Gateway Health
It's Wholecare.

Gateway Health Plan
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

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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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AUSTEDO (deutetrabenazine) PRIOR AUTHORIZATION FORM

☐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 ☐Austedo _____			Strength:
Dose/directions:		Quantity:	Refills:
Diagnosis (*submit documentation*):		Dx codes (*required*):	

ALL requests

Do any of the following contraindications apply to the beneficiary? *Check all that apply*. ☐Actively suicidal ☐Taken an MAO inhibitor in the past 14 days ☐Hepatic impairment ☐Taken reserpine in the past 20 days ☐Taking Xenazine or Ingrezza ☐Depression that is untreated or inadequately treated	☐Yes ☐No	*Submit supporting documentation, including liver function test (LFT) results, mental health evaluation, and medication list.*
If the beneficiary is known to be a poor CYP2D6 metabolizer or will be taking a strong CYP2D6 inhibitor (such as bupropion, fluoxetine, paroxetine, or quinidine), will the dose of Austedo be adjusted accordingly?	☐Yes ☐No	*Submit documentation of dosing and beneficiary's complete medication list.*
Is Austedo being prescribed by or in consultation with a neurologist or psychiatrist?	☐Yes ☐No	*If prescriber is not a specialist, submit documentation of consultation.*

INITIAL requests

Does the beneficiary have one of the following diagnoses? ☐Chorea associated with Huntington's disease ☐Tardive dyskinesia	☐Yes – *Submit documentation supporting beneficiary's diagnosis.* ☐No – *Submit medical literature documentation supporting the use of Austedo for the beneficiary's diagnosis.*	
Did the beneficiary have a mental health evaluation?	☐Yes ☐No	*Submit documentation of evaluation.*
If the beneficiary has a history of prior suicide attempt, bipolar disorder, or major depressive disorder, was the beneficiary evaluated in the past 6 months and treated by a psychiatrist?	☐Yes ☐No	*Submit documentation of evaluation and treatment.*

For the treatment of tardive dyskinesia, submit documentation of the following as it applies to the beneficiary:

☐Has no other causes of involuntary movement ☐A dose decrease of dopamine receptor blocking agents is not appropriate
☐Has documentation of TD severity

RENEWAL requests

Since starting Austedo, did the beneficiary experience an improvement in the medical condition being treated?	☐Yes ☐No	*Submit documentation of beneficiary's response to therapy.*
Was the beneficiary reevaluated (and treated, if applicable) for new onset or worsening symptoms of depression and determined to be a candidate for treatment with Austedo?	☐Yes ☐No	*Submit documentation of evaluation.*

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Prescriber Signature:	Date:

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INGREZZA (valbenazine) PRIOR AUTHORIZATION FORM

☐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:	☐Ingrezza capsule ☐Ingrezza initiation pack ☐Ingrezza _____		Strength:
Dose/directions:		Quantity:	Refills:
Diagnosis *(<u>submit documentation</u>)*:		Dx codes (*<u>required</u>*):	

ALL requests

Do any of the following reasons for dose adjustment apply to the beneficiary? *Check all that apply*. ☐Taking a strong 3A4 inhibitor (eg, protease inhibitor, azole antifungal) ☐Hepatic impairment ☐Taking a strong 2D6 inhibitor (eg, bupropion, fluoxetine, paroxetine)	☐Yes ☐No	*Submit documentation of dosing, complete medication list, and LFT results.*
Is the beneficiary taking a strong CYP3A4 inducer (eg, rifampin, carbamazepine, phenytoin, St. John's Wort)?	☐Yes ☐No	*Submit beneficiary's complete medication list.*
Is Ingrezza being prescribed by or in consultation with a neurologist or psychiatrist?	☐Yes ☐No	*If not a specialist, submit documentation of consultation.*

INITIAL requests

Is the beneficiary being treated for a diagnosis of tardive dyskinesia (TD)?	☐Yes – *Submit documentation supporting beneficiary's diagnosis.* ☐No – *Submit medical literature documentation supporting the use of Ingrezza for the beneficiary's diagnosis.*

Did the beneficiary have a mental health evaluation?	☐Yes ☐No	*Submit documentation of evaluation.*
<u>If the beneficiary has a history of prior suicide attempt, violent behavior, bipolar disorder, or major depressive disorder</u>, was the beneficiary evaluated in the past 6 months and treated by a psychiatrist?	☐Yes ☐No	*Submit documentation of evaluation and treatment.*

<u>For the treatment of tardive dyskinesia</u>*, submit documentation of the following* as it applies to the beneficiary*:*

☐Has no other causes of involuntary movement ☐A dose decrease of dopamine receptor blocking agents is not appropriate
☐Has documentation of TD severity

RENEWAL requests

Since starting Ingrezza, did the beneficiary experience an improvement in the medical condition being treated?	☐Yes ☐No	*Submit documentation of beneficiary's response to therapy.*
Was the beneficiary reevaluated (and treated, if applicable) for new onset or worsening symptoms of depression and determined to be a candidate for treatment with Ingrezza?	☐Yes ☐No	*Submit documentation of evaluation.*

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XENAZINE (tetrabenazine) PRIOR AUTHORIZATION FORM

☐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:	☐ tetrabenazine tablet *(preferred with clinical PA required)*	☐ Xenazine tablet *(non-preferred)*	
Strength:	Dose/directions:	Quantity:	Refills:
Diagnosis (*submit documentation*):		Dx codes (*required*):	

ALL requests		
Do any of the following contraindications apply to the beneficiary? *Check all that apply*. ☐actively suicidal ☐taken an MAO inhibitor in the past 14 days ☐hepatic impairment ☐taken reserpine in the past 20 days ☐taking Austedo or Ingrezza ☐depression that is untreated or inadequately treated	☐Yes ☐No	*Submit supporting documentation, including liver function test (LFT) results, mental health evaluation, and medication list.*
If the beneficiary will be taking a strong CYP2D6 inhibitor (such as bupropion, fluoxetine, paroxetine, or quinidine), will the dose of tetrabenazine be adjusted accordingly?	☐Yes ☐No	*Submit documentation of dosing and Beneficiary's complete medication list.*
If the beneficiary's dose of tetrabenazine exceeds 50 mg per day, does the beneficiary have documentation of therapeutic failure at a dose of ≤ 50 mg/day AND of CYP450 2D6 genotyping that shows intermediate or extensive metabolism?	☐Yes ☐No	*Submit documentation of dose and therapeutic failure AND results of genotype testing.*
Is Xenazine (tetrabenazine) being prescribed by or in consultation with a neurologist or psychiatrist?	☐Yes ☐No	*If prescriber is not a specialist, submit documentation of consultation.*

INITIAL requests		
Does the beneficiary have one of the following diagnoses? ☐chorea associated with Huntington's disease ☐tardive dyskinesia	☐Yes – *Submit documentation supporting beneficiary's diagnosis.* ☐No – *Submit medical literature documentation supporting the use of tetrabenazine for the beneficiary's diagnosis.*	
Did the beneficiary have a mental health evaluation?	☐Yes ☐No	*Submit documentation of evaluation.*
If the beneficiary has a history of prior suicide attempt, bipolar disorder, or major depressive disorder, was the beneficiary evaluated in the past 6 months and treated by a psychiatrist?	☐Yes ☐No	*Submit documentation of evaluation and treatment.*
For the treatment of tardive dyskinesia, submit documentation of the following as it applies to the beneficiary*:* ☐has no other causes of involuntary movement ☐a dose decrease of dopamine receptor blocking agents is not appropriate ☐has documentation of TD severity		
Requests for non-preferred Xenazine: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred VMAT2 Inhibitors? *Check all that apply.* ☐Austedo ☐Ingrezza ☐tetrabenazine	☐Yes ☐No	*Submit documentation.*

RENEWAL requests		
Since starting tetrabenazine, did the beneficiary experience an improvement in the medical condition being treated?	☐Yes ☐No	*Submit documentation of beneficiary's response to therapy.*
Was the beneficiary reevaluated (and treated, if applicable) for new onset or worsening symptoms of depression and determined to be a candidate for treatment with tetrabenazine?	☐Yes ☐No	*Submit documentation of evaluation.*

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Prescriber Signature:	Date: