Protocol for Ingrezza® (valbenazine)
Approved April 2024

Ingrezza *is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia or chorea associated with Huntington's disease.*

Tardive dyskinesia *is a syndrome that includes a group of iatrogenic movement disorders caused by the blockade of dopamine receptors. The movement disorders include akathisia, dystonia, buccolingual stereotypy, myoclonus, chorea, tics, and other abnormal involuntary movements, which are commonly caused by the long-term use of typical antipsychotics.*

Chorea *is a neurological disorder characterized by spasmodic involuntary movements of the limbs or facial muscles.*

Criteria for approval:

Tardive dyskinesia:

1. Patient has a diagnosis of moderate to severe tardive dyskinesia confirmed by an Abnormal Movement Scale (AIMS) score of 3 or 4 on any one of the items 1 through 7
2. Diagnosis of tardive dyskinesia with symptoms that have been present for at least 4 to 8 weeks
3. Medication is prescribed by or in consultation with a neurologist, psychiatrist, or a specialist in the field at treating this disease state
4. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimen or in accordance with medically appropriate off-label indications and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Chorea associated with Huntington's disease:

1. Patient has a diagnosis of chorea associated with Huntington's disease that is disruptive to functioning
2. Huntington disease has been confirmed by genetic testing.
3. Use with caution in patients with depression, agitation, psychosis
4. Medication is prescribed by or in consultation with a neurologist, psychiatrist or a specialist in the field at treating this disease state

Continuation of therapy:

1. Documentation of positive clinical response to therapy based in change in AIMS for tardive dyskinesia
2. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimen or in accordance with medically appropriate off-label indications and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Approval Duration and Quantity Restrictions:

- Initial approval: 6 months
- Renewal approval: 12 months

Quantity Level Limit:

- Ingrezza 40 mg capsule: 30 per 30 days
- Ingrezza 60 mg capsule: 30 per 30 days
- Ingrezza 80 mg capsule: 30 per 30 days
- Ingrezza 4-week Initiation Pack (7- 40 mg capsules, 21- 80 mg capsules): 1 pack (28 capsules) per 28 days
- Ingrezza 4-week Initiation Pack (14 x 40 mg capsules, 14 x 60 mg capsules): 1 pack (28 capsules) per 28 days

References:

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2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Bhidayasiri R, Fahn S, et al. Evidence-based guideline: Treatment of tardive syndromes. Neurology; July 30, 2013:
4. 81 (5) 463-469. https://doi.org/10.1212/WNL.0b013e31829d86b6
5. Vasan S, Padhy RK. Tardive Dyskinesia. [Updated 2023 Apr 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448207/
6. Merical B, Sánchez-Manso JC. Chorea. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430923/