Clinical Policy Title:	valbenazine
Policy Number:	RxA.172
Drug(s) Applied:	Ingrezza®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Tardive Dyskinesia (must meet all)**:**

1. Diagnosis of tardive dyskinesia;
2. Prescribed by or in consultation with a psychiatrist or neurologist;
3. Age ≥ 18 years;
4. At the time of request, tetrabenazine or deutetrabenazine is not prescribed concurrently;
5. Dose does not exceed 80 mg per day.

Approval Duration

Commercial: 12 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Tardive Dyskinesia (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Tetrabenazine or deutetrabenazine is not prescribed concurrently;
4. If request is for a dose increase, new dose does not exceed 80 mg per day.

Approval Duration

Commercial: 12 months

Medicaid: 6 months

References

1. Factor S, Comella C, Correll C, et al. Efficacy of valbenazine (NBI-98854) in subjects with tardive dyskinesia: Results of a long-term study (KINECT 3 extension) (S56.005). Neurology. April 18, 2017; 88(16): S56.005. Available at: https://n.neurology.org/content/88/16_Supplement/S56.005/tab-article-info. Accessed January 18, 2023.
2. Hauser RA, Factor SA, Marder SR. KINECT 3: A phase 3 randomized, double-blind, placebo-controlled trial of valbenazine for tardive dyskinesia. Am J Psychiatry. May 1, 2017; 174(5): 476-484. doi: 10.1176/appi.ajp.2017.16091037. Epub 2017 Mar 21. Available at: https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2017.16091037. Accessed January 18, 2023.

3. Waln O, Jankovic J. An update on tardive dyskinesia: From phenomenology to treatment. Tremor Other Hyperkinet Mov (N Y). July 12, 2013; 3. pii: tre-03-161-4138-1. doi: 10.7916/D88P5Z71. Print 2013. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3709416/. Accessed January 18, 2023.
4. O'Brian CF, Jimenez R, Hauser RA, et al. NBI-98854, a selective monoamine transport inhibitor for the treatment of tardive dyskinesia: A randomized, double-blind, placebocontrolled study. Movement Disorders. 2015; 30(12): 1681-1687. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5049616/. Accessed January 18, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 2. Reference reviewed and updated. 3. Approval duration for commercial was updated to 12 months from length of benefit.	06/18/2020	12/07/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.6 was updated to include "At the time of request, no documented congenital long QT syndrome…" 2. Continued Therapy Approval Criteria II.A.1 was rephrased to " Member is currently receiving the medication that has been authorized by..." 3. Continued Therapy Approval criteria II.A.5 was updated to include "No documented congenital QT long syndrome or arrythmias associated…" 4. References were reviewed and updated.	5/28/2021	9/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated to remove "secondary to a centrally acting dopamine receptor blocking agent (DRBA), the status of the agent as a centrally acting DRBA as well as its association with tardive dyskinesia should be confirmed". 2. Initial Approval Criteria, I.A: Updated to remove criteria 6: "At the time of request, no documented congenital long QT syndrome or arrythmias associated with a prolonged QT interval. It may cause an increase in QT interval and it is recommended to avoid use. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dose." 3. Continued Therapy Approval Criteria, II.A:	02/03/2022	04/18/2022

Updated to remove criteria 5: “No documented congenital QT long syndrome…before increasing the dose”. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. References were reviewed and updated.		
Policy was reviewed: 1. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023