Protocol for Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

Approved January 2025

Ingrezza® (valbenazine)
Austedo® (deutetrabenazine)
Xenazine® (tetrabenazine)

Background:

Tardive dyskinesia is a syndrome that includes a group of iatrogenic movement disorders caused by the blockade of dopamine receptors. The movement disorders include akathisia, dystonia, buccolingual stereotypy, myoclonus, chorea, tics, and other abnormal involuntary movements, which are commonly caused by the long-term use of typical antipsychotics.

Chorea is a neurological disorder characterized by spasmodic involuntary movements of the limbs or facial muscles.

Criteria for approval:

1. The patient unable to take the preferred formulary alternatives, Ingrezza and tetrabenazine, for the given diagnosis, due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.
2. Patient meets the FDA-approved or compendial supported age for the product being requested
3. Patient will not use concomitantly with another VMAT inhibitor
4. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
5. Patient has ONE of the following:
    A. A diagnosis of tardive dyskinesia
    B. A diagnosis of chorea associated with Huntington's disease, that has been confirmed by genetic testing, that is disruptive to functioning. Caution is recommended in patients with depression, agitation and/or psychosis

Continuation of therapy:

1. Documentation of positive clinical response to therapy
2. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimen or in accordance with a medically appropriate off-label indications and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Initial Approval Duration: 6 months

Renewal Approval Duration: 12 Months

Quantity Level Limit:

Medication	Standard Limit
Austedo 6mg tablet	60 per 30 days
Austedo 9mg tablet	120 per 30 days

Medication	Standard Limit
Austedo 12mg tablet	120 per 30 days
Austedo XR 6mg tablet	90 per 30 days
Austedo XR 12mg tablet	120 per 30 days
Austedo XR 18mg tablet	30 per 30 days
Austedo XR 24mg tablet	60 per 30 days
Austedo XR 30mg tablet	30 per 30 days
Austedo XR 36mg tablet	30 per 30 days
Austedo XR 42mg tablet	30 per 30 days
Austedo XR 48mg tablet	30 per 30 days
Austedo XR Titration Kit (6mg, 12mg, 24mg tablets)	1 kit (42 tablets) per 90 days
Austedo XR Titration Kit (12mg, 18mg, 24mg, 30mg tablets)	1 kit (28 tablets) per 90 days

References:

1. Ingrezza® [prescribing information]. Neurocrine Biosciences, Inc. San Diego, CA 92130. August 2023
2. Austedo® [prescribing information] Teva Pharmaceuticals USA, Inc.North Wales, PA 19454. April 2017
3. Xenazine® [prescribing information] Recipharm Fontaine SAS. 21121 Fontaine-les-Dijon, France. June 2015
4. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
5. Vasan S, Padhy RK. Tardive Dyskinesia. [Updated 2023 Apr 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448207/
6. Merical B, Sánchez-Manso JC. Chorea. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430923/