Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

# I. Requirements for Prior Authorization of VMAT2 Inhibitors

A. Prescriptions That Require Prior Authorization

All prescriptions for VMAT2 Inhibitors must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a VMAT2 Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the VMAT2 Inhibitor for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; **AND**

5. Does not have a contraindication to the prescribed medication; **AND**

6. **One** of the following:
   a. For a beneficiary with a history of a prior suicide attempt, bipolar disorder, or major depressive disorder, was evaluated within the previous 6 months and treated by a psychiatrist
   b. For all others, had a mental health evaluation performed;
   **AND**

7. If being treated for a diagnosis of tardive dyskinesia, **all** of the following:
   a. Was assessed for and determined to have no other causes of involuntary movement,
   b. Was evaluated for appropriateness of dose decrease of dopamine receptor blocking agents,
   c. Has documentation of tardive dyskinesia severity using a validated scale or assessment of impact on daily function;
   **AND**

8. For a non-preferred VMAT2 Inhibitor, has a documented therapeutic failure or intolerance to the preferred VMAT2 Inhibitors approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred VMAT2 Inhibitors at: https://papdl.com/preferred-drug-list

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR VMAT2 INHIBITORS: The determination of medical necessity of a request for renewal of a prior authorization for a VMAT2 Inhibitor that was previously approved will take into account whether the beneficiary:

1. **One** of the following:
   a. For a diagnosis of chorea, experienced a clinical benefit from the prescribed VMAT2 inhibitor based on the prescriber's clinical judgment
   b. For a diagnosis of tardive dyskinesia, experienced an improvement in tardive dyskinesia severity documented by a validated scale or improvement in daily function;

   **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. Was re-evaluated and treated for new onset or worsening symptoms of depression and determined to continue to be a candidate for treatment with the prescribed VMAT2 Inhibitor.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a VMAT2 Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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# VMAT2 INHIBITORS PRIOR AUTHORIZATION FORM *(form effective 2/1/2022)* – PAGE 1 of 2

| | | | |
|---|---|---|---|
| ☐New request ☐Renewal request | Total # of pages: _____ | Prescriber name: | |
| Name of office contact: | | Specialty: | |
| Contact's phone number: | | NPI: | State license #: |
| LTC facility contact/phone: | | Street address: | |
| Beneficiary name: | | Suite #: | City/state/zip: |
| Beneficiary ID#: | DOB: | Phone: | Fax: |

## CLINICAL INFORMATION

Drug requested:
☐Austedo tablet
☐Ingrezza capsule
☐Ingrezza initiation pack
☐tetrabenazine tablet
☐Xenazine tablet *(submit documentation showing why generic tetrabenazine cannot be used)*
☐ _____

| | | |
|---|---|---|
| Strength: | Quantity: | Refills: |
| Dose/directions: | | |
| Diagnosis *(submit documentation)*: | | Dx codes (*required*): |
| Is the requested medication being prescribed by or in consultation with a specialist (ie., neurologist or psychiatrist)? | | ☐Yes ☐No *Submit documentation of consultation if applicable.* |

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐For AUSTEDO (DEUTETRABENAZINE):
- ☐Has a contraindication to Austedo *(check all that apply)*:
  - ☐Actively suicidal
  - ☐Hepatic impairment
  - ☐Taking Xenazine or Ingrezza
  - ☐Taken an MAO inhibitor in the past 14 days (eg, phenelzine, rasagiline, selegiline, tranylcypromine)
  - ☐Taken reserpine in the past 20 days
  - ☐Depression that is untreated or inadequately treated
- ☐Is known to be a poor CYP2D6 metabolizer
  - ☐Austedo dose is adjusted accordingly based on dosing recommendations in the package labeling
- ☐Will be taking a strong CYP2D6 inhibitor while taking Austedo (e.g., bupropion, fluoxetine, paroxetine, quinidine)
  - ☐Austedo dose is adjusted accordingly based on dosing recommendations in the package labeling

☐For INGREZZA (VALBENAZINE):
- ☐Is taking a strong CYP3A4 inhibitor (eg, some azole antifungals, nefazodone, some protease inhibitors)
  - ☐Ingrezza dose is adjusted accordingly based on dosing recommendations in the package labeling
- ☐Is taking a strong CYP2D6 inhibitor (eg, bupropion, fluoxetine, paroxetine, quinidine)
  - ☐Ingrezza dose is adjusted accordingly based on dosing recommendations in the package labeling
- ☐Has moderate or severe hepatic impairment (Child-Pugh score 7 to 15)
  - ☐Ingrezza dose is adjusted accordingly based on dosing recommendations in the package labeling
- ☐Is taking a strong CYP3A4 inducer (eg, carbamazepine, phenytoin, rifampin, St. John's Wort) *(concomitant use not recommended per package labeling)*

☐For TETRABENAZINE / XENAZINE:
- ☐Has a contraindication to tetrabenazine / Xenazine *(check all that apply)*:
  - ☐Actively suicidal
  - ☐Hepatic impairment
  - ☐Taking Austedo or Ingrezza
  - ☐Taken an MAO inhibitor in the past 14 days (eg, phenelzine, rasagiline, selegiline, tranylcypromine)
  - ☐Taken reserpine in the past 20 days
  - ☐Depression that is untreated or inadequately treated
- ☐Will be taking a strong CYP2D6 inhibitor while taking tetrabenazine (eg, bupropion, fluoxetine, paroxetine, quinidine)
  - ☐Tetrabenazine dose is adjusted accordingly based on dosing recommendations in the package labeling
- ☐Is prescribed a tetrabenazine dose that exceeds 50 mg per day
  - ☐Has documentation of therapeutic failure of tetrabenazine at a dose of ≤50 mg/day
  - ☐Has documentation of CYP450 2D6 genotyping showing intermediate or extensive metabolism

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# VMAT2 INHIBITORS PRIOR AUTHORIZATION FORM *(form effective 2/1/2022)* – PAGE 2 of 2

| Name of office contact: | Beneficiary name: | |
|---|---|---|
| Contact's phone number: | ID#: | DOB: |

## CLINICAL INFORMATION

Drug requested:
- ☐ Austedo tablet
- ☐ Ingrezza capsule
- ☐ Ingrezza initiation pack
- ☐ tetrabenazine tablet
- ☐ Xenazine tablet *(submit documentation showing why generic tetrabenazine cannot be used)*
- ☐ _____

### INITIAL requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐ Had a mental health evaluation
- ☐ Has a history of suicide attempt, bipolar disorder, or major depressive disorder
  - ☐ Was evaluated in the past 6 months and treated by a psychiatrist
- ☐ Was determined to be a candidate for treatment with the requested medication based on the mental health evaluation

☐ For treatment of TARDIVE DYSKINESIA:
- ☐ Has no other causes of involuntary movement
- ☐ Has documentation of tardive dyskinesia severity using a validated scale or assessment of impact on daily function
- ☐ A decrease in dose of dopamine receptor blocking agents is not appropriate

### RENEWAL requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐ Was reevaluated for new onset or worsening symptoms of depression
- ☐ If applicable, was or is being treated for symptoms of depression

☐ Was determined to remain a candidate for treatment with the requested medication based on the mental health evaluation

☐ For treatment of CHOREA:
- ☐ Experienced clinical benefit from the requested medication based on the prescriber's clinical judgement

☐ For treatment of TARDIVE DYSKINESIA:
- ☐ Experienced an improvement in tardive dyskinesia severity documented by a validated scale
- ☐ Experienced an improvement in daily functioning

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

| Prescriber Signature: | Date: |
|---|---|