)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Xenazine, approved by the FDA in 2008, is a vesicular monoamine transporter 2 (VMAT) inhibitor indicated for the treatment of chorea associated with Huntington’s disease.

Huntington’s disease is a hereditary, progressive, neurodegenerative disease characterized by involuntary movements, cognitive dysfunction, and psychiatric symptoms. A prominent Huntington disease symptom is chorea, an involuntary, sudden movement that can affect any muscle and flow randomly across body regions.

Xenazine (tetrabenazine) will be considered for coverage when the following criteria are met:

Huntington’s Disease (HD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of Huntington’s Disease, confirmed by family history or genetic testing (expanded CAG repeat in the HTT gene); AND
4. Member is experiencing bothersome symptoms of chorea associated with Huntington’s Disease ; AND
5. Documented consultation on risks of suicidal ideation or behavior while on Xenazine is submitted with member’s chart notes (Xenazine is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression); AND
6. Member’s baseline Total Maximal Chorea Score (of the Unified Huntington’s Disease Rating Scale (UHDRS)) is submitted with chart notes; AND
7. For doses above 50 mg per day, CYP2D6 genotyping is required. The total daily dose should not exceed 50 mg in poor metabolizers.
8. **Dosage allowed/Quantity limit:** Start with 12.5 mg once daily. Titrate slowly and individually per package insert. For extensive and intermediate CYP2D6 metabolizers only, the max dose is 100 mg per day in divided doses. QL: 112 tablets per 28 days

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must have documentation of improved Total Maximal Chorea (TMC) score compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Xenazine (tetrabenazine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/11/2022	New policy for Xenazine created.
11/14/2023	Added requirement for confirmation of diagnosis. Added new references. Added QL.

References:

1. Xenazine [prescribing information]. Lundbeck; 2019.
2. Armstrong MJ, Miyasaki JM; American Academy of Neurology. 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
3. Reilmann R. Pharmacological treatment of chorea in Huntington's disease-good clinical practice versus evidence-based guideline. *Mov Disord*. 2013;28(8):1030-1033. doi:10.1002/mds.25500
4. Claassen DO, Carroll B, De Boer LM, et al. Indirect tolerability comparison of deutetrabenazine and tetrabenazine for huntington disease. *J Clin Mov Dis* 2017(4):3. doi: 10.1186/s40734-017-0051-5.
5. Frank S. Tetrabenazine as anti-chorea therapy in Huntington disease: an open-label continuation study. Huntington Study Group/TETRA-HD Investigators [published correction appears in *BMC Neurol*. 2011;11:18]. *BMC Neurol*. 2009;9:62. Published 2009 Dec 18. doi:10.1186/1471-2377-9-62
6. Bachoud-Lévi AC, Ferreira J, Massart R, et al. International Guidelines for the Treatment of Huntington's Disease. *Front Neurol*. 2019;10:710. Published 2019 Jul 3. doi:10.3389/fneur.2019.00710
7. Ferreira JJ, Rodrigues FB, Duarte GS, et al. An MDS Evidence-Based Review on Treatments for Huntington's Disease. *Mov Disord*. 2022;37(1):25-35. doi:10.1002/mds.28855

Effective date: 04/01/2024

Revised date: 11/14/2023