MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Tardive Dyskinesia	**P&T DATE:**	12/08/2020
CLASS:	Neurologic Disorders	**REVIEW HISTORY** (MONTH/YEAR)	12/2019
LOB:	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Tardive syndromes are characterized by the following: "history of at least 3 months' total cumulative neuroleptic exposure, presence of at least "moderate" abnormal involuntary movements in one or more body areas or at least 'mild' movements in 2 or more body areas, and absence of other conditions that might produce abnormal involuntary movements." Approximately 30% of patients with schizophrenia who are treated with neuroleptic medications develop TD, and this condition develops at a 5% rate annually.[1]

Health Plan of San Joaquin has been receiving prior authorizations for these medications and the purpose of this coverage policy is to review the coverage criteria of HPSJ's formulary antiviral agents (Table 1).

Table 1: Available Agents *(Current as of 09/2020)*

Generic (Brand)	Available Strengths	Formulary Limits	Cost per Rx	Notes
Vesicular Monoamine Transporter 2 Inhibitors				
Valbenazine (Ingrezza)	40 mg capsule	PA, SP, QL	$6,213.85	PA required. Patients ≥ 18 years with a diagnosis of moderate to severe tardive dyskinesia for at least 3 months, an Abnormal Involuntary Movement Scale ≥ 6, and no active diagnosis of suicidal ideation within 6 months. Limit 30 capsules per 30 days. Restricted to specialty pharmacy.
	80 mg capsule			
Deutetrabenazine (Austedo)	6 mg tablet	PA, SP, QL	$4,896.88	PA required. Patients ≥ 18 years with a diagnosis of moderate to severe tardive dyskinesia for at least 3 months, an Abnormal Involuntary Movement Scale ≥ 6, and no active diagnosis of suicidal ideation within 6 months. Limit 60 tablets per 30 days. Restricted to specialty pharmacy.
	9 mg tablet			
	12 mg tablet			

PA = Prior Authorization; SP = Specialty Pharmacy; QL = Quantity Limit; FL = Fill Limit; NF = Non-formulary

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed & approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Vesicular Monoamine Transporter 2 Inhibitors
Valbenazine (Ingrezza), Deutetrabenazine (Austedo)

Valbenazine (Ingrezza)

- ❒ **Coverage Criteria:** Reserved for patients who meet **all** of the following criteria**:**
  - Member is at least 18 years of age **AND**
  - Documented diagnosis of moderate to severe tardive dyskinesia according to DSM V criteria for at least 3 months **AND**
  - Abnormal Involuntary Movement Scale ≥ 6 **AND**
  - No active diagnosis of suicidal ideation within 6 months
- ❒ **Limits:** Restricted to 30 capsules per 30 days for the 40 mg and 80 mg capsules.
- ❒ **Required Information for Approval:** Relevant clinical documentation with patient's age, patient's medical history, indication for use, and Abnormal Involuntary Movement Scale value.
- ❒ **Other Notes:** Medication is to be dispensed by specialty pharmacy.

Deutetrabenazine (Austedo)

- ❒ **Coverage Criteria:** Reserved for patients who meet **all** of the following criteria**:**
  - Member is at least 18 years of age **AND**
  - Documented diagnosis of moderate to severe tardive dyskinesia according to DSM V criteria for at least 3 months **AND**
  - Abnormal Involuntary Movement Scale ≥ 6 **AND**
  - No active diagnosis of suicidal ideation within 6 months
- ❒ **Limits:** Restricted to 60 tablets per 30 days for the 6 mg, 9 mg, and 12 mg tablets.
- ❒ **Required Information for Approval:** Relevant clinical documentation with patient's age, patient's medical history, indication for use, and Abnormal Involuntary Movement Scale value.
- ❒ **Other Notes:** Medication is to be dispensed by specialty pharmacy.

CLINICAL JUSTIFICATION

According to the 2013 American Academy of Neurology guidelines for the treatment of tardive syndromes, there are a few agents that may improve TD.[1] The medications that have efficacy include clonazepam and Ginkgo biloba, but are currently not yet FDA-approved for this indication.[1] However, a meta-analysis that analyzed 4 trials of benzodiazepine usage in TD recommended to avoid clinical use due to the evidence being of very-low quality.[5] One meta-analysis that included 157 patients using Ginkgo biloba supported its use for TD.[3] Tetrabenazine and amantadine were also included in the guidelines as agents that may treat TD. In one meta-analysis, there was not enough evidence and clinical data to support tetrabenazine having efficacy for this condition.[2] Currently, there is limited and low-quality evidence that withdrawal of antipsychotics or switching antipsychotics can improve TD.[6] Although one meta-analysis illustrated that switching to clozapine monotherapy improved TD, there were only 48 patients who were included in it.[4]

In 2017, Austedo® and Ingrezza™, two VMAT2 inhibitors, became the first FDA-approved medications for the treatment of tardive dyskinesia. Austedo® is also indicated for the treatment of chorea associated with Huntington's disease. The clinical trials for these medications included patients with a moderate to severe TD diagnosis of at least three months, and excluded patients with any comorbid movement disorders, active suicidal ideation, and QT prolongation. Patients on both medications had a significant reduction in their AIMS scores over the course of six or twelve weeks.[9,12] Two meta-analyses also demonstrate the efficacy of these two medications for this indication.[2,3] So far, these medications appear to be well-tolerated, with the most common adverse event being somnolence. There have been some reports of QT prolongation associated with VMAT2 inhibitors.[7,8] Overall, these two medications have been shown to be safe and efficacious. There are currently no other FDA-approved medications for this indication other than these two medications.

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPS Coverage Policy – Tardive Dyskinesia 2019-12.docx	12/2019	Matthew Garrett, PharmD
Review Policy	HPS Coverage Policy – Tardive Dyskinesia.docx	12/2020	Matthew Garrett, PharmD