

SPECIALTY GUIDELINE MANAGEMENT

INGREZZA (valbenazine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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.

II. 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.

III. 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

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members with an indication listed in Section III who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

V. 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.