UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3103-8
Program	Step Therapy
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:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Austedo® or Austedo® XR before providing coverage for Ingrezza* for the treatment of tardive dyskinesia or chorea associated with Huntington's disease.

Ingrezza*, Austedo, and Austedo XR are vesicular monoamine transporter 2 (VMAT2) inhibitors indicated for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease.

2. Coverage Criteria[a]:

A. Tardive Dyskinesia

1. **Ingrezza*** will be approved based on **both** of the following criteria:

   a. Diagnosis of tardive dyskinesia

   -AND-

   b. 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)

   Authorization will be issued for 12 months.

B. Chorea associated with Huntington's disease

1. **Ingrezza*** will be approved based on **both** of the following criteria:

   a. Diagnosis of Chorea associated with Huntington's disease

   -AND-

   b. 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)

   Authorization will be issued for 12 months.

C. Other Diagnoses

1. Ingrezza* will be approved

   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.
- Medical Necessity, Notification, and/or Supply limits may be in place

4. References:

1. Ingrezza [package insert]. San Diego CA: Neurocrine Biosciences, Inc.; August 2023.
2. Austedo [package insert]. Parsippany, NJ: Teva Pharmaceuticals Inc.; February 2023.
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	Step Therapy - 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 references.
11/2020	Annual review. Updated references.
6/2021	Added Ingrezza exclusion statement. Removed continuation of therapy allowance from coverage criteria. Updated references.
6/2022	Annual review. Updated references.
6/2023	Annual review. Updated background and criteria to include extended-release Austedo formulation. Updated references.
10/2023	Updated criteria to include chorea associated with Huntington's disease. Updated background and reference.