Clinical Policy: Valbenazine (Ingrezza)

Reference Number: CP.PHAR.340
Effective Date: 07/17
Last Review Date: 07/17
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Valbenazine (Ingrezza™) is a vesicular monoamine transporter 2 (VMAT2) inhibitor.

FDA approved indication

Ingrezza is indicated for the treatment of adults with tardive dyskinesia.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ingrezza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Tardive Dyskinesia (must meet all)**:**

1. Prescribed by or in consultation with a psychiatrist or neurologist;
2. Age ≥ 18 years;
3. Diagnosis of tardive dyskinesia secondary to a centrally acting dopamine receptor blocking agent (DRBA);
   **See Appendix D; if the offending agent is not included in Appendix D, the status of the agent as a centrally acting DRBA as well as its association with tardive dyskinesia should be confirmed*
4. Dose does not exceed 80 mg/day (2 capsules/day).

Approval duration: 6 months

B. Other diagnoses/indications:

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Tardive Dyskinesia (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documented positive response to therapy;
3. Dose does not exceed 80 mg/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DRBA: dopamine receptor blocking agent

Appendix B: General Information

- 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.[6]
- Tardive dyskinesia is a type of movement disorder that occurs secondary to therapy with *centrally acting* dopamine-receptor blocking agents (DRBAs) (Appendix C).[6]
- Typical therapeutic drug classes containing DRBAs include first- and second-generation antipsychotics, antiemetics and tri-cyclic antidepressants (Appendix D).[6]
- Other therapeutic drug classes containing agents that have been variously associated with movement disorders are listed below:[8,10,11,14]
  - antiarrhythmics
  - antibiotics
  - anticholinergics
  - antidepressants
  - antiepileptics
  - antihistamines
  - antimanics
  - bronchodilators
  - calcium channel blockers
  - central nervous system stimulants
  - dopamine agonists
  - dopamine depleting agents
  - dopaminergics
  - glucocorticoids
  - immunosuppressants
  - mood stabilizers
  - muscle relaxants
  - oral contraceptives

Appendix C: DSM-V Definition of Tardive Dyskinesia[6]

Tardive Dyskinesia *(ICD-9 333.85/ICD-10 G24.01)*
• 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.

Appendix D: Centrally Acting Dopamine Receptor Blocking Agents (Neuroleptics)[6,10,13,18,19]

Pharmacologic Class	Therapeutic Class		
	First-generation (typical) antipsychotics	Antiemetic agents	Tri-cyclic antidepressants
Phenothiazine	Chlorpromazine Fluphenazine Perphenazine Thioridazine Thiothixene Trifluoperazine	Chlorpromazine Perphenazine Prochlorperazine Promethazine* Thiethylperazine	Amoxapine†
Butryophenone	Haloperidol	Droperidol Haloperidol**	
Substituted benzamide		Metoclopromide Trimethobenzamide	
Dibenzazepine	Loxapine		
Diphenylbutylpiperidine	Pimozide		
	Second-generation (atypical) antipsychotics		
Quinolone	Aripiprazole, brexpiprazole		
Dibenzazepine	Asenapine		
Piperazine	Cariprazine		
Dibenzodiazephine	Clozapine, quetiapine		
Benzisoxazole	Iloperidone		
Benzisothiazole	Lurasidone, ziprasidone		
Thienobenzodiazepine	Olanzapine		
Pyrimidinone	Paliperidone, risperidone		

**First generation H1 antagonist.*
***Off-label use.*
†A dibenzoxapine that shares properties with phenothiazines

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Treatment of adults with tardive dyskinesia.	40 mg once daily; after a week, increase to 80 mg if needed.	80 mg once daily

VI. Product Availability

Ingrezza oral capsules: 40 mg

VII. References

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Reviews, Revisions, and Approvals	Date	Approval Date
Policy created.	06/17	07/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.