

PRIOR AUTHORIZATION POLICY

POLICY: Vesicular Monoamine Transporter Type 2 Inhibitors – Ingrezza™ (valbenazine capsules)

TAC APPROVAL DATE: 05/22/2019

OVERVIEW

Ingrezza, a vesicular monoamine transporter type 2 (VMAT2) inhibitor, is indicated for the treatment of adults with tardive dyskinesia (TD).¹ Ingrezza is thought to provide benefit in TD through the reversible inhibition of VMAT2, a transporter that regulates monoamine (e.g., dopamine) uptake from the cytoplasm to the synaptic vesicle for storage and release, thereby reducing presynaptic release of dopamine. The initial dose is 40 mg once daily (QD) taken with or without food. After one week, increase to the recommended dose of 80 mg QD. Continuation of 40 mg QD dosing may be considered for some patients.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Ingrezza. 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, approval requires Ingrezza to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 1 year in duration.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Tardive Dyskinesia (TD).** Approve for 1 year if Ingrezza is prescribed by or in consultation with a neurologist or psychiatrist.

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.

REFERENCES

1. Ingrezza™ capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc.; August 2018.

OTHER REFERENCES UTILIZED

- 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.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New policy	--	04/26/2017
Annual revision	No change to criteria.	04/25/2018
Annual revision	No change to criteria.	05/22/2019

TAC – Therapeutic Assessment Committee; DEU – Drug Evaluation Unit; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>.