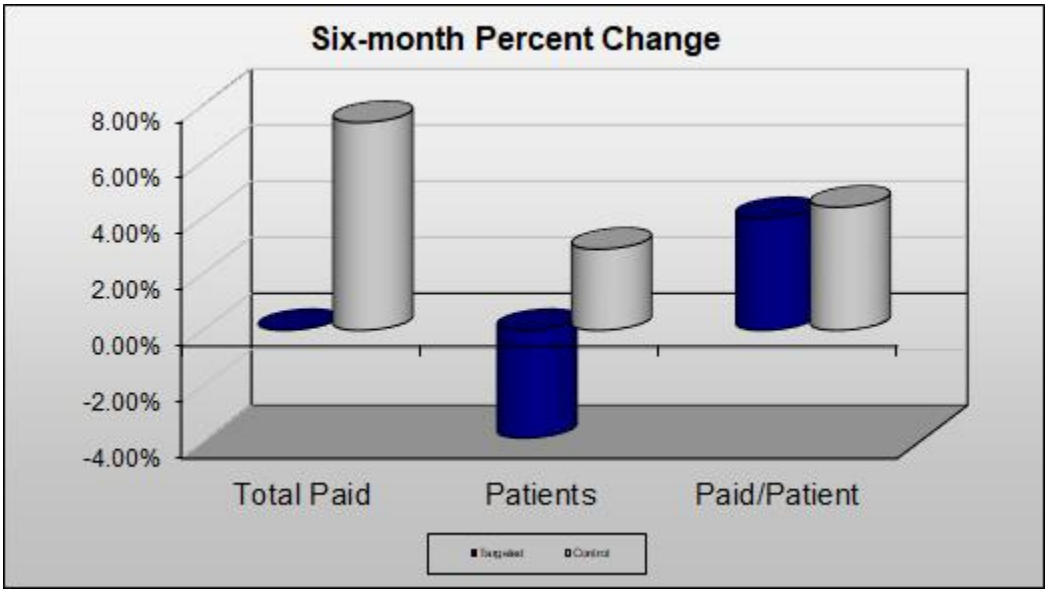
Management of Psychotropic Drugs in Pediatric Patients

Prepared for Texas Medicaid in February 2023

EXECUTIVE SUMMARY

Purpose of Intervention	This intervention is designed to assist prescribers in the evaluation of psychotropic drugs in pediatric patients to maximize therapeutic benefits while minimizing risks and adverse outcomes, avoiding unnecessary concomitant therapy, and providing cost-avoidance opportunities.

Intervention	Intervention Type	Population-based mailing
	Intervention Mailing Date	April 28, 2022
	Pre-intervention Period (Pre)	November 2021 – April 2022
	Post-intervention Period (Post)	June 2022 – November 2022
	Number of Letters Mailed	143
	Number of Targeted Physicians	154



Savings Calculation

*

State Cost Savings Calculation:	
Targeted Group: Actual Psychotropic Drugs Average Cost Per Patient Per Month (Pre)	$163.09
% Change in Control Group from Pre to Post	4.39%
Estimated Psychotropic Drugs Paid Amount Per Targeted Patient Per Month if No Intervention	$170.25
Targeted Group: Psychotropic Drugs Cost Per Patient Per Month (Post)	$169.59
Estimated Cost Savings Per Patient Per Month	$0.66
Total Number of Targeted Panel Patients Served in Post Period	55,620
6-Month Total Savings	$36,709.20
6-Month State General Revenue Funds Savings	$14,687.35
12-Month Total State Savings	$29,374.70

BACKGROUND

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]

Indicator #1: High Dose: Oral Antipsychotics

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 (see Appendices 1 and 2).[5]

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

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.

Indicator #3: Polypharmacy: ≥ 4 Psychotropic Drugs Concurrently

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 drugs (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)

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

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.

Indicator #5: Monitoring of SGAs: Lipid Panel

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.

Indicator #6: SGA Use with New Diabetes and/or Lipid-Lowering Medication

SGAs are associated with metabolic adverse effects, including dyslipidemia, new onset diabetes, and disruption of blood glucose, all of which can occur in concordance with rapid increases in body weight. If metabolic adverse effects occur while on SGA therapy, current guidelines recommend switching to an SGA with a lower metabolic risk profile, if possible.[7]

Candidates (denominator):	All patients < 18 years of age receiving SGA therapy for ≥ 45 days in the last 180 days.
Exception Criteria (numerator):	Candidates who have received an antidiabetic and/or lipid lowering therapy in the past 90 days and not in the previous 91-365 days.

METHODOLOGY

In April 2022, all physicians treating pediatric patients with any of the aforementioned drug-related problems were identified. Based on the distribution of patients/physician, the minimum patient/month threshold was set at one or more patients (i.e., physicians with one or more patients having a drug-related problem received the mailing). Providers were mailed the intervention materials on April 28, 2022.

Operational definitions:

Targeted Group – physicians treating one or more pediatric patients with any of the aforementioned drug-related problem(s) and who received mailed intervention materials *(Section 1.e.1.A Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal).*

Control Group - physicians treating pediatric patients taking a psychotropic drug but did not receive mailed intervention materials *(Section 1.e.1.A Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal).*

Intervention Drugs – Psychotropic Drugs

Pre-Intervention Time Period – November 2021 through April 2022

Post-Intervention Time Period – June 2022 through November 2022

6-month Total Paid – total drug costs can be defined as the total amount of paid intervention drug claims for the above time periods for the prescribers in the control and target groups. The target group consisted of those prescribers who had prescribed intervention drug therapy to more than one Medicaid patients. The control group consisted of all other prescribers who prescribed psychotropic drugs in the designated time periods *(Sections 1.e.1. and 1.e.2 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal).*

Average Number of Panel Patients per Month - during the 6-month pre and post time periods, the number of unique Medicaid patients with a drug claim submitted using a respective provider number was captured each month. Medicaid patients that did not have a drug claim were not counted in the prescriber's panel. The monthly numbers were totaled then divided by six to calculate the monthly average. For example, in Table 1, the physician (with provider number AB123456) had an average of 12 patients with at least one drug claim per month. If a patient had two different claims in June, they would be counted as one patient. By evaluating all

patients seen by a specific physician, changes in prescribing patterns can be evaluated on existing and new patients *(Sections 1.e.1. and 1.e.2 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal).*

Table 1: Average Number of Panel Patients per Month

Provider Number	Month #	Number of Unique Patients with a Drug Claim
AB123456	1	10
	2	10
	3	10
	4	12
	5	13
	6	17
Total		72
Average Number of Panel Patients per Month		12

Average Cost/Patient per Month – this was calculated by dividing the total dollars paid for drug claims during the analysis time period by the total number of Medicaid panel patients during the respective time period. For example, in the targeted group post analysis; there were a total of 9,270 patients who had an intervention drug claim during the six-month review period, for a total of 55,620 patient-months. The total amount of dollars paid for drug claims for these patients during the post analysis was $9,432,795. Dividing these two numbers ($9,432,795/55,620) yields an average cost per patient of $169.59. *(Sections 1.e.1. and 1.e.2 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal).*

$$\text{Average Cost/Patient/per Month} = \frac{\text{6-month Total Amount Paid for Intervention Drugs}}{\text{Average number of Panel Patients per Month}} / \text{(\# Months)}$$

Total State Savings *(Sections 1.e.3 and 1.e.4 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal)***:**

- Intervention Average Cost Savings per Month - the percent change seen in the control group was applied to the intervention group baseline Average Cost per Patient per Month. This amount represents the estimated Amount Paid per Targeted Physician per Patient in the absence of the intervention (i.e., Estimated Paid Amount). The Estimated Paid Amount per Patient per Month was then subtracted from the actual Intervention Target Group Average Cost per Patient per Month to estimate the Average Cost Savings per Patient per Month.
- 6-Month Total Savings - the Intervention Average Cost Savings per Patient per Month was multiplied by the total number of targeted patients served over the 6-month time frame.
- 6-Month State General Revenue Funds Savings= 6-Month Total State Savings X 0.4001.
- Total State Savings = 6-Month State General Revenue Funds Savings X 2.

RESULTS

Population-based intervention

A total of 154 physicians were targeted, and 11 letters were removed due to incomplete addresses. A total of 143 physicians received intervention materials. Table 2 compares the 6-month total amount paid for psychotropic drugs, the total number of patients in each physician's panel per month, and the average cost per patient for the targeted and control groups during the six-month pre and post periods. When comparing the pre-Average Cost per Patient per Month between the targeted and control groups, the cost was approximately $47 lower for the targeted group. This difference may be due to such factors as the targeted group having fewer patients prescribed psychotropic drugs per physician or that associated average psychotropic drug costs are inherently lower in the targeted group.

The target group saw a 0.00% decrease in the amount paid for intervention-related drugs while the control group saw a 7.41% increase. Additionally, the average number of monthly patients for the physician's panel decreased 3.84% for the target group and increased 2.89% for the control group. To control for changes in case load variance (i.e., the change in the number of panel patients) between the two groups, the average cost per patient was also calculated. Total amount paid and number of panel patient trends led to a 3.99% increase in average cost per patient per month in the targeted group and a 4.39% increase for the control group.

Table 2: Six-Month Trends for Overall Targeted vs Control Group

Group	Psychotropic Drugs -- Six Months Total Paid Pre/Post			Average Number of Panel Patients per Month			Psychotropic Drugs Average Cost per Patient per Month		
	Pre	Post	Change	Pre	Post	Change	Pre	Post	Change
Targeted	$9,433,091	$9,432,795	0.00%	9,640	9,270	-3.84%	$163.09	$169.59	3.99%
Control	$83,939,714	$90,160,058	7.41%	66,581	68,507	2.89%	$210.12	$219.35	4.39%

Table 3 shows the Intervention Average Cost Savings per Patient per Month and the savings calculations. Had the intervention not been mailed, the targeted pre average cost per patient per month would have increased 4.39% from $163.09 to $170.25. The net difference between the actual and estimated average cost/patient for the targeted group was $0.66. Based on 55,620 targeted patients served during the six-month post period, the six-month Total Savings and Total State Savings were $36,709.20 and $14,687.35 respectively. Over a twelve-month period, the Total State Savings was $29,374.70.

Table 3: Overall Intervention Average Cost Savings

State Cost Savings Calculation:	
Targeted Group: Actual Psychotropic Drugs Average Cost Per Patient Per Month (Pre)	$163.09
% Change in Control Group from Pre to Post	4.39%
Estimated Psychotropic Drugs Paid Amount Per Targeted Patient Per Month if No Intervention	$170.25
Targeted Group: Psychotropic Drugs Cost Per Patient Per Month (Post)	$169.59
Estimated Cost Savings Per Patient Per Month	$0.66
Total Number of Targeted Panel Patients Served in Post Period	55,620
6-Month Total Savings	$36,709.20
6-Month State General Revenue Funds Savings	$14,687.35
12-Month Total State Savings	$29,374.70

Table 4 shows the changes in the clinical indicators based on the intervention. The overall change in indicators is a decrease of 26.4%.

Table 4: Overall Intervention Changes in Clinical Indicators

Clinical Indicators			
	Baseline	Nov-2022	% Change
Indicator 1: High Dose: Oral Antipsychotics	7	4	-42.9%
Indicators 2 and 3: Multiple (2 or more) Oral Antipsychotics or Polypharmacy (4 or more Psychotropic Medications)	51	34	-33.3%
Indicators 4 and 5: Monitoring of Second-Generation Antipsychotics: Glucose or Hemoglobin A1c/Lipid Panel	394	295	-25.1%
Indicator 6: Second-Generation Antipsychotic Use with New Diabetes and/or Lipid-lowering Medication	2	1	-50.0%
Total	454	334	-26.4%

CONCLUSIONS

This population-based intervention was successful in encouraging appropriate use of psychotropic drugs for pediatric patients and providing prescribers with educational tools to better communicate with their patients' issues regarding appropriate treatment. This resulted in an economic impact on Texas Medicaid's pharmacy program expenditures, with a calculated twelve-month overall savings of $73,418.40 and savings to the State of $29,374.70 and a decrease in clinical indicators of 26.4%.

REFERENCES

1. American Academy of Child and Adolescent Psychiatry. Practice parameter on 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.
2. Crystal SC, Olfson M, Huang C, et al. Broadened use of atypical antipsychotic drugs: safety, effectiveness, and policy challenges. Health Aff (Millwood). 2009;28(5):w770-w781. doi:10.1377/hlthaff.28.5.w770.
3. Centers for Medicare & Medicaid Services, Medicaid Integrity Group. Atypical antipsychotic medications: use in pediatric patients. October 2015. Available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-pediatric-factsheet11-14.pdf. Accessed December 6, 2021.
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.

Appendix 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 13-17 years with schizophrenia: 4 Age < 18 years with other indications: 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.

Appendix 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

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.