Effective Date: 04/01/2023
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Next Review Due By: 01/2027
Policy Number: C25457-A

Ingrezza (valbenazine), IL Medicaid Only

PRODUCTS AFFECTED

Ingrezza (valbenazine)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Tardive dyskinesia, Chorea associated with Huntington's Disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. TARDIVE DYSKINESIA (TD):
1. Documented diagnosis of moderate to severe TD
   AND

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2. Documentation of baseline evaluation of condition documented by Abnormal Involuntary Movement Scale (AIMS) OR Extrapyramidal Symptom Rating Scale (ESRS) score [DOCUMENTATION REQUIRED]
   Note: Documentation of the member's current AIMS score from items 1-7 (results range from 0 to 28) with higher scores indicating more severe involuntary movements) required OR Extrapyramidal Symptom Rating Scale (ESRS) NOTE: Reauthorization requires positive response or demonstrated efficacy to therapy. Baseline score reviewed at Continuation of Therapy.
   AND
3. Documentation member has had an inadequate response to at least ONE of the following alternative approaches to treat tardive dyskinesia: (a) Adjustments to possible offending medication(s) known to cause TD (dose reduction or discontinuation) were attempted but ineffective in resolving TD symptoms, OR (b) Switched from a first-generation to a second-generation antipsychotic, OR (c) Switched to an antipsychotic with a different mechanism of action (i.e., xanomeline/trospium) OR (d) Member is not a candidate for a trial of dose reduction, tapering, discontinuation of the offending medication or switching to an alternative antipsychotic therapy [Appendix] [DOCUMENTATION REQUIRED]
   AND
4 . Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Ingrezza (valbenazine) include: Known hypersensitivity to valbenazine or any components of Ingrezza, avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval, avoid concomitant use with MAOIs (e.g., selegiline (Emsam), isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)).]

B. CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE (HD):
1. Diagnosis of HD with chorea symptoms confirmed by documentation of ONE of the following [DOCUMENTATION REQUIRED]:
   (a) Huntington Disease Mutation Analysis: indicating an expanded CAG repeat (≥ 36) in the Huntington gene (HTT) (also known as HD gene)
   OR
   (b) A positive family history of HD, with autosomal dominant inheritance pattern
   AND
2. Documentation of baseline evaluation and documentation of Total Chorea Score [using the Unified Huntington's Disease Rating Scale (UHDRS)]
   Note: Reauthorization requires positive response or demonstrated efficacy to therapy. Baseline score reviewed at Continuation of Therapy.
   AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Ingrezza (valbenazine) include: Known hypersensitivity to valbenazine or any components of Ingrezza, avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval, avoid concomitant use with MAOIs (e.g., selegiline (Emsam), isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)).]

CONTINUATION OF THERAPY:
A. ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber and member's medication fill history (review Rx history for compliance)
   AND
2. Documentation member's condition has stabilized or improved based on Prescriber's assessment while on therapy [DOCUMENTATION REQUIRED]:
   (a) TD: Disease stabilization or improvement in TD symptoms as documented by decrease from baseline in AIMS score of at least 2 points OR ESRS score of at

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least 4 points
OR
(b) Chorea Associated with HD: Disease stabilization or improvement from baseline in Total Maximal Chorea Scores or chorea symptoms
AND

3. Prescriber attests to (or clinical reviewer has found) no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 12 months; Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
TD: Prescribed by, or in consultation with, a board-certified psychiatrist or neurologist.
Chorea associated with HD: Prescribed by, or in consultation with, a board-certified neurologist with expertise in HD. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
80 mg/day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor

FDA-APPROVED USES:
Indicated for the treatment of adults with tardive dyskinesia, or chorea associated with Huntington's disease

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX 1:

- First Generation (Typical) Antipsychotics: Chlorpromazine, Fluphenazine, Haloperidol, Loxapine Perphenazine, Pimozide, Thioridazine, Thiothixene, Trifluoperazine
- Tricyclic Antidepressants: Amoxapine
- Antiemetic Agents: Chlorpromazine, Droperidol, Haloperidol, Metoclopramide, Perphenazine, Prochlorperazine, Thiethylperazine, Trimethobenzamide

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- Second-Generation (Atypical) Antipsychotics: Aripiprazole, Asenapine, Brexpiprazole, Cariprazine, Clozapine, Iloperidone, Lurasidone, Olanzapine, Paliperidone, Quetiapine, Risperidone, Ziprasidone

DSM-V Definition of Tardive Dyskinesia
Diagnostic and statistical manual of mental disorders, 5th Ed. American Psychiatric Association. Tardive dyskinesia is a type of movement disorder that occurs secondary to therapy with centrally acting DRBAs

Medication-induced movement disorders, including tardive dyskinesia, are organized in the DSM-V as follows: neuroleptic-induced parkinsonism/other medication-induced parkinsonism, neuroleptic malignant syndrome, medication-induced acute dystonia, medication-induced acute akathisia, tardive dyskinesia, tardive dystonia/tardive akathisia, medication-induced postural tremor, other medication-induced movement disorder, antidepressant discontinuation syndrome, and other adverse effects of medication. Involuntary athetoid or choreiform movements (lasting at least a few weeks) generally of the tongue, lower face and jaw, and extremities (but sometimes involving the pharyngeal, diaphragmatic, or trunk muscles) developing in association with the use of a neuroleptic medication for at least a few months. Symptoms may develop after a shorter period of medication use in older persons. In some patients, movements of this type may appear after discontinuation, or after change or reduction in dosage, of neuroleptic medications, in which case the condition is called neuroleptic withdrawal emergent dyskinesia. Because withdrawal emergent dyskinesia is usually time limited, lasting less than 4-8 weeks, dyskinesia that persists beyond this window is considered to be tardive dyskinesia.

ASSESSING TARDIVE DYSKINESIA (TD) has been complicated by the use of different research criteria and rating scales. We studied concordance between two commonly used scales, the Abnormal Involuntary Movement Scale (AIMS) and Extrapyramidal Symptom Rating Scale (ESRS), to study interscale concordance and criteria to define TD.

Abnormal Involuntary Movement Scale (AIMS)
The most widely used instrument is the Abnormal Involuntary Movement Scale (AIMS) developed by the Psychopharmacology Research Branch of the National Institute of Mental Health (see the image below). Because the AIMS can be readily administered in a few minutes, it is recommended in patients receiving treatment with substances that may cause TD. Administer the AIMS at baseline before the institution of pharmacotherapy to document any movements present, then at least every 3 months thereafter during the course of treatment.

The AIMS is a 12-item scale; items 1 to 7 assess the severity of involuntary movements across body regions and these items were used in this study. Each of the 7 items was scored on a 0 to 4 scale, rated as: 0=no dyskinesia; 1=low amplitude, present during some but not most of the exam; 2=low amplitude and present during most of the exam (or moderate amplitude and present during some of the exam); 3=moderate amplitude and present during most of exam; or 4=maximal amplitude and present during most of exam. The AIMS dyskinesia total score (sum of items 1 to 7) could range from 0 to 28, with a decrease in score indicating improvement.

Extrapyramidal Symptom Rating Scale (ESRS)
The Extrapyramidal Symptom Rating Scale (ESRS) was developed to assess four types of drug- induced movement disorders (DIMD): Parkinsonism, akathisia, dystonia, and TD. Comprehensive ESRS definitions and basic instructions are given. Factor analysis provided six ESRS factors: 1) hypokinetic Parkinsonism; 2) orofacial dyskinesia; 3) trunk/limb dyskinesia; 4) akathisia; 5) tremor; and 6) tardive dystonia. Two pivotal studies found high inter-rater reliability correlations in both antipsychotic-induced movement disorders and idiopathic Parkinson disease. For inter-rater reliability and certification of raters, >or=80% of item ratings of the complete scale should be +/-1 point of expert ratings and >or=70% of ratings on individual items of each ESRS subscale should be +/-1 point of expert ratings. During a cross-scale comparison, AIMS and ESRS were found to have a 96% (359/374) agreement between TD-defined cases by DSM-IV TD criteria. Two recent international studies using the ESRS included over 3000 patients worldwide and showed an incidence of TD ranging from 10.2% (2000) to 12% (1998). ESRS specificity was investigated through two different approaches, path analyses and

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ANCOVA PANSS factors changes, which found that ESRS measurement of drug-induced EPS is valid and discriminative from psychiatric symptoms. (Gharabawi GM et al. 2005 PMID: 15913963 DOI: 10.1016/j.schres.2005.03.008)

APPENDIX 2:

RESULTS AND RECOMMENDATIONS:
New evidence was combined with the existing guideline evidence to inform our recommendations. Deutetrabenazine and valbenazine are established as effective treatments of TD (Level A) and must be recommended as treatment. **Clonazepam** and Ginkgo biloba probably improve TD (Level B) and should be considered as treatment. **Amantadine** and tetrabenazine might be considered as TD treatment (Level C). Pallidal deep brain stimulation possibly improves TD and might be considered as a treatment for intractable TD (Level C). There is insufficient evidence to support or refute TS treatment by withdrawing causative agents or switching from typical to atypical DRBA (Level U).

Tardive Dyskinesia: Treatment Update
Current Neurology and Neuroscience Reports (2019) 19:69https://doi.org/10.1007/s11910-019-0976-1

Treatment options for TSs/TD		
Managing the DRBAs	Reassessing the need of antipsychotics Reducing or switching the DRBAs to newer generation agent (only if tolerated by the patient)	
Pharmacological agents	Most effective treatment—VMAT2 inhibitors	Valbenazine Deutetrabenazine Tetrabenazine
	Less effective—other agents	GABA-ergic compounds—diazepam, clonazepam, baclofen Antioxidants—vitamin E, *Ginkgo biloba* NMDA receptor antagonist—amantadine
	Insufficient evidence [29, 30]	Bromocriptine, buspirone, levetiracetam, melatonin, r eserpine, selegiline, vit B6, zonisamide, trihexyphenidyl
Chemodenervation treatment	Most evidence is for tardive dystonia	
Surgical therapy	Bilateral Globus pallidus interna DBS stimulation for severe TD/TSs refractory to other treatments	

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BACKGROUND

BACKGROUND:
A summary of the American Academy of Neurology (AAN) guideline regarding management of tardive syndromes (TDS), including tardive dyskinesias (TD)
https://www.aan.com/Guidelines/Home/GetGuidelineContent/613

Evidence-based guideline: Treatment of tardive syndromes
Report of the Guideline Development Subcommittee of the American Academy of Neurology
http://n.neurology.org/content/81/5/463.long

Tardive dyskinesias (TDs) are involuntary movements of the tongue, lips, face, trunk, and extremities that occur in patients treated with long-term dopaminergic antagonist medications. Although TDs are associated with the use of neuroleptics, TDs apparently existed before the development of these agents. Patients with schizophrenia and other neuropsychiatric disorders are especially vulnerable to the development of TDs after exposure to conventional neuroleptics, anticholinergics, toxins, substances of abuse, and other agents. TDs are most common in patients with schizophrenia, schizoaffective disorder, or bipolar disorder who have been treated with antipsychotic medication for long periods, however TDs may occasionally occur in other patients as well, such as people with fetal alcohol syndrome, other developmental disabilities, and other brain disorders are vulnerable to the development of TDs, even after receiving only one dose of the causative agent (primarily antipsychotics but may include gastric motility agents and antiemetics such as metoclopramide and prochlorperazine). According to the manufacturer, the condition is estimated to affect at least 500,000 people in the United States.

The exact mechanism of TD is unknown; however, is theorized to be due to upregulation and increased sensitivity of dopamine receptors and alteration in central nervous system neurotransmitter activity in response to chronic antagonism from DRBAs which leads to dysregulation of the brainstem skeletal motor circuit.

Movements are involuntary and repetitive and usually involve the orofacial area but may affect movement in other areas as well. TD usually presents after 1-2 years of chronic exposure to a DRBA but may occur as early as 3 months (or 1 month in patients ≥ 60 years old). The risk of development of TD is related to both the dose and duration of exposure to DRBAs Reported in about 20%-50% of patients treated with DRBAs. Typical (first generation) antipsychotics may be more likely to cause TD than atypical (second generation) antipsychotics.

The Abnormal Involuntary Movement Scale (AIMS) has been used in clinical and research settings to assess the general severity of symptoms and the impact of treatment. (Gharabawi GM, etal. 2005; cited by ICER 2017)

Valbenazine, a selective inhibitor of VMAT-2, is the first drug approved by the FDA for the treatment of TD. There were no FDA approved therapies before the recent approval of two VMAT2 inhibitors: Ingrezza (valbenazine) and Austedo (deutetrabenazine).

The mechanism of action of valbenazine in the treatment of TD is unknown but is thought to be mediated through the reversible inhibition of vesicular monoamine transporter 2 (VMAT2), a transporter that regulates monoamine uptake from the cytoplasm to the synaptic vesicle for storage and release. Valbenazine is a selective inhibitor of human VMAT-2 but has no appreciable binding affinity for VMAT-1. VMAT-2 is a presynaptic protein that regulates monoamine uptake (e.g., dopamine) from the cytoplasm to the synaptic vesicle for storage and release. Inhibition of VMAT-2modulates dopaminergic transmission, potentially resulting in a reduction in synaptic dopamine levels and improvement in TD symptoms.

The FDA approval was based on results from the KINECT 3 study, which was a phase III randomized, double-blind, placebo-controlled, parallel-group, fixed-dose trial.

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The efficacy of Ingrezza was shown in a clinical trial of 234 participants that compared Ingrezza to placebo. The trial enrolled subjects with schizophrenia, schizoaffective disorder, or a mood disorder and moderate or severe TD. Subjects were randomly to treatment with valbenazine 80 mg once daily, valbenazine 40 mg once daily, or placebo in a 1:1:1 ratio for six weeks. All the patients were put on once-daily 40mg or once-daily 80mg of Ingrezza through week 48 upon completion of six-week placebo- controlled dosing.

The AIMS was the primary efficacy measure for the assessment of TD severity. The primary efficacy endpoint was the mean change from baseline in the AIMS dyskinesia total score at the end of week 6.

The results of the study demonstrated that the patients treated with Ingrezza 80mg once-daily dose met the primary endpoint of change-from-baseline in AIMS at week six compared to placebo. The change from baseline in the AIMS total dyskinesia score in the 80 mg valbenazine group was statistically significantly different from the change in the placebo group. Valbenazine reduced the AIMS score by 3.2 points compared to 0.1 points for placebo-treated patients following six weeks of treatment. The treatment difference between valbenazine and placebo was 3.1 points. The study also revealed that patients treated with Ingrezza 80mg/day achieved higher AIMS response compared to placebo. At week six, approximately 40% of the patients that received the Ingrezza 80mg/day dose had a 50% improvement in AIMS dyskinesia score compared to 8.7% in placebo- administered patients. Valbenazine 40 mg, was associated with a 1.9-point decrease in AIMS score, while valbenazine 80mg, was associated with a 3.2 point decrease in AIMS score, and compared with 0.1 point decrease for placebo ($P < .05$ for valbenazine, 40 mg, $P < .001$ for valbenazine, 80 mg).

This difference for the 40-mg dosage did not meet the pre-specified analysis endpoints; however, for the 80-mg valbenazine dosage, the effect size for this difference (Cohen's d) was large 0.90. There also were statistically significant differences between 40 mg and 80 mg at weeks 2, 4, and 6 in the intent-to-treat population. Of the 79 participants, 43 taking the 80-mg dosage completed a 48-weekextension. Efficacy was sustained in this group; however, when valbenazine was discontinued at Week 48, AIMS scores returned to baseline after 4 weeks.

The treatment difference in this trial was considered statistically significant; however, the minimal clinically important difference for the change in AIMS score has not been established partially due to the lack of comparability between multiple versions of the AIMS used in previous studies in TD. It is unknown if the change in score observed in this study improves function or quality of life in patients with tardive dyskinesia.

Xanomeline/Trospium is a novel muscarinic agonist/antagonist approved to treat schizophrenia in adults. In clinical trials, there were no significant changes in weight, lipid levels, glucose, insulin, or alertness. It is also not expected to cause tardive dyskinesia. The most common adverse reactions with this therapy were nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and gastroesophageal reflux disease. The product label does not carry antipsychotic class warnings or precautions, and it does not include a Boxed Warning. It is contraindicated in patients with urinary retention, moderate or severe kidney or liver disease, gastric retention, untreated narrow-angle glaucoma, or hypersensitivity.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Ingrezza (valbenazine) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Ingrezza (valbenazine) include: known hypersensitivity to valbenazine or any components of Ingrezza, avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval, avoid concomitant use with MAOIs.

Exclusions/Discontinuation:
Do not use concurrently with other VMAT2 inhibitors (tetrabenazine, deutetrabenazine).

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OTHER SPECIAL CONSIDERATIONS:
Ingrezza (valbenazine) has a Black Box Warning for depression and suicidal ideation and behavior in patients with Huntington's Disease. VMAT2 inhibitors, including INGREZZA, can increase the risk of depression and suicidal thoughts and behavior in patients with Huntington's disease. Anyone considering the use of INGREZZA must balance the risks of depression and suicidal ideation and behavior with the clinical need for treatment of chorea. Closely monitor patients for the emergence or worsening of depression, suicidal ideation, or unusual changes in behavior. Inform patients, their caregivers, and families of the risk of depression and suicidal ideation and behavior and instruct them to report behaviors of concern promptly to the treating physician. Particular caution should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in patients with Huntington's disease.

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry- standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Ingrezza CAPS 40MG, 60MG, 80MG
Ingrezza CPSP 40MG, 60MG, 80MG
Ingrezza CPPK 40 & 80MG

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SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW – Notable revisions: Required Medical Information Available Dosage Forms References	02/2026
ANNUAL REVIEW – Notable revisions: Required Medical Information Background	01/2025
Off-Cycle updates: Required Medical Information Prescriber requirements Other Special Considerations References	04/2024
ANNUAL REVIEW – Notable revisions: Required Medical Information References	01/2024
Off-Cycle updates: Required Medical Information Appendix	07/2023
New criteria creation	04/2023

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