MEDICAL MUTUAL®

Drug Policy

Policy:	Ingrezza (valbenazine)	Annual Review Date: 07/20/2023 Last Revised Date: 10/19/2023

OVERVIEW

Ingrezza (valbenazine) capsules, a vesicular monoamine trasporter type 2 inhibitor, is indicated in adults for the treatment of Tardive Dyskinesia and Chorea associated with Huntington's Disease.

POLICY STATEMENT

This policy involves the use of Ingrezza. Prior authorization is recommended for pharmacy benefit coverage of Ingrezza. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Ingrezza as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ingrezza be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ingrezza is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Adults with Tardive Dyskinesia (TD), Initial Therapy**

   Criteria. *Patient must meet the following criteria (a, b, c, d, e, and f)*

   - **a.** Patient is 18 years of age or older; AND
   - **b.** Ingrezza is prescribed by or in consultation with a neurologist or psychiatrist; AND
   - **c.** Patient has been clinically diagnosed with TD according to the DSM V Criteria (i, ii, and iii) [documentation required]:
     - i. Involuntary athetoid or choreiform movements; AND
     - ii. History of treatment with a neuroleptic agent (i.e. antipsychotic); AND
     - iii. Symptoms lasting longer than 4-8 weeks

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx and is subject to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx

© 2023 Medical Mutual of Ohio

d. Adjustments to possible offending medication such as dose reduction or discontinuation were attempted but ineffective in resolving TD symptoms or patient is not a candidate for dose reduction or discontinuation of the offending medication; AND

e. If a patient is using the offending medication for a behavioral health indication, the use of a second generation (atypical) antipsychotic has been attempted unless contraindicated; AND

f. The patient has tried a tetrabenazine product (generic tetrabenazine or brand Xenazine) and has demonstrated inadequate efficacy or unacceptable safety or tolerability to a tetrabenazine product, according to the prescribing physician [documentation required].

2. **Adults with Tardive Dyskinesia (TD), Patient is Currently Receiving Therapy**
Criteria. *Patient must meet the following criteria (a, b, c, d, and e):*
   - **a.** Ingrezza is prescribed by or in consultation with a neurologist or psychiatrist; AND
   - **b.** Adjustments to possible offending medication such as dose reduction or discontinuation were attempted but ineffective in resolving TD symptoms or patient is not a candidate for dose reduction or discontinuation of the offending medication; AND
   - **c.** If a patient is using the offending medication for a behavioral health indication, the use of a second generation (atypical) antipsychotic has been attempted unless contraindicated; AND
   - **d.** The patient has had a beneficial response to the requested medication; AND

3. e. The patient has tried a tetrabenazine product (generic tetrabenazine or brand Xenazine) and has demonstrated inadequate efficacy or unacceptable safety or tolerability to a tetrabenazine product, according to the prescribing physician [documentation required]. **Adults with Chorea associated with Huntington's Disease, Initial Therapy**
Criteria. *Patient must meet the following criteria (a, b, c, d, and e):*
   - **a.** Patient is 18 years of age or older; AND
   - **b.** Diagnosis of Huntington's Disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of as leaset 36); AND
   - **c.** Ingrezza is prescribed by or in consultation with a neurologist or psychiatrist; AND
   - **d.** The patient has tried a tetrabenazine product (generic tetrabenazine or brand Xenazine) and has demonstrated inadequate efficacy or unacceptable safety or tolerability to a tetrabenazine product, according to the prescribing physician; AND [documentation required].
   - **e.** Provider attestation that risks of depression and suicidality have been discussed with the patient and the provider has determined that the benefits of the therapy outweigh the risks.

4. **Adults with Chorea associated with Huntington's Disease, Continuing Therapy**
Criteria: *Patient must meet the following criteria (a, b, and c):*
   a. Ingrezza is perscribed by or in consultation with a neurologist or psychiatrist; AND

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx and is subject to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx

© 2023 Medical Mutual of Ohio

b. The patient has tried a tetrabenazine product (generic tetrabenazine or brand Xenazine) and has demonstrated inadequate efficacy or unacceptable safety or tolerability to a tetrabenazine product, according to the prescribing physician; AND [documentation required].

c. Provider attestation that risks of depression and suicidality have been discussed with the patient and the provider has determined that the benefits of the therapy outweigh the risks.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Ingrezza has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES
1. Ingrezza® capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc.; August 2023.
2. American Psychiatric Association. (2013). Medication-induced movement disorders and other adverse effects of medication. In Diagnostic and statistical manual of mental disorders (5th ed.). Available at: http://dx. doi/full/10.1176/appi.books.9780890425596.MedicationInduced#x45151.2829056. Accessed on May 15, 2017.
3. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2013;81(5):463-469.

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx and is subject to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx

© 2023 Medical Mutual of Ohio

4. Valbenazine. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated on 18 June 2019. Accessed on 15 July 2019.

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx and is subject to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx

© 2023 Medical Mutual of Ohio