Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Ingrezza under the patient's prescription drug benefit.

Description:

FDA-Approved Indications
Treatment of adults with:
A. Tardive dyskinesia
B. Chorea associated with Huntington's disease

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Ingrezza

Policy/Guideline:

Documentation:
Submission of the following information is necessary for both initial approval and continuation of therapy prior authorization reviews (where applicable): Documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS).

Criteria for Initial Approval:

A. Tardive dyskinesia
Authorization of 6 months may be granted for treatment of tardive dyskinesia when the baseline AIMS score for items 1 to 7 is obtained;
AND
Patient must also be unable to take Austedo and tetrabenazine for the given diagnosis, due to a trial and inadequate treatment response, or intolerance, or a contraindication

B. Chorea associated with Huntington's disease
Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:
1. Member demonstrates characteristic motor examination features
2. Member meets one of the following conditions:
   i. Laboratory results indicate an expanded *HTT* CAG repeat sequence of at least 36
   ii. Member has a positive family history for Huntington's disease

AND

Patient must also be unable to take Austedo and tetrabenazine for the given diagnosis, due to a trial and inadequate treatment response, or intolerance, or a contraindication

Criteria for Continuation of Therapy:

A. Tardive dyskinesia

Authorization of 12 months may be granted for treatment of tardive dyskinesia when the member's tardive dyskinesia symptoms have improved as indicated by a decreased AIMS score (items 1 to 7) from baseline.

B. Chorea associated with Huntington's disease

Authorization of 12 months may be granted for treatment of chorea associated with Huntington's disease when the disease has improved or stabilized.

Approval Duration and Quantity Restrictions:

Approval:

- Initial approval: 6 months
- Renewal: 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:

1. Ingrezza [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; August 2023.
2. Hauser, Robert, et al. KINECT-3: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Valbenazine for Tardive Dyskinesia. *American Journal of Psychiatry*. 2017 Mar 21: 1-9.
3. American Psychiatric Association. (2021). *Practice Guideline for the Treatment of Patients With Schizophrenia, third edition.* https://doi.org/10.1176/appi.books.9780890424841.
4. Armstrong MJ, Miyasaki JM. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2012; 79(6):597-603.

5. Stimming EF, Claassen DO, Kayson E, et al. Safety and efficacy of valbenazine for the treatment of chorea associated with Huntington's disease (KINECT-HD): a phase 3, randomized, double-blind, placebo-controlled trial. *Lancet Neurol*. 2023; 22:494-504.