Utah Department of Health & Human Services

Resources and Options Regarding Tardive Dyskinesia

State of Utah
Division of Integrated Healthcare
November 2023

To:	Social Services Appropriation Subcommittee
From:	Jennifer Strohecker, State Medicaid Director
Subject:	Report Regarding Tardive Dyskinesia Legislative Request

Purpose

As required by 26B-1-241, the Department of Health and Human Services (DHHS) submits the following report regarding tardive dyskinesia:

> *With respect to tardive dyskinesia, the department shall report on the following to the Health and Human Services Interim Committee before November 1, 2023:*
> *(1) resources available to help health care providers, including mental health providers, accurately diagnose and appropriately treat tardive dyskinesia;*
> *(2) resources available to help an individual with tardive dyskinesia, and the individual's caregivers, respond to the functional and social challenges posed by the condition;*
> *(3) options for improving screening, diagnosis, and treatment of tardive dyskinesia, including actions the department may take on behalf of:*
> > *(a) residents of the state generally;*
> > *(b) Medicaid program enrollees; and*
> > *(c) individuals receiving services under a local mental health authority, as defined in Section 26B-5-101; and*
> *(4) the potential costs and benefits of implementing the options reported under Subsection (3).*

Executive summary

Tardive dyskinesia (TD) is a medication-induced movement disorder associated with the use of a class of medications called dopamine receptor-blocking agents. First- and second-generation antipsychotics (SGAs) are common medications that may cause TD. They are considered first-line

treatments for serious mental illness by leading psychiatric guidelines worldwide. For those on antipsychotics long term, there is a 20-30% lifetime incidence of developing TD. TD is often irreversible and can be disfiguring and disabling, with major negative impacts on psychological health and quality of life. The number of people at increased risk for developing TD is disproportionally high in Medicaid compared to the general population due to higher utilization of atypical antipsychotics in this group.[2/3] These symptoms can be avoided with prevention, screening, and early withdrawal of the medication that can cause this disorder.

The signs and symptoms of TD are important to recognize early on, since early discontinuation of the antipsychotic offers the best chance of reversal of symptoms. Unfortunately, there are few TD specific clinical resources to support providers. However, there is a standard structured assessment for the initial screening and the routine monitoring of TD symptoms called the Abnormal Involuntary Movement Scale (AIMS). It is a rating scale that was designed in the 1970s to measure involuntary movements associated with TD. (Appendix A)

Resources for TD patients, caregivers, and family include the National Alliance for Mental Illness, the National Organization for Tardive Dyskinesia, the Movement Disorders Policy Coalition, and industry sponsored sites, including Neurocrine Biosciences.

TD is associated with high health care utilization costs and negative social, psychological, and occupational impacts besides the obvious physical impacts.

Background

Tardive Dyskinesia (TD) is a movement disorder caused by dopamine receptor antagonists, which includes first generation antipsychotics (FGA) and second-generation antipsychotics (SGA), metoclopramide, and prochlorperazine. The most common symptoms include movement of the mouth and tongue but can include movement of the arms, legs, trunk, and respiratory muscles. These symptoms are in most cases irreversible and can significantly impact quality of life.[1] Medicaid members are disproportionately impacted by TD and nearly 1 in 8 Medicaid members receiving second generation antipsychotics developed tardive dyskinesia symptoms within one year of treatment initiation.[2/3] Discontinuation of the causative medication can resolve symptoms, but many individuals affected by TD have significant psychiatric disorders that will require lifelong therapy with antipsychotic medications.

An analysis from the Agency of Healthcare Research and Quality found utilization of antipsychotics in the U.S. increased from 5 million individuals in 2013 to 6.1 million individuals in 2018.[4] The use of psychotropic medication for the treatment of mental health problems in children and youth is increasing, doubling in frequency as the primary management strategy between 1995 and 2010.[5] Although second generation antipsychotic medications have a significantly lower risk of causing TD compared with first generation antipsychotics, the increase in utilization of second generation antipsychotics to treat psychiatric diagnoses includes a risk for increased prevalence of tardive dyskinesia.

Lifetime TD prevalence has been estimated to range from 20–50% among patients with long-term exposure to antipsychotics, with increased prevalence associated with older age, female gender, smoking, and longer duration and type of antipsychotic treatment. While most individuals who develop TD have mild symptoms, a small proportion will develop severely disabling, permanent symptoms.

In addition to the burden on the individual, studies show that there is a significant economic burden associated with TD. For patients with TD, the mean total all-cause health care costs increased by 26.2% from prior to their diagnoses. The major cost driver was inpatient admissions with an increase of 56.1%. However, increases in cost in outpatient clinic, outpatient pharmacy, and emergency room services were all substantially higher for those with TD than for those without TD.[6]

Though there are two FDA approved drugs available for treatment of TD, they have not been shown to be cost effective due to their high cost. The wholesale acquisition cost, or list price to wholesalers, for a 30-count bottle of valbenzine is $6,225. The wholesale acquisition cost, or list price to wholesalers, for a 30-count bottle of deutetrabenazine is $6,144. The incremental cost-effectiveness ratios over a lifetime horizon were approximately $750,000 per QALY for valbenazine and $1.1 million per QALY for deutetrabenazine, much higher than standard accepted thresholds of $150,000 per QALY.[7] The quality-adjusted life year (QALY) is a generic measure of disease burden, including both the quality and the quantity of life lived. It is used in economic evaluation to assess the value of medical interventions.

(1) Resources available to help health care providers, including mental health providers, accurately diagnose and appropriately treat tardive dyskinesia:

Our review found an overall paucity of resources for clinical support resources for health care providers. Those that we have identified which are objective and evidence-based are:

1) National Institute of Neurological Disorders and Stroke: articles on evidence based screening and treatment practices. https://www.ninds.nih.gov/health-information/disorders/tardive-dyskinesia
2) National Organization for TD: https://tdhelp.org/resources/; links to expert panel and clinical trials.
3) AIMS has achieved widespread acceptance as an easy-to-use and objective measure. The AIMS has been effective at enhancing compliance with routine monitoring and screening for TD and at fostering standardization and comparability between research trials.[8] It is recommended to administer the AIMS at baseline before initiating antipsychotic medications, with a follow-up screening performed no longer than three months later. [9]

(2) Resources available to help an individual with tardive dyskinesia, and the individual's caregivers, respond to the functional and social challenges posed by the condition:

Resources for patients and caregivers with TD include:

1) The National Alliance for Mental Illness, the nation's largest grassroots mental health

organization dedicated to building better lives for the millions of Americans affected by mental illness. NAMI has numerous resources for patients with tardive dyskinesia, including FAQ sheets, articles, personal stories, and support groups.

2) The National Organization for Tardive Dyskinesia, which provides numerous resources such as discussions of self-help techniques, pharmaceutical and alternative treatments, information on their Zoom TD support groups, and patients' personal stories.
3) University of Utah Health - TD informational website with links to make appointments with a neurologist. https://healthcare.utah.edu/neurosciences/neurology/movement-disorders/tardive-dyskinesia
4) The Movement Disorders Policy Coalition, which supports people living with movement disorders beyond TD and has free resources for providers, patients, and caregivers.
5) Industry sponsored sites, such as Talk About TD.
6) There are social media support groups that patients may consider accessing.

(3) Options for improving screening, diagnosis, and treatment of tardive dyskinesia, including actions the department may take on behalf of:

(a) residents of the state generally;
(b) Medicaid program enrollees; and
(c) individuals receiving services under a local mental health authority, as defined in Section 26B-5-101:

- **(a)/(b)/(c)** Establish a standardized statewide monitoring procedure to detect abnormal involuntary movements of individuals who take neuroleptic (antipsychotic) medication and to ensure early diagnosis and treatment of Tardive Dyskinesia (TD).[10] See Appendix B for an example used in Connecticut.
- **(a)/(b)/(c)** Coordinate care for people at risk of TD and provide peer-to-peer outreach with Medicaid's Accountable Care Organizations (ACOs), Prepaid Mental Health Plans (PMHPs), and the Department of Corrections to provide education regarding the need for prevention and screening of TD.
- **(b)** Ensure that providers are adhering to recommended screening and management recommendations including use of AIMS.
- **(b)/(c)** Standardize informed consent practices to improve patient awareness.
- **(b)** Implement retrospective utilization review to monitor patients with high risk of developing TD.
- **(b)** Implement retrospective DUR to monitor providers with panels with high incidence of TD and provide outreach as needed.
- **(b)** Monitor trends in the proportion of Medicaid members with a diagnosis of TD
- **(a)/(b)/(c)** Create a resource for those who are on antipsychotics to learn about the signs and symptoms of TD, learn about treatment options for their illness - both mental health and TD, as well as links to local resources including local peer support groups.

- **(a)/(b)/(c)** Make peer to peer neurologist consultation available to providers for support in early screening and differentiating TD from other movement disorders
- **(a)/(b)/(c)** Make expedient neurologist consultation available to all those who develop symptoms consistent with TD

(4) the potential costs and benefits of implementing the options reported under Subsection (3)

Potential costs

Depending on the options selected, costs could range from minimal (e.g., modifying Medicaid's websites to add links to various resources) to >$100,000 per year (e.g., peer-to-peer outreach to selected prescribers of antipsychotics) in addition to the time committed to carrying out these interventions.

Potential benefits

Several studies have documented the increase in health care resource utilization by those with TD versus prior to developing TD. In a retrospective study in the U.S. total health care and medication costs were $54,656 for patients with TD and $28,777 for those without TD. This increase in health care cost was driven by higher inpatient admissions, outpatient services, and outpatient pharmacy costs in the TD population. In a similar claims database analysis using Medicaid claims, patients with TD had significantly more mental health–related outpatient visits compared with patients without TD as well as more claims for drugs to treat TD. In a retrospective cohort study using electronic health record (EHR) data from the Optum EHR database, patients with TD compared with patients without TD had a higher proportion of emergency room visits and inpatient stays. Taken together, these studies indicate a significant increase in health care burden associated with a diagnosis of TD compared with patients with mental health conditions who do not have TD.[11]

Besides the economic benefits, there are significant social, physical and psychological impacts on the individual who develops TD. An online survey of 435 patients with tardive dyskinesia (TD) revealed that TD negatively affects their quality of life across psychological, social, physical, and occupational domains, in addition to significant impairment of work and activity.[12]

The Work Productivity and Activity Impairment (WPAI) questionnaire is a well validated instrument to measure impairments in work and activities. The impact of TD reported via the WPAI on work absenteeism (29.1%), presenteeism (68.4%), and overall work impairment (73.5%) were greater than those reported for lung cancer (absenteeism, 15%; presenteeism, 31%; overall work impairment, 37%) and for locally recurrent or metastatic breast cancer (20%, 30%, and 40%, respectively). Patients with TD and MDD reported greater impact on absenteeism (22.1%), presenteeism (53.2%), and overall work impairment (58.8%) than previously recorded with the WPAI for US patients with MDD

alone (absenteeism, 5.7%; presenteeism, 33.7%; and overall work impairment, 36.5%). Likewise, patients with TD and schizophrenia reported greater overall work impairment than US patients with severe schizophrenia.[13]

Conclusions

In aggregate, the above information regarding the increasing prevalence of use of antipsychotics, the associated significant risk of developing TD, and the high social and economic cost of TD makes a strong case for the benefits of prevention of and screening for TD. The existence of screening tools makes this feasible.

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Appendix A

ABNORMAL INVOLUNTARY MOVEMENT SCALE (AIMS)

Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration
National Institute of Mental Health

NAME:_____
DATE: _____
Prescribing Practitioner: _____

CODE: 0 = None
1 = Minimal, may be extreme normal
2 = Mild
3 = Moderate
4 - Severe

INSTRUCTIONS:
Complete Examination Procedure (attachment d.) before making ratings

MOVEMENT RATINGS: Rate highest severity observed. Rate movements that occur upon activation one less than those observed spontaneously. Circle movement as well as code number that applies.		RATER Date	RATER Date	RATER Date	RATER Date
Facial and Oral Movements	**1. Muscles of Facial Expression** e.g. movements of forehead, eyebrows periorbital area, cheeks, including frowning blinking, smiling, grimacing	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
	2. Lips and Perioral Area e.g., puckering, pouting, smacking	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
	3. Jaw e.g. biting, clenching, chewing, mouth opening, lateral movement	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
	4. Tongue Rate only increases in movement both in and out of mouth. NOT inability to sustain movement. Darting in and out of mouth.	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	O 1 2 3 4
Extremity Movements	**5. Upper (arms, wrists,, hands, fingers)** Include choreic movements (i.e., rapid, objectively purposeless, irregular, spontaneous) athetoid movements (i.e., slow, irregular, complex, serpentine). DO NOT INCLUDE TREMOR (i.e., repetitive, regular, rhythmic)	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
	6. Lower (legs, knees, ankles, toes) e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot.	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
Trunk Movements	**7. Neck, shoulders, hips** e.g., rocking, twisting, squirming, pelvic gyrations	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
Global Judgments	**8. Severity of abnormal movements overall**	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
	9. Incapacitation due to abnormal movements	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
	10. Patient's awareness of abnormal movements. Rate only patient's report No awareness 0 Aware, no distress 1 Aware, mild distress 2 Aware, moderate distress 3 Aware, severe distress 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
Dental Status	**11. Current problems with teeth and/or dentures**	No Yes	No Yes	No Yes	No Yes
	12. Are dentures usually worn?	No Yes	No Yes	No Yes	No Yes
	13. Edentia?	No Yes	No Yes	No Yes	No Yes
	14. Do movements disappear in sleep?	No Yes	No Yes	No Yes	No Yes

Appendix B

DDS MEDICAL ADVISORY #2000-2

(Revised #86-3, # 92-1) Monitoring for Abnormal Involuntary Movements (Tardive Dyskinesia) September 2000

PURPOSE: The intent of this advisory is to establish a standardized statewide monitoring procedure to detect abnormal involuntary movements of individuals who take neuroleptic (antipsychotic) medication and to ensure early diagnosis and treatment of Tardive Dyskinesia (TD).

INTRODUCTION: Early detection of Tardive Dyskinesia is critical. The department, therefore, recommends that individuals receive screening for abnormal movement disorders at intervals defined in the following sections, or more frequently as recommended by the prescribing practitioner. Screening should be done by the individual's prescribing practitioners as part of their routine assessments, preferably using the AIMS or DISCUS assessment tools, or minimally, by direct observations. As a result of the screening, the practitioner may subsequently diagnose TD. Additionally, because of the risks associated with the use of neuroleptic medications, IDTs including the prescribing practitioner shall determine the risk versus benefit for each individual taking such medication and shall consider the necessity for continuing the medication.

PROCEDURE:

I. Prescribing practitioners shall assess individuals for abnormal movement disorders as follows:
   A. Any individual not currently taking a neuroleptic medication shall receive a baseline screening under the following circumstances:
      a. upon recommendation for treatment with neuroleptic medication, prior to the administration of the drug or
      b. upon admission to a DDS operated, funded, or licensed facility or program if the individual has a recent history (i.e. within the last 6 months) of previously taking neuroleptic medication, (e.g., campus facilities, CLAs, SL, CTH) but not including individuals receiving respite services).
   B. All individuals currently taking a neuroleptic medication shall be assessed at least once every six months or more frequently as necessary by symptom assessment or determined by the prescribing practitioner.
   C. Any individual currently taking a neuroleptic medication who is newly admitted to a DMR operated, funded, or licensed facility shall have an initial screening within one month of admission.
   D. Any individual whose neuroleptic medication is discontinued shall be screened after the discontinuation at the following intervals:
      a. one month
      b. three months, or
      c. whenever the prescribing practitioner determines and documents that the individual does not have TD
   E. NOTE: In rare instances withdrawal movement disorders can emerge after three months following the discontinuation of a neuroleptic. This is more apt to occur following the use of a long acting, injectable neuroleptic. If movements are observed

after the three-month screening, the individual should be referred to the prescribing practitioner for assessment.

II. All screenings and/or prescribing practitioner assessments, diagnoses and treatment plans shall be documented in the individual's medical record and entered into the department's mainframe computer system (CAMRIS, Client Data, Diagnosis screen)

III. Individuals showing signs of TD should be considered for referral to an appropriate specialist (i.e., neurologist) by the prescribing practitioner for the purpose of evaluation, diagnosis, and treatment recommendations.

IV. When an individual is diagnosed with TD, the following shall occur:
    A. The prescribing practitioner shall notify the individual's case manager or nurse of the diagnosis and treatment recommendations.
    B. The case manager or nurse shall notify the individual's interdisciplinary team (IDT), family or guardian, advocate, and the DDS health service director or training school medical director.
    C. The IDT shall meet within 30 days of the notification and shall ensure that all appropriate recommendations are provided and documented in the individual's health file.

V. If an individual is diagnosed with tardive dyskinesia (TD), the IDT including the prescribing practitioner, shall examine the risk versus benefit for this individual and consider the necessity for continuing the medication.
    A. When a decision is made to discontinue or reduce a neuroleptic medication, the IDT shall refer to DDS Medical Advisory #91-1, Neuroleptic Dose Reduction Protocol, for recommended guidelines.
    B. When a decision is made not to reduce or discontinue the neuroleptic medication, the IDT must ensure that documentation details the following:
        a. the risks versus benefits of continuing the neuroleptic medication and
        b. the consent for the medication clearly states that the individual will continue to take the medication even though TD has been diagnosed.

VI. The central office director of health & clinical services shall aggregate and analyze TD screening and diagnosis data annually as part of the psychotropic medication monitoring system.