AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Ingrezza	Page:	1 of 2
Effective Date:	8/19/2024	Last Review Date:	7/22/2024
Applies to:	☒Florida Kids	☒New Jersey	☒Pennsylvania Kids

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 to initiate the prior authorization review for initial requests:

A. Tardive dyskinesia: Chart notes or medical record documentation of clinical manifestations of disease.
B. Chorea associated with Huntington's disease: Chart notes or medical record documentation of characteristic motor examination features.
C. For both indications, the patient is unable to take Austedo and tetrabenazine for the given diagnosis, due to a trial and inadequate treatment response, or intolerance, or a contraindication. Documentation is required for approval.

Criteria for Initial Approval:

A. Tardive dyskinesia
Authorization of 6 months may be granted for treatment of tardive dyskinesia when BOTH of the following criteria are met:
1. Member exhibits clinical manifestations of disease.
2. Member's tardive dyskinesia has been assessed through clinical examination or with a structured evaluative tool (e.g., Abnormal Involuntary Movement Scale [AIMS], Dyskinesia Identification System: Condensed User Scale [DISCUS]).

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

Criteria for Continuation of Therapy:

A. Tardive dyskinesia
Authorization of 12 months may be granted for members with an indication of Tardive Dyskinesia who are experiencing benefit from therapy as evidenced by disease stability or disease improvement..

B. Chorea associated with Huntington's disease
Authorization of 12 months may be granted for members with an indication of Chorea associated with Huntington's disease who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Approval Duration and Quantity Restrictions:

Approval:
- Initial approval: 6 months
- Renewal approval: 12 months

Quantity Level Limit:
- Ingrezza 40 mg capsule/sprinkle: 30 per 30 days
- Ingrezza 60 mg capsule/sprinkle: 30 per 30 days
- Ingrezza 80 mg capsule/sprinkle: 30 per 30 days
- Ingrezza 4-week Initiation Pack (7-40mg caps, 21-80 mg caps): 1 pack (28 caps) per 28 days
- Ingrezza 4-week Initiation Pack (14 x 40mg caps, 14 x 60mg caps): 1 pack (28 caps) per 28 days

References:

1. Ingrezza [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2024.
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. *Am J Psychiatry*. 2017;174(5):476-484.
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. 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.