CONDUENT

Texas Medicaid

Management of Psychotropic Drugs in Pediatric Patients

Educational RetroDUR Mailing	☐Initial Study ☑Follow – up /Restudy

Executive Summary

Purpose:	To assist prescribers in the evaluation of psychotropic drug therapy in pediatric patients to maximize therapeutic benefits while minimizing risks and adverse outcomes, avoiding unnecessary concomitant therapy, and providing cost-avoidance opportunities.		
Why Issue was Selected:	Psychotropic medications play an important role in the treatment of psychiatric disorders and their utilization in the pediatric population continues to increase.[1,2,3] Second-generation antipsychotics (SGAs) are one class of psychotropic medications with utilization that has come under close scrutiny, especially in the Medicaid population. Despite their efficacy, use of SGAs should be balanced against their risk of adverse effects and lack of long-term safety data in children.[1,2,4] Other areas of concern identified with their use pertain to: dose, duration of therapy, off-label use, lack of monitoring, and polypharmacy.[4,5] Additionally, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act now requires that states implement programs to monitor and manage the appropriate use of antipsychotics in children in the Medicaid program.[6]		
Program Specific Information:	**Performance Indicators**	**Exceptions**	
		FFS	**MCO**
	• High Dose: Oral Antipsychotics	6	552
	• Multiple (2 or more) Oral Antipsychotics	9	359
	• Polypharmacy: ≥ 4 Psychotropic Medications	63	4,685
	• Monitoring of SGAs: Glucose or Hemoglobin A1c	217	11,001
	• Monitoring of SGAs: Lipid Panel	218	11,589
Setting & Population:	All patients <18 years of age receiving targeted psychotropic drug therapy in the past 30 days.		
Types of Intervention:	Cover letter and individual patient profiles		

Main Outcome Measures:	The performance indicators will be re-measured when six months of outcome data are available.
Anticipated Results:	• Minimization of the adverse effects associated with psychotropic medications • Evaluation and discontinuation of unnecessary psychotropic medications • Increased monitoring for metabolic adverse effects associated with SGAs

Performance Indicator #1: High Dose: Oral Antipsychotics

Why has this indicator been selected?	Doses of antipsychotics above the recommended maximum daily dosage may place patients at increased risk for adverse effects, especially extrapyramidal symptoms.[7]
Candidates (denominator):	All patients < 18 years of age receiving oral antipsychotic therapy in the last 30 days.
Exception criteria (numerator):	Candidates who received an oral antipsychotic at a dose above the recommended daily dose as established by the Texas Health and Human Services Commission in the past 30 days (Table 1 and Table 2).[5]

Performance Indicator #2: Multiple (2 or more) Oral Antipsychotics

Why has this indicator been selected?	Adequate research to support the efficacy of concurrent use of multiple antipsychotic agents has not been published and is generally not recommended.[1] Additionally, more complicated regimens may be associated with increased adverse effects, drug regimen nonadherence, and increased costs.[8] Increasing prescriber awareness and encouraging review of duplicate therapy may result in discontinuation of drug therapy that is no longer necessary.[1,4,5]
Candidates (denominator):	All patients < 18 years of age receiving oral antipsychotic therapy in the last 60 days.
Exception criteria (numerator):	Candidates who received two or more oral antipsychotics with greater than 35 days of overlapping therapy in the past 60 days.

Performance Indicator #3: Polypharmacy: ≥ 4 Psychotropic Drugs Concurrently

Why has this indicator been selected?	Patients with mental health disorders are at risk for polypharmacy since combination therapy with multiple medications may be used to treat different disorders in the same patient. However, this may increase the risk of adverse effects, drug-drug interactions, and medication nonadherence.[1,8] Increasing prescriber awareness and encouraging the review of medications used by patients on complex medication regimens may result in discontinuation of drug therapy that is no longer necessary.[1,4,5]
Candidates (denominator):	Patients < 18 years of age receiving psychotropic medication therapy (e.g., anticonvulsants, antidepressants, antipsychotics, anxiolytics, mood stabilizers, non-stimulant attention-deficit/hyperactivity disorder medications, sedative-hypnotics, stimulants) in the last 30 days.
Exception criteria (numerator):	Candidates with therapy consisting of four or more psychotropic drugs for two consecutive 30-day periods in the last 60 days. Exclusions: • Anticonvulsant claims in patients with a history of epilepsy (submitted ICD-10 codes in the past 730 days)

	• Diazepam claims for patients with multiple sclerosis, muscular dystrophy, or cerebral palsy(submitted ICD-10 codes in the past 730 days) • Anxiolytic or sedative-hypnotic claims where the days supply is ≤ 1 day and the quantity is ≤ 4 units (most likely acute/procedure-related use)

Performance Indicator #4: Monitoring of SGAs: Glucose or Hemoglobin A1C

Why has this indicator been selected?	SGAs are associated with metabolic adverse effects. When used for extended periods of time, patients should be monitored for changes in their glycemic control. Baseline and routine laboratory monitoring that includes fasting blood glucose and/or hemoglobin A1C is recommended.[3,5,7,9]
Candidates (denominator):	All patients < 18 years of age receiving SGA therapy for ≥ 45 days in the last 90 days.
Exception criteria (numerator):	Candidates with SGA therapy in the last 30 days who do not have a documented blood glucose and/or hemoglobin A1C (submitted CPT code) in the past year.

Performance Indicator #5: Monitoring of SGAs: Lipid Panel

Why has this indicator been selected?	SGAs are associated with metabolic adverse effects. When used for extended periods of time, patients should be monitored for changes in their lipid profile. Baseline and routine laboratory monitoring that includes a fasting lipid panel is recommended.[3,5,7,9]
Candidates (denominator):	All patients < 18 years of age receiving SGA therapy for ≥ 45 days in the last 90 days.
Exception criteria (numerator):	Candidates with SGA therapy in the last 30 days who do not have a documented lipid panel (submitted CPT code) in the past 2 years.

References

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4. Department of Health and Human Services Office of Inspector General. Second-generation antipsychotic drug use among Medicaid-enrolled children: quality-of-care concerns. March 2015. Available at: https://oig.hhs.gov/oei/reports/oei-07-12-00320.pdf. Accessed December 6, 2021.
5. Texas Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th version), Texas Department of Health and Human Services, June 2019. Available at: https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/facilities-regulation/psychiatric/psychotropic-medication-utilization-parameters.pdf. Accessed December 6, 2021.
6. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018, H. R. 6, 115th Cong. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6. Accessed December 6, 2021.
7. Muench J, Hamer AM. Adverse effects of antipsychotic medications. Am Fam Physician. 2010;81(5):617-622.
8. Halli-Tierney AD, Scarbrough C, Carroll D. Polypharmacy; evaluating risks and deprescribing. Am Fam Physician. 2019;100(1):32-38.

9. American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, North American Association for the Study of Obesity. Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. J Clin Psychiatry. 2004;65:267-72.
10. Drugs@FDA: FDA Approved Drug Products. U.S. Food & Drug Administration website. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed December 6, 2021.

Table 1. Second-Generation Antipsychotics Maximum Doses (excludes injectable dosage forms) [5,10]

Drug (generic)	Drug (brand)	Texas PEFC Literature-Based Maximum Dosage* (mg/day)
aripiprazole	Abilify®, Abilify Discmelt®	Age 4-11 years: 15 Age 12 to 17 years: 30
asenapine	Saphris®	Age 10 to 17 years: 20
brexpiprazole[10]	Rexulti®	Age < 18 years: Not FDA-Approved
cariprazine[10]	Vraylar®	Age < 18 years: Not FDA-Approved
clozapine	Clozaril®, FazaClo®	Age 8-11 years: 300 Age 12 to 17 years: 600
iloperidone[10]	Fanapt®	Age < 18 years: Not FDA-Approved
lumateperone[10]	Caplyta®	Age < 18 years: Not FDA-Approved
lurasidone	Latuda®	Age 10 to 17 years: 80
olanzapine	Zyprexa®, Zyprexa Zydis®	Age 4 to 5 years: 12.5 Age 6 to 17 years: 20
olanzapine/samidorphan[10]	Lybalvi™	Age < 18 years: Not FDA-Approved
paliperidone	Invega®	Age 12 to 17 years: 12
quetiapine	Seroquel®, Seroquel XR®	Age 5 to 9 years: 400 Age 10 to 17 years: 800
risperidone	Risperdal®, Risperdal M-TAB®	Age 4 to 11 years: 3 Age 12 to 17 years: 6
ziprasidone	Geodon®	Age 10 to 17 years: 160

PEFC: Psychiatric Executive Formulation Committee
*Some literature-based maximum dosages published by PEFC are weight-based. For more information, refer to the full publication at: https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/facilities-regulation/psychiatric/psychotropic-medication-utilization-parameters.pdf.

Table 2. First-Generation Antipsychotics Maximum Doses (excludes injectable dosage forms)[5]

Drug (generic)	Drug (brand)	Texas PEFC Literature-Based Maximum Dosage* (mg/day)
chlorpromazine	Thorazine® (brand name discontinued)	Age < 5 years: 40 Age 5-12 years: 75 Age > 12 years: 800
haloperidol	Haldol® (brand name discontinued)	Age 3-12 years: 6 Age > 12 years: 15
perphenazine	Trilafon® (brand name discontinued)	Age > 12 years: 64
pimozide	Orap®	Age 7-12 years: 6 Age ≥ 12 years: 10

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TEXAS
Health and Human Services

Cecile Erwin Young
Executive Commissioner

<<Date>>

«dea»
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RE: Management of Psychotropic Drugs in Pediatric Patients

Dear Dr. <<Name>>:

Thank you for providing quality care for Texas Fee-For-Service (FFS) Medicaid patients. The content of this letter has been approved by the Texas Drug Utilization Review (DUR) Board, whose function is to promote safe and cost-effective drug therapy for Medicaid FFS patients and provide opportunities for continuous improvement of care.

This retrospective claims review was designed to assist you in caring for your pediatric patients receiving psychotropic drugs and to encourage prudent psychotropic utilization in the Texas Medicaid FFS program based on guidance from the Texas Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th version)[1] and relevant clinical literature. Additionally, in 2018, the United States Congress passed "The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment [SUPPORT] for Patients and Communities Act" to promote opioid use disorder prevention, recovery, and treatment. Section 1004 of the SUPPORT Act requires that states implement programs to monitor and manage the appropriate use of antipsychotics in children in the Medicaid program.[2]

Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version) is available at: https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/facilities-regulation/psychiatric/psychotropic-medication-utilization-parameters.pdf

The 2018 SUPPORT Act is available at: https://www.congress.gov/bill/115th-congress/house-bill/6

The total Texas Medicaid FFS performance indicators for all pediatric patients with opportunities for improving the safe and effective use of psychotropic medications are shown in the table below.

Total Texas Medicaid FFS Specific Data

Management of Psychotropic Drugs in Pediatric Patients	Number of Opportunities*
• High Dose: Antipsychotics	6
• Multiple (2 or more) Oral Antipsychotics or Polypharmacy (4 or more Psychotropic Medications)	72
• Monitoring of Second-Generation Antipsychotics: Glucose or Hemoglobin A1c and Lipid Panel	435

*Based on data through 12/17/2021

The enclosed patient profiles reflect one or more of the above issues and are provided as a medical record reminder for when your patients return for their next appointments.

We acknowledge that there may be clinical variables influencing an individual patient's management that are not apparent in claims data. However, we believe the issues identified may assist you in caring for your patient(s). It is possible that your license number may have been inadvertently assigned to the claim as an error at the pharmacy during the billing process. **Also, some prescribed medications as well as some recommended laboratory monitoring or physical examinations may not appear on the patient's profile because they may have been privately purchased or were not billable to Medicaid Services.** We thank you for reviewing this information and caring for Texas Medicaid patients, and we welcome the opportunity to discuss any comments or concerns you may have about our quality management program. Please feel free to call our office at 1-866-923-7208 with questions or concerns. If your mailing address is incorrect, it must be updated through the Texas Medical Board online at http://www.tmb.state.tx.us/page/change-address.

Sincerely,

Medicaid Drug Use Review Board
Vendor Drug Program H-630

Management of Psychotropic Drugs in Pediatric Patients Summary
• **Identify potentially unnecessary utilization of high dose antipsychotic drug regimens:** Doses above recommended daily maximums (Tables 1 and 2) may place patients at increased risk for adverse effects, especially extrapyramidal symptoms. Minimizing use of antipsychotics at doses above recommended daily maximums may decrease adverse outcomes and associated costs.[1,3]
• **Regularly evaluate regimens containing multiple psychotropic agents:** The need for continued psychotropic drug therapy should be assessed on a regular basis because individuals who receive multiple psychotropic medications are at an increased risk for drug-drug or drug-disease interactions, duplicate or unnecessary therapy, medication non-adherence, and hospitalizations. Similarly, adequate research to support the efficacy of concurrent use of multiple antipsychotic agents has not been published and is generally not recommended. Improvements in communication between providers and coordination of care may lessen potential problems.[1,4-6]
• **Encourage appropriate monitoring of second-generation antipsychotic (SGA) therapy:** SGAs are associated with metabolic adverse effects. Because of concerns about their safety risks when used long-term, a monitoring plan should be in place before SGA therapy is initiated. The management of metabolic side effects of SGAs in children and adolescents should include baseline and regular monitoring of weight, blood pressure, blood glucose or hemoglobin A1c, and lipid profiles.[1,3,7]

Table 1. Second-Generation Antipsychotics Maximum Doses (excludes injectable dosage forms) [1,8]

Drug (generic)	Drug (brand)	Texas PEFC Guideline Based Maximum Dosage* (mg/day)
aripiprazole	Abilify®, Abilify Discmelt®	Age 4-11 years: 15 Age 12 to 17 years: 30
asenapine	Saphris®	Age 10 to 17 years: 20
brexpiprazole[8]	Rexulti®	Age < 18 years: Not FDA-Approved
cariprazine[8]	Vraylar®	Age < 18 years: Not FDA-Approved
clozapine	Clozaril®, FazaClo®	Age 8-11 years: 300 Age 12 to 17 years: 600
iloperidone[8]	Fanapt®	Age < 18 years: Not FDA-Approved
lumateperone[8]	Caplyta®	Age < 18 years: Not FDA-Approved
lurasidone	Latuda®	Age 10 to 17 years: 80
olanzapine	Zyprexa®, Zyprexa Zydis®	Age 4 to 5 years: 12.5 Age 6 to 17 years: 20
olanzapine/samidorphan[8]	Lybalvi™	Age < 18 years: Not FDA-Approved
paliperidone	Invega®	Age 12 to 17 years: 12
quetiapine	Seroquel®, Seroquel XR®	Age 5 to 9 years: 400 Age 10 to 17 years: 800
risperidone	Risperdal®, Risperdal M-TAB®	Age 4 to 11 years: 3 Age 12 to 17 years: 6
ziprasidone	Geodon®	Age 10 to 17 years: 160

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Table 2. First-Generation Antipsychotics Maximum Doses (excludes injectable dosage forms)[1]

Drug (generic)	Drug (brand)	Texas PEFC Literature-Based Maximum Dosage* (mg/day)
chlorpromazine	Thorazine® (brand name discontinued)	Age < 5 years: 40 Age 5-12 years: 75 Age > 12 years: 800
haloperidol	Haldol® (brand name discontinued)	Age 3-12 years: 6 Age > 12 years: 15
perphenazine	Trilafon® (brand name discontinued)	Age > 12 years: 64
pimozide	Orap®	Age 7-12 years: 6 Age ≥ 12 years: 10

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*Some literature-based maximum dosages published by PEFC are weight-based. For more information, refer to the full publication at: https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/facilities-regulation/psychiatric/psychotropic-medication-utilization-parameters.pdf.

References

1. Texas Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th version), Texas Department of Health and Human Services, June 2019. Available at: https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/facilities-regulation/psychiatric/psychotropic-medication-utilization-parameters.pdf. Accessed December 6, 2021.
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3. Muench J, Hamer AM. Adverse effects of antipsychotic medications. Am Fam Physician. 2010;81(5):617-622.
4. American Academy of Child and Adolescent Psychiatry. Practice Parameter for the Use of Psychotropic Medications in Children and Adolescents. J Am Acad Child Adolesc Psychiatry. 2009;48(9):961-973. Available at: https://www.jaacap.org/article/S0890-8567(09)60156-8/fulltext. Accessed December 6, 2021.
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External Messages

Flag	Internal Messages	External Messages
8775	Child Psychotropic Polypharmacy	Increased Risk of ADE - Multiple Concurrent Psychotropic Medications: According to submitted pharmacy claims, it appears that your patient has received multiple psychotropic medications concurrently. While combinations of psychotropic medications may be occaisonally necessary, the simultaneous use of numerous agents in children is not supported by the literature. A drug therapy regimen consisting of multiple agents increases the risks for drug-related problems. These include an increased risk of drug-drug or drug-disease interactions, duplicate or unnecessary therapy, and medication nonadherence. Available guidelines recommend further review of psychotropic polypharmacy. Please review your patient's drug therapy regimen and evaluate the continued need for each psychotropic medication.
102380	Second-Generation Antipsychotic Lipid Monitoring	Monitoring of Lipid Levels During Second-Generation Antipsychotic Use: According to submitted pharmacy claims, it appears your patient is receiving a second-generation antipsychotic (SGA) and has not had a lipid panel performed in the past two years. The Consensus Statement on Antipsychotic Drugs, Obesity, and Diabetes states that lipid levels should be evaluated 3 months after initiation of SGA therapy. If lipid values are within normal limits, a repeat test should be performed every 5 years, or more frequently if clinically indicated. Changes in serum lipids (increased total cholesterol, LDL, and triglycerides; decreased HDL) which can occur in concordance with rapid increases in body weight, may not reach a plateau even after one year of therapy. If necessary, please coordinate the appropriate monitoring with other providers who care for your patient.
102381	Second-Generation Antipsychotic Blood Glucose Monitoring	Monitoring of Blood Glucose During Second-Generation Antipsychotic Use: According to submitted pharmacy claims, it appears your patient is receiving a second-generation antipsychotic (SGA) and has not had a blood glucose measurement in the past year. SGAs are associated with metabolic adverse effects, including new onset diabetes and disruption of blood glucose. While different agents appear to have different levels of risks, blood glucose levels should be checked 3 months after SGA initiation and then at least annually. If metabolic adverse events develop, it is recommended to change to an SGA with a lower metabolic risk profile, if possible. If necessary, please coordinate the appropriate monitoring with other providers who care for your patient.
113555	High Dose Second-Generation Antipsychotics: TX	High Dose Second-Generation Antipsychotic Use: According to submitted pharmacy claims, your patient has received one or more second-generation antipsychotics (SGAs) that may not be FDA-approved for your patient or the SGA dose exceeds the maximum approved daily dose recommended by the Texas Health and Human Services Commission Parameters Workgroup of the Psychiatric Executive Formulary Committee Guidelines. There is an increased risk for adverse events with the use of high doses. Please review the need for the non-approved or high dose SGA in your patient and modify drug therapy as appropriate.

External Messages

Flag	Internal Messages	External Messages
116349	Multiple Antipsychotic Use in Kids	Multiple Antipsychotic Use in Kids: According to submitted pharmacy claims, it appears that your patient has received more than two antipsychotic medications concurrently. Although use of this combination may be intentional, the risk of adverse events is significant. Please review your patient's drug therapy regimen and evaluate the continued need for each antipsychotic medication.