UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2137-8
Program	Prior Authorization/Medical Necessity
Medication	Ingrezza® (valbenazine)*
P&T Approval Date	11/2017, 11/2018, 11/2019, 11/2020, 6/2021, 6/2022, 6/2023, 10/2023
Effective Date	1/1/2024

1. Background

Ingrezza* is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease.[1]

2. Coverage Criteria[a]:

A. Tardive Dyskinesia

1. **Initial Authorization**

a. **Ingrezza*** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe tardive dyskinesia

-AND-

(2) **One** of the following:

(a) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

-OR-

(b) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

-AND-

(3) History of failure, contraindication, or intolerance to Austedo (deutetrabenazine) or Austedo XR (deutetrabenazine) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

-AND-

(4) Prescribed by or in consultation with **one** of the following:

(a) Neurologist
(b) Psychiatrist

Authorization will be issued for 12 months.

1. **Reauthorization**

a. Documentation of positive clinical response to Ingrezza* therapy

Authorization will be issued for 12 months.

B. Chorea associated with Huntington's disease

1. **Initial Authorization**

a. **Ingrezza*** will be approved based on the following criteria:

(1) Diagnosis of chorea associated with Huntington's disease

-AND-

(2) History of failure, contraindication, or intolerance to Austedo (deutetrabenazine) or Austedo XR (deutetrabenazine) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

-AND-

(3) Prescribed by or in consultation with **one** of the following:

(a) Neurologist
(b) Psychiatrist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Ingrezza* therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Ingrezza is excluded from coverage for the majority of our benefits.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place and Step Therapy may be in place.

4. References:

1. Ingrezza [packate insert]. San Diego, CA: Neurocrine Biosciences, Inc.; August 2023.

2. Hauser RA, Factor SA, Marder SR, et al. Kinect 3: A phase 3 randomized, double-blind, placebo-controlled trial of valbenazine for tardive dyskinesia. American Journal of Psychiatry. May 2017. 174:5.
3. Waln O, Jankovic J: An update on tardive dyskinesia: from phenomenology treatment. Tremor Other Hyperkinet Mov (N Y) 2013; 3: tre-03-161-4138-1.

Program	Prior Authorization/Medical Necessity - Ingrezza (valbenazine)
Change Control	
11/2017	New program
11/2018	Annual review. No changes to clinical coverage criteria. Updated reference.
11/2019	Annual review. No changes to clinical coverage criteria. Updated reference.
11/2020	Annual review. Updated references.
6/2021	Added Ingrezza exclusion statement. Removed continuation of therapy allowance from coverage criteria. Updated reference.
6/2022	Annual review. No changes.
6/2023	Annual review. Updated criteria to include extended-release Austedo formulation. Updated reference.
10/2023	Added criteria for chorea associated with Huntington's disease. Updated background and reference.