UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2137-9
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, 4/2024
Effective Date	7/1/2024

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) 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 **both** of the following criteria:

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

      -AND-

      (2) 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.

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.

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.
4/2024	Removed notation that Ingrezza is typically excluded. Removed failure, contraindication, or intolerance to Austedo/Austedo XR from criteria.