A. Policy Statement

Antipsychotic medications have demonstrated effectiveness in the clinical management of various psychiatric disorders. Nonetheless, several movement disorders have been associated with their use. Some of these movement disorders, such as parkinsonian-like extrapyramidal symptoms, may be more easily identified, controllable with medication, and reversible upon discontinuation of the antipsychotic medication. However, tardive movement disorders (e.g., tardive dyskinesia, tardive dystonia, tardive akathisia) are often irreversible and may not emerge until months or years after initiation of medication. The New York State Office of Mental Health (OMH) promotes and supports the judicious prescribing of antipsychotic medications, along with routine assessment of medication-related movement disorders. Such assessment includes a comprehensive medication history, a movement disorders history, and the patient's current clinical status. Because of the slowly developing nature of tardive movement disorders, it is important to document this assessment consistently and objectively so that changes can be noted and addressed in a timely manner.

While the primary goal of antipsychotic treatment is to maximize clinical effectiveness while minimizing the risk of adverse side effects, an inherent risk of tardive movement disorders remains. Though new medications (e.g., vesicular monoamine transporter type 2 inhibitors) have recently arisen for the management of tardive movement disorders, they are not wholly reversal agents. Additionally, in prior policies, the risk for tardive movement disorders had primarily been correlated with first-generation versus second-generation antipsychotic medications; however, newer evidence suggests a broader clinical spectrum for the risk of developing tardive movement disorders, such as age, sex, race/ethnicity, presence of mood or intellectual developmental disorders, prior history of movement disorders, prior history of central nervous system injury, and degree of medication dopamine D2 receptor antagonism. This revised policy acknowledges these newer and ongoing developments.

B. Purpose

The purpose of this policy directive is to provide instruction to each State-operated facility regarding the early detection, possible prevention, and treatment of tardive movement disorders for all populations receiving clinical treatment in the facility's written plan.

C. Applicability

This policy applies to all OMH Facilities, including Inpatient, Mental Health Outpatient Treatment and Rehabilitative Service (MHOTRS), and Assertive Community Treatment (ACT) or similar crisis service programs, among adult, child & youth, civil, and adult, forensic treatment settings, including the Secure Treatment and Rehabilitation Center (STARC).

D. Relevant Statutes and Standards

Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision *(American Psychiatric Association, March 2022)*

The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia *(American Psychiatric Association, September 2020)*

Evidence-based guideline: Treatment of tardive syndromes: Report of the Guideline Development Subcommittee of the American Academy of Neurology *(Bhidayasiri et al., Neurology July 30, 2013)*

E. Definitions

1. Abnormal Involuntary Movement Scale (AIMS) means the 12-item clinician-rated anchored scale developed by the National Institute of Mental Health to assess the severity of tardive dyskinesia.

2. Antipsychotic medication means a medication used to treat psychotic symptoms.

3. Tardive akathisia means a late-developing and/or slow-evolving movement disorder associated with use of antipsychotic medications characterized by persistent inner restlessness, producing an inability to sit still or remain in one place or position.

4. Tardive dyskinesia means a late-developing and/or slow-evolving movement disorder associated with use of antipsychotic medications characterized by a wide variety of involuntary repetitive movements, including abnormal oral-lingual-facial and choreoathetoid movements.

5. Tardive dystonia means a late-developing and/or slow evolving movement disorder associated with use of antipsychotic medications characterized by sustained muscle contraction, often causing twisting, repetitive movements or abnormal sustained postures.

6. Tardive movement disorders (or tardive syndrome) means disorders with delayed onset and/or slow evolution that are characterized by abnormal movements likely caused by medications that block dopamine receptors. These disorders include tardive akathisia, tardive dyskinesia, tardive dystonia, and other stereotypies that may be caused by antipsychotic medications.

F. Body of Directive

This policy directive consists of three components:

1. General consideration and Principles
2. Written Plan
3. Requirements for Plan Components

1) General Consideration and Principles:

(a) Prior to the initiation of medication therapy for any patient, including antipsychotic treatment, the following must be considered:

i. an objective and accurate diagnosis of the illness to be treated;

ii. review of the patient's clinical history and response to treatment;

iii. analysis of the risk-to-benefit ratio of the proposed treatment for the individual patient;

iv. education of the patient concerning the risks and benefits of treatment; and

v. informed consent of the patient, including consideration of the patient's goals for treatment.

(b) Upon establishing antipsychotic therapy as one treatment of choice, the safest effective drug and lowest effective antipsychotic medication dose must be utilized, including consideration of the relative risk of development of tardive movement disorders.

2) Written Plan:

(a) Each facility shall develop a written plan consisting of five components:

i. Prescription of Antipsychotic Medications;

ii. Monitoring System;

iii. Treatment of Tardive Movement Disorders;

iv. Patient and Advocate Education; and

v. Quality Improvement Activities.

3) Requirements for Plan Components:

(a) Prescription of Antipsychotic Medications: The written plan shall reaffirm certain basic clinical principles related to the prescription of antipsychotic medications. At a minimum, the plan must address the following:

i. The choice of drug, considering risk of tardive movement disorders, or other serious side effects, while weighing other relevant clinical factors such as patient perspective and effectiveness of medication;

ii. The need to prescribe the lowest effective dose and the fewest number of effective medications;

iii. The need for continued use of the medication after stabilization of symptoms;

iv. Justification for doses beyond usual therapeutic range; and

v. The inclusion of antipsychotic medication as a component of the individual service plan.

(b) Monitoring System: The plan shall identify a mechanism to develop, implement, and periodically evaluate a system for monitoring the onset of tardive movement disorders and the need for continued antipsychotic treatment. At a minimum, this system must include detection, documentation, reporting, and evaluation provisions. To facilitate the integration of the monitoring system within the facility's operations, the detection procedures must be developed in cooperation with the facility's Pharmacy & Therapeutic Committee (or equivalent), the documentation procedures must be developed in cooperation with the Health Information Management Department (or equivalent), and the reporting and evaluation procedures must be developed in cooperation with the Quality Improvement Department (or equivalent).

(1) Detection

i. The written plan developed by each facility must delineate the minimum standards for the detection component of the monitoring system. These standards shall include, at a minimum, assessments of tardive dyskinesia using the Abnormal Involuntary Movement Scale (AIMS). The initial AIMS must be completed for each patient newly admitted to a clinical setting within 24 hours of admission, and prior to commencing treatment with antipsychotic medication for a patient who has not received antipsychotic medication previously.

ii. The written plan developed by each facility must ensure that patients regardless of age, diagnosis, or other risk factors who are currently receiving antipsychotic medications receive screening at a minimum of every six months using the AIMS. Facilities may additionally outline screening for individuals at higher risk of developing tardive movement disorders to be

performed more frequently.

iii. As part of the detection component of the monitoring system, each facility must identify the professional staff members who may administer the AIMS. It is the responsibility of the Clinical Director to ensure that such staff members receive appropriate training in the administration of the scale.

iv. If a patient is uncooperative or unable to participate in the AIMS evaluation, the staff person conducting the assessment must describe the circumstances in the clinical record (including the patient's condition) that hinder the completion of the assessment. Such situations do not preclude global assessments and observations of the patient's movements, which shall be documented in the clinical record. In these situations, the treating physician must ensure that future attempts at completing the AIMS are made, particularly for patients who may be at high risk of developing tardive dyskinesia.

(2) Documentation

Each facility shall develop, implement, and evaluate a system to document the monitoring of tardive movement disorders. At a minimum, this system shall represent the inclusion of the completed AIMS forms in the patient's medical record, and documentation of the risks and benefits of the continued use of antipsychotic medication, if that is the treatment of choice.

(3) Reporting

As part of each facility's monitoring system, a reporting process shall be developed and implemented. This process must include procedures whereby appropriate persons are notified when a patient receives an abnormal score on the AIMS (i.e., a score of 2 or more in any body area). At a minimum, the treating physician must be notified to ensure the initiation of a comprehensive case review if the assessment is completed by someone other than the treating physician. Confirmed cases of tardive movement disorders should be reported to the facility’s Pharmacy & Therapeutics Committee (or equivalent).

(4) Evaluation

Each facility's monitoring system must include evaluation procedures, including procedures for periodic reviews of cases of abnormal AIMS scores. At a minimum, monitoring shall include the following:

i. Periodic review of the possible relationship between the occurrence of tardive dyskinesia and individual physician prescribing practices;

ii. The occurrence of new cases of tardive dyskinesia and their relationship to hospital prescribing patterns by the Pharmacy & Therapeutics Committee (or

equivalent); and

iii. Periodic analyses, when requested, of facility trends related to tardive dyskinesia and other medication-related movement disorders by the Quality Improvement Department (or equivalent).

(c) Treatment of Tardive Movement Disorders

(1) The occurrence of a score of two or more in any body area on the AIMS shall generate a comprehensive review of the case by the treating physician. Such a review shall include the following:

i. The differential diagnosis of the abnormal involuntary movement disorder;

ii. Incorporation of the movement disorder, and a strategy to address its associated symptoms, in the patient's individual service plan;

iii. An assessment of the appropriateness of ongoing antipsychotic treatment and the management of tardive movement disorders;

iv. Consideration of the appropriateness of a trial of medication for which there is an indication by the Food and Drug Administration (FDA) for the treatment of tardive dyskinesia, or medication for which there is evidence in peer-reviewed journals or treatment guidelines of effectiveness in palliating symptoms or modifying the course of the tardive movement disorder; and

v. In severe cases of tardive movement disorder, consideration of referral to neurologists specializing in the treatment of movement disorders.

(2) Through the Office of the Clinical Director, each facility must ensure that tardive movement disorder issues are addressed by the Drug Monitoring Committee or other comparable standing committee. This committee shall provide a mechanism whereby clinical consultation is provided, upon request, regarding issues related to tardive movement disorders, including differential diagnosis and treatment. Such consultation may be provided by facility staff members, outside experts, the OMH Consultation Service, or other arrangements, depending on the needs of the patient population and the expertise available in the facility and professional community.

(d) Patient and Advocate Education

(1) Educating patients about the nature of their illnesses and the potential risks and benefits of available treatments is an integral part of the treatment process. Patients and their advocates need to be provided with appropriate and accessible information about any medication therapy, including antipsychotic treatment that is being considered as part of their treatment.

(2) Each facility's written plan, at a minimum, must address the provision of education to patients about provided medications, including type, dose, purpose and benefits, potential short- and long-term side effects (including potential risk of tardive movement disorders) as well as plans for monitoring, and potential drug-drug interactions. Patients should be given information about the medication in the language of their choice. The frequency and nature of information provided about medication therapies is a clinical decision and should be based upon an assessment of the patient's clinical and cognitive status, the patient's medical literacy and relevant sociodemographic factors, patient interest and preference, the degree and time frame of development of potential risks and benefits, and other pertinent factors. The appropriateness of such discussions should be determined at the time of the AIMS evaluation and any change in the patient's medication regimen.

(3) To the extent that patients' families are involved in the treatment planning process and appropriate consent is obtained, information should also be made available to them, along with appropriate written material. For children and adolescents, parents/guardians must also be provided with information about medications. Furthermore, since tardive movement disorders may not be noticed in their early stages by patients themselves, it is essential that their families and/or advocates be informed about how to recognize early symptoms of these movement disorders.

(4) The treating physician is responsible for initiating and directing the process of patient education. At the direction of the physician, designated staff may provide adjunctive education as appropriate to their qualifications, experience, and training.

(5) Staff who provide patient education must document its provision in an appropriate section of the patient's medical record. At a minimum, documentation by responsible staff must address the nature and extent of information provided to the patient and/or the family.

(e) Quality Improvement Activities

As part of the facility's quality improvement program, the Quality Improvement Department (or equivalent) shall monitor the implementation of the facility's written plan. In addition, the quality and appropriateness of patient care services related to antipsychotic medication treatment shall be monitored and evaluated, and steps taken to resolve identified problems. Such quality and appropriateness activities shall incorporate the results of any analyses conducted by the Pharmacy & Therapeutics Committee or other comparable committee which are related to tardive movement disorders.