Initial Approval: March 11, 2009
Revised Dates: October 14, 2020,
October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Monoamine Depletors (VMAT2 Inhibitors)

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Deutetrabenazine (Austedo®)
Tetrabenazine (Xenazine®)
Valbenazine (Ingrezza®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Must be prescribed by or in consultation with a neurologist or psychiatrist.
- For the treatment of tardive dyskinesia (TD):
  - The prescriber must provide the patient's baseline AIMS rating evaluation.[4]
- For the treatment of chorea associated with Huntington's disease:
  - Patient must NOT be suicidal or have a history of untreated or inadequately treated depression.[1,2]
  - Prescriber must provide the patient's baseline Total Chorea Score.[5]
- If the request is for tetrabenazine and the dose is greater than (>) 50 mg daily, the prescriber must provide CYP2D6 genotyping test results confirming the patient is an intermediate or extensive metabolizer.[3]

LENGTH OF APPROVAL (INITIAL): 6 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- For the treatment of TD, patient has an improvement (reduction) in AIMS scores of at least 3 points from baseline.[8]
- For the treatment of chorea associated with Huntington's disease, patient has an improvement (reduction) in Total Chorea Score of at least 2 points from baseline.[5]
- Must not exceed dosing limits listed in Table 1.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for Monoamine Depletors (VMAT2 Inhibitors)[1-3]

Agents	Indication(s)	Age	Dosing Limits
Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors			
Deutetrabenazine (Austedo®)	Chorea associated with Huntington's disease Tardive dyskinesia	≥ 18 years	48 mg orally daily
Tetrabenazine (Xenazine®)	Chorea associated with Huntington's disease	≥ 18 years	50 mg orally daily Intermediate or extensive metabolizers of CYP2D6: 100 mg orally daily
Valbenazine (Ingrezza®)	Tardive dyskinesia	≥ 18 years	80 mg orally daily

References

1. Austedo (deutetrabenazine) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; June 2020.
2. Ingrezza (valbenazine) [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc; April 2020.
3. Xenazine (tetrabenazine) [prescribing information]. Deerfield, IL: Lundbeck; November 2019.
4. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: Treatment of tardive syndromes: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology Jul 2013;81(5):463-469. Available at http://n.neurology.org/content/81/5/463 . Accessed on September 10, 2020.
5. 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 Aug 2012;79(6):597-603. Available at http://n.neurology.org/content/79/6/597. Accessed on September 10, 2020.
6. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA: American Psychiatric Association, 2013. Available at http://cdn.website-editor.net/30f11123991548a0af708722d458e476/files/uploaded/DSM%2520V.pdf. Accessed on September 10, 2020.
7. American Psychiatric Association: Practice Guideline for the Treatment of Patients with Schizophrenia, Third Edition. Washington, DC: American Psychiatric Association, 2020. Available at http://psychiatryonline.org/doi/pdf/10.1176/appi/books.9780890424841. Accessed on September 10, 2020.
8. Stacy M, Sajatovic M, Kane JM, et al. Abnormal involuntary movement scale in tardive dyskinesia: Minimal clinically important difference. Mov Disord 2019 Aug;34(8):1203-1209. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6772010/. Accessed on September 10, 2020.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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