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A Review of State Medicaid Approaches on Child Antipsychotic Monitoring Programs

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Arkansas

Arkansas Medicaid Summary of Antipsychotic Edits for All Children Less Than 18 Years of Age

Antipsychotic drug utilization for children < 18 years of age has *substantially decreased* in both the foster care and non-foster care population in AR Medicaid.

From July 2008 to July 2015	***OVERALL DECREASED* UTILIZATION OF ANTIPSYCHOTIC DRUGS BY:**
Foster care < 6 years of age	85.70%
Foster care 6 - 12 years of age	36.03%
Foster care 13-17 years of age	13.50%
NON-Foster care < 6 years of age	94.20%
NON-Foster care 6 - 12 years of age	53.60%
NON-Foster care 13-17 years of age	26.50%

The above chart is a summary of the percent decrease in the number of AR Medicaid children < 18 years of age receiving an ANTIPSYCHOTIC DRUG that compares the month of July 2008 to the month of July 2015. To avoid the sentinel effect, the month of July 2008 was selected for the comparison because it was one year prior to any PA edits implemented for antipsychotic agents prescribed to children less than 18 years of age. Below is a summary of the edits implemented beginning July 2009 to current (2015).

The number of new prescriptions of a 2nd generation antipsychotic agents in children <18 years of age in AR- Medicaid *doubled* between 2001 and 2005. All educational efforts to reduce the use of antipsychotic agents in children, including a 3 year project with Comprehensive NeuroScience (CNS) working with behavioral health and Medicaid, failed. High profile cases regarding child deaths in other states due to antipsychotic drugs started making the Medicaid news in Arkansas in 2006 and 2007. In July 2008, AR Medicaid did not have any type of edit or limitations in the system for antipsychotic agents for children < 18 years of age and utilization continued to increase. Something had to change.

In about January 2008, the Medicaid pharmacy program staff began working with 2 psychiatrists, the medical director at the Division of Behavioral Health Services (DBHS) and a child psychiatrist with DBHS, to review utilization of antipsychotic agents in children < 18 years of age and began developing the first set of edits for antipsychotic agents and focused on children. As the work progressed, additional stakeholders were brought in to the discussions for input and "buy-in". Based on the utilization pattern, the focus of the edits was on High Doses, Therapeutic Duplication (TD), and Use In Children <5 Years of Age.

The DUR Board reviewed and approved the proposals in April 2009. In July 2009 the first prior authorization criteria on antipsychotic agents were implemented, which included Manual Review PA, performed by specific child psychiatrists, for 1) requests for an antipsychotic agent for children below the lower age limit of 5 years of age, 2) requests for therapeutic duplication of an additional antipsychotic agent for any age child, 3) requests for a dose that was higher than the allowed dose for the drug for the specific age group. The age groups were broken into 3 groups (< 5 years of age, 5-12 years, 13-17 years); 4) requests for doses above the maximum dose edits implemented for the alpha agonists, clonidine and guanfacine, and 5) requests for therapeutic duplication of the alpha agonists, clonidine with guanfacine. There were 4 child psychiatrists employed at DBHS/ASH (AR State Hospital)

who volunteered their time and rotated call to review all requests that required a Manual Review PA as noted above.

Initially there was a significant decrease in utilization in the < 5 years of age group. This is the age group that required a Manual Review PA by a child psychiatrist and the prescriber was required to fax in a letter explaining the medical necessity along with chart notes to substantiate the request. In the next 2 age groups, the 5-12 years of age and the 13-17 years of age, there was a small decrease in the number of children receiving an antipsychotic agent, about 10%. The number of children receiving more than 1 antipsychotic drug decreased due to the denial by the therapeutic duplication point-of-sale edits, although the overall number of children age 5 years and older receiving antipsychotic medications did not decrease significantly. The prescribers just learned to stay within the allowed doses for the claims to go through at POS and did not prescribe additional antipsychotic agents that would require a manual review by the child psychiatrist.

In November 2011, while the therapeutic duplication edits remained in place, the pharmacy program implemented additional edits on all oral antipsychotic agents for children: 1) the lower age limit that required a Manual Review PA was increased to < 6 years of age; 2) the age groups for the dose edits were revised to < 6 years, 6-12 years, and 13-17 years; 3) the prescriber was required to submit a copy of the signed informed consent for the specific antipsychotic agent and was required to monitor metabolic labs for fasting glucose and a lipid panel. The PA requirements of the signed informed consent and the metabolic lab monitoring were implemented in 2 phases: 1) "new start" patient, defined as a child who had not received an antipsychotic agent in previous 6 months, was implemented in Nov 2011, and 2) "established patients", defined as children who were currently receiving an antipsychotic agent, implemented in June 2012. To initiate the PA for a "new start" patient, before the antipsychotic agent would pay at point-of-sale, the prescriber was required to fax a copy of the signed informed consent for the antipsychotic agent and the copy of the metabolic lab results to the PA Call Center. A one-time 6-month manual PA was entered into the system for the requested antipsychotic agent and would continue as long as the CPT codes for the metabolic labs were found in the system every 6 months and the chemical entity of the antipsychotic agent did not change. In June 2012, the second phase was implemented for the "established" patients who were currently receiving an antipsychotic agent. For the "established" patients, the prescriber did not have to submit a signed informed consent unless the prescriber changed agents (e.g., Abilify to Risperdal). However, in order for the claims to continue paying at point-of-sale without a phone call for a PA, new CPT codes for the appropriate metabolic labs were required to be in the Medicaid system every 6 months for point-of-sale approval of the drug. If the prescriber changed the antipsychotic agent, the drug claim would reject at point-of-sale until a new signed informed consent was faxed to the PA Call Center and the PA process started again.

In January 2013, the Pharmacy Program made a change regarding the child psychiatrists who reviewed the manual review PA requests. Medicaid hired 1 ½ FTE psychiatrists to the Medicaid pharmacy program. The ½ time psychiatrist is a child psychiatrist who reviews everything that requires a manual review PA regarding antipsychotic agents for children < 18 years of age (e.g., TD requests, high dose requests, manual review for < 6 years of age, LA injectable antipsychotic agents). Having one child psychiatrist review all manual review PA requests provided consistency to the program. The 1 FTE psychiatrist is the "senior" psychiatrist may review the more difficult cases or assist/consult with the child psychiatrist if needed, and he has additional duties outside of the pharmacy program that involve mental health, including consulting with the DCFS (Division of Children and Family Services (Foster care) staff regarding the use of psychotropic medications in foster children. Either psychiatrist will call the

requesting prescriber on the manual review PA cases or the difficult cases and question the use of the antipsychotic(s), or may refer difficult cases to the System of Care (SOC) clinical staff and request their assistance in working with the prescribing provider and family of the child to determine if the treatment plans are adequate to address the child's psychosocial issues. The POS edits do allow claims to process without looking at the diagnosis as long as the dose does not exceed the allowed dose for the age and there are no therapeutic duplications. However, when the child psychiatrist is reviewing a request manually she will look at the whole picture, including diagnosis and target symptoms being treated, and will question if the antipsychotic drug is appropriate treatment for the child and can (and has) denied requests for the antipsychotic agent.

In July 2013, additional edits were added to antipsychotic agents prescribed to children: 1) Manual Review PA to all long-acting (LA) or depot injectable antipsychotic agents for all children < 18 years of age; 2) therapeutic duplication (TD) edits were added between LA/depot injectable antipsychotic agents and oral agents so the therapeutic duplication claim could not go through without a Manual Review PA (e.g., if prescriber received a PA for a LA injectable antipsychotic agent, then prescriber could not add an oral later).

In October 2013, additional edits were added to antipsychotic agents for children: 1) dose edits for age were added to all 1st general antipsychotic agents for children < 18 years of age; 2) the dose edits for age were added to the newer agents (Fanapt®, Latuda®, and Saphris®); 3) the dose edits for age groups were changed from 3 age groups to 4 age groups (from < 6 years, 6-12 years, 13-17 years to < 6 years, 6-9 years, 10-12 years, 13-17 years), and 4) some of the maximum dose edits were reduced for the 2nd generation antipsychotic agents. Also in October 2013, manual review PA was added to the off-label use of naltrexone in children and the off-label use of all Alzheimer's drugs in children. The Medicaid psychiatrists also developed an educational intervention letter with the RDUR contractor to mail to prescribing providers regarding children who are receiving an antipsychotic agent and the child has a trauma diagnosis in medical history with no other mental health diagnosis to support its use.

Beginning February 16, 2016, the lower age limit that will require a Manual Review PA will be increased again by one year to < 7 years of age and these requests will be reviewed by the child psychiatrist. The manual review for the 6 year old children will begin with "new starts", meaning the child has not received an antipsychotic drug in the previous 6 months or the prescriber is changing the chemical entity of the antipsychotic drugs in the "established" patients.

<u>What did not work:</u>

- Simple educational / intervention letters mailed to prescribers did not have any type of long-term effects or reduction in prescribing habits;

<u>What worked well:</u>

- The requirement that the prescriber must fax a signed and dated informed consent when starting a new antipsychotic agent that stated the targeted symptoms being treated by the antipsychotic agent and the adverse effects of antipsychotic agents and signed by the prescriber and the parent/guardian seems to have had a dramatic effect in reducing the number of children in all age groups receiving an antipsychotic agent.

- The Manual Review PA in the younger ages dramatically reduced the number of young children receiving an antipsychotic agent with reductions of 94% (non-foster care) and 86% (foster care). Although the decrease in antipsychotic utilization is continued in the older age groups, the

reduction is not to the same extent as the manual review PA age group. The older children do show a decrease in antipsychotic utilization in the non-foster care 6 years – 12 years age group of almost 54% and a decrease in antipsychotic utilization in the foster care 6 years – 12 years age group of 36%, but that may also be due to the required signed informed consent form.

- Manual Review PA for all age children for therapeutic duplication requests of additional antipsychotic agent and requests for doses higher than the doses allowed in the point of sale criteria.

The top 3 outcomes of the project:

- Significant decrease in the number of children < 18 years of age receiving an antipsychotic agent for all age groups in both foster care and non-foster care children, but especially in the manual review PA age group where the < 6 year old non-foster care children receiving an antipsychotic agent *decreased by 94%*, and the < 6 year old Foster care children receiving an antipsychotic agent *decreased by almost 86%*;

- Using a child-psychiatrist for Manual Review PA has eliminated inappropriate therapeutic duplication and the high doses of antipsychotic agents in children, and improved patient safety for these children;

- The 2 Medicaid psychiatrists are able to identify difficult cases and consult with the prescribers regarding therapy, refer the case(s) to the System of Care, and ensure that the children receive behavioral therapy counseling when necessary;

Future Plans:

- Raise the lower age limit that requires a Manual Review PA by the Medicaid child psychiatrist. A one year increase (to "< 7 years of age", or 6 years old) will be implemented on February 16, 2016.

- Hire another ½ FTE child psychiatrist 2016 spring/early summer. Because we have seen such significant decreases in the manual review PA group reducing the number of children < 6 years of age receiving an antipsychotic agent, we will take the proposal to the April 2016 DUR Board meeting to increase the lower age limit again, beginning in July 2016, for the manual review PA of antipsychotic agents to include the 7 year olds ("< 8 years of age"), and the 8 year olds ("< 9 years of age") when the 2nd child psychiatrist is hired. We anticipate additional "savings" due to a decrease in the number of children receiving an antipsychotic agent and the resulting decrease in the antipsychotic claim counts. The decrease in antipsychotic expenditures will more than justify hiring an additional ½ FTE child psychiatrist.

- Continue increasing the lower age limit that will require a Manual Review PA for any antipsychotic agent to < 12 years of age (11 year olds) or possibly go up to < 13 years of age (12 year olds) so that all requests for an antipsychotic agent for pre-teens are reviewed manually by a child psychiatrist.

We believe the edits currently in place for the use of antipsychotic agents in children < 18 years of age, along with the manual review by the child psychiatrists for PA requests, limits inappropriate use and excessive use of antipsychotic agents in children, which will promote the health and well-being of the AR Medicaid children. This will also raise awareness about the importance of using behavioral therapy

counselling, rather than just using antipsychotic agents, and will help address psychosocial issues in the children.

California

California Medicaid (Medi-Cal): Improving Psychotropic Medication Use for Children and Youth in Foster Care

January 2016

Background

Because children in foster care often have significant emotional and behavioral challenges as a result of maltreatment and trauma, a high proportion of them receive psychotropic medications. In recent years, several federal laws and regulations require states to develop plan for ongoing oversight of psychotropic medication use:

1. Fostering Connections to Success and Increasing Adoptions Act of 2008 (PL 110-351) requires states to develop a plan for the ongoing and oversight of the provision of health care services, including "oversight of prescription medicines".
2. The Child and Family Services Improvement and Innovation Act of 2011 (PL 112-34) amended the law by adding to the requirements for the health care oversight and coordination plan. Whereas the law had previously required that the plan address "oversight of prescription medicines," the new provision builds on this requirement by specifying that the plan must include an outline of "protocols for the appropriate use and monitoring of psychotropic medications." Additionally, the law requires that the health care oversight and coordination plan outline "how health needs identified through screenings will be monitored and treated, including emotional trauma associated with a child's maltreatment and removal from home".

In 2012, recognizing effective oversight of psychotropic medication use requires high level of collaboration between agencies providing services to these children, the Administration on Children and Families (ACF), in collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Centers for Medicare and Medicaid Services (CMS), convened a two-day meeting "Because Minds Matter" Summit, to bring together representatives from State Child Welfare, Medicaid and mental health systems from 50 states, to work together to strengthen oversight and monitoring of psychotropic medications for this population.

California sent six delegates to attend the summit. The team consists of representatives from Pharmacy, Mental Health and Child Welfare Services. Based on previous work in California and new resources provided at the summit, the team developed a framework for a state-wide collaborative quality improvement project (QIP) to improve psychotropic medication use. The team also recognizes improving psychotropic medication for foster care children would also benefit non-foster care children. In designing system or policy improvement, when applicable, improvement would also extend and apply to all Medi-Cal children populations.

Previous Studies

California is one of 16 states participated in a study of psychotropic medications. It is a collaboration of the 16 states, the Medicaid Medical Directors Learning Network (MMDLN) and Rutgers CERTs (Center for Education and Research in Mental Health Therapeutics). The link to the study report and resource guide is as follows:

http://rci.rutgers.edu/~cseap/MMDLNAPKIDS.html

State-Wide Collaborative Quality Improvement Project (QIP)

Organizational Structure and Purpose

In October 2012, the Department of Health Care Services (DHCS) and the California Department of Social Services (CDSS) convened a statewide Quality Improvement Project (QIP) to design, pilot and evaluate effective practices to improve psychotropic medication use among children and youth in foster care. The QIP is managed and coordinated by the Project Team staff from both departments. The team developed a charter and conducted an initial stakeholders' analysis. Over seventy stakeholders representing about 35 stakeholder organizations attended the kick off meeting. Three workgroups were established:

- Clinical Workgroup
- Date & Technology Workgroup
- Family & Youth Education Workgroup

Each workgroup holds regularly meetings to set goals, timeline and deliverables. As work progresses, the workgroups present updates and progress reports to the Expert Panel, which consists of subject matter experts. The Expert Panel meets quarterly to review work in progress and to provide recommendation and feedback.

Updates and progress reports are also presented to the California Health and Human Services (CHHS) Child Welfare Council, at the quarterly Council meetings.

Information Dissemination

DHCS established a webpage dedicated to the state-wide QIP. Information posted on this webpage includes background, resources, reports, event dates, meeting agendas and contact information. The link to the webpage is:

www.dhcs.ca.gov/services/Pages/qip.aspx

2015-2016 Deliverables:

Clinical Workgroup:

1. Established "The California Guidelines for the Use of Psychotropic Medication in Children and Youth in Foster Care", published in April, 2015.
2. In development is a "Guidelines Dissemination Plan" and a "Guidelines Training and Education Plan" which consists of training modules slides and webinars.

The California Guidelines and appendices are available on the QIP dedicated webpage:

http://www.dhcs.ca.gov/services/Pages/qip-clinical-w.aspx

Data & Technology Workgroup:

1. Established a Data Use Agreement (DUA) between DHCS and CDSS. The agreement enables sharing and combining pharmacy, administrative and child welfare services data and including court authorization information to provide meaning use.
2. Established a global data sharing agreement between CDSS and counties. This agreement enables sharing of data to counties and to providers.
3. In development is a set of performance measures for quality improvement tracking and trending purposes.

Youth & Family Education Workgroup**:**

1. Produced a brochure for foster care youth: a) "Bill of Rights" and b) "Questions to Ask about Your Medications".
2. In development is a "Wellness Workbook" suitable for adolescents.

California Legislations: SB 238, SB 484 & SB 319

On October 6, 2015 Governor Brown approved a package of legislations on psychotropic medication use:

1. SB 238 (Mitchell): Foster care: psychotropic medication.

In summary, the bill would provide care givers and professionals, including child welfare services workers and social workers, with the data, information and tools needed to provide care safely to foster care children. The California Department of Social Services (CDSS), in consultation with the Department of Health Care Services (DHCS), to develop monthly reports on foster care children receiving psychotropic medications and to provide data to counties. CDSS to provide updated training on use of psychotropic medications to child welfare services workers and other professionals. The Judicial Council to update forms and rules (JV 220 process).

2. SB 484 (Beall): Juvenile.

The bill requires CDSS to compile and post on internet website specified information on psychotropic medication use in group homes, and requires CDSS, in consultation with specified associations and other stakeholders to develop additional performance standards and outcome measures to determine effectiveness of care and supervision in group homes, and to include Healthcare Effectiveness Data and Information Set (HEDIS) psychotropic medication measures in reports.

3. SB 319 (Beall): Child welfare services: public health nursing

The bill authorizes a foster care public health nurse, as part of his or her requirement to participate in medical care planning and coordinating for a child, to monitor and oversee the child's use of psychotropic medications. It also authorizes the disclosure of health care and mental health care information to a foster care public health nurse, as specified. The bill would provide training to public health nurses specific to monitoring and oversight of psychotropic medication use.

Additional information is available at:
https://leginfo.legislature.ca.gov/faces/billHistoryClient.xhtml?bill_id=201520160SB238

The QIP is forming a new workgroup to implement the legislations.

Medi-Cal Pharmacy Policy

Medi-Cal has always required an approved Treatment Authorization Request (TAR) for the use of any drugs, including antipsychotics for non-FDA approved indications.

Since June 1, 2006, Medi-Cal requires (TAR) for any antipsychotic use in children less than 6 years of age.

Since May 1, 2012, antipsychotic use for Medi-Cal beneficiaries 6 – 17 years of age has been restricted to the use of one antipsychotic, except during titration period; and, within this age group, concurrent use of two or more antipsychotics has required an approved TAR.

As of October 1, 2014, **any** use of antipsychotics for Medi-Cal beneficiaries 0 – 17 years of age requires an approved TAR. For additional information about this policy, a frequently asked questions document is available on the California Department of Health Care Services Pharmacy Benefits Division website at:
http://www.dhcs.ca.gov/services/Pages/PharmacyBenefits2.aspx

A TAR supplemental form is available on the same website at:

http://www.dhcs.ca.gov/provgovpart/Documents/PharmacyBenefits/Antipsych/Antipsych_TAR_Supplement.pdf

Drug Utilization Review (DUR) Program

In collaboration with the California Department of Social Services and the Department of Health Care Services, the DUR Board aims to improve safe and appropriate prescribing and monitoring of psychotropic medication use for all children and adolescents, including those in foster care. The DUR Board advises and provides recommendations regarding draft guidelines for improving oversight and monitoring of psychotropic medication use for children and youth in foster care and optimal prescribing standards to engage prescribers to use minimum number of psychotropic medications, at the lowest appropriate dosage and at the appropriate age.

A DUR educational bulletin entitled, "*Improving the Quality of Care: Antipsychotic Use in Children and Adolescents*", was developed in collaboration with the Foster Care Quality Improvement Project Clinical Workgroup. In addition to reviewing current evidence on appropriate use of psychotropic medications in children and adolescents, the educational bulletin reviewed a policy change to require an approved *Treatment Authorization Request* for any prescriptions for antipsychotic medications for the population 0 through 17 years of age. Links to additional resources for providers, including the FAQ document for the policy change, were provided in the bulletin. The link to the bulletin is at:
http://files.medi-cal.ca.gov/pubsdoco/dur/articles/dured_23511.01.pdf

In addition, DHCS and the DUR Board supported educational outreach to providers to improve metabolic monitoring rates among children and adolescents prescribed antipsychotic medication. Intervention letters were sent to all prescribers of antipsychotic medications to children and adolescents between 0 and 17 years of age who did not have medical claim for metabolic monitoring for over one year. A summary of the intervention results will be available in May 2016.

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DUR Study: Antipsychotic Use among Children and Adolescents in the Medi-Cal Fee- for-Service Population

A retrospective cohort study was conducted to evaluate two of the HEDIS performance measures for antipsychotic medication use among children and adolescents (APM and APC) in the Medi-Cal fee-for-service population, using medical and pharmacy claims data. Study population selection criteria were adapted from HEDIS performance indicators and included all Medi-Cal beneficiaries who met the following inclusion criteria:

- Continuously eligible beneficiary enrolled in the Medi-Cal fee-for-service program for the duration of the measurement year (October 1, 2013, through September 30, 2014)
- Age 1 – 17 years as of September 30, 2014
- At least one paid pharmacy claim for an antipsychotic medication during the measurement year

Descriptive statistics were used to summarize beneficiary characteristics and HEDIS rates.

Data were stratified into three age groups, per HEDIS specifications.

Results

A total of 6,688 Medi-Cal fee-for-service beneficiaries met the inclusion criteria and within this group there were a total of 58,598 paid claims for an antipsychotic medication. Demographic characteristics of the beneficiaries are listed in Table 2, including gender and race/ethnicity.

Table 2. Demographic Characteristics of the Medi-Cal Fee-for-Service Study Population.

	1 – 5 years	6 – 11 years	12 – 17 years
Overall population (n=6,688)	82 (1%)	2,038 (30%)	4,568 (68%)
Gender			
• Male (n=4,349; 65%)	61 (74%)	1,409 (69%)	2,879 (63%)
• Female (n=2,339; 35%)	21 (26%)	629 (31%)	1,689 (37%)
Race/Ethnicity			
• White/Caucasian, non-Hispanic (n=3,173; 47%)	29 (35%)	924 (45%)	2,220 (49%)
• All other races/ethnicities (n=3,515; 53%)	53 (65%)	1,114 (55%)	2,348 (51%)

The study population was almost two-thirds male (n=4,439; 65%) and almost half of these beneficiaries identified as White/Caucasian race, non-Hispanic ethnicity (n=3,173; 47%).

Overall rates for APM (Table 3) and APC (Table 4), as well as rates stratified by the three age groups are listed below. Of note, for the APM calculation, a total of 675 beneficiaries were excluded as they only had one paid claim for an antipsychotic medication during the measurement year (leaving a

denominator of 6,013 beneficiaries) and, for the APC calculation, a total of 1,313 beneficiaries were excluded as they had less than 90 days of continuous antipsychotic medication treatment during the measurement year (leaving a denominator of 5,375 beneficiaries).

Table 3. Metabolic Monitoring in Children and Adolescents with ≥ 2 Paid Claims for Antipsychotic Medications during the Measurement Year (October 1, 2013, through September 30, 2014)

Age Group	**Numerator** Children and adolescents with ≥ 1 test for **both** blood glucose/HbA1C and LDL-C/cholesterol	**Denominator** Children and adolescents with ≥ 2 paid claims for antipsychotic medications	Percentage of children and adolescents with ≥ 2 paid claims for antipsychotic medications and metabolic testing
1 – 5 years	18	68	26.5%
6 – 11 years	575	1,838	31.3%
12 – 17 years	1,653	4,107	40.2%
TOTAL	**2,246**	**6,013**	**37.4%**

Although the 37.4 percent figure calculated using HEDIS measure parameters gives the rate at which both tests were completed (blood glucose or HbA1C and LDL-C or cholesterol), individual testing rates were also calculated for the study population. The rate of glucose or Hb1Ac monitoring (n=3,151; 52.4 percent), was much greater than LDL-C or cholesterol monitoring (n=2,279; 37.9 percent), suggesting there is an opportunity for outreach to providers, who could raise the metabolic monitoring rate calculated in the HEDIS measure by ordering both tests at the same time.

Of note, the HEDIS documentation for this measure included an analysis using the 2008 Medicaid Analytic eXtract (MAX) data files. These data showed an average metabolic monitoring rate across data collected from 11 states of 18.5 percent (range: 4.8 percent – 36.2 percent), more than half the rate found in the Medi-Cal fee-for-service population.

Aligning DUR Program with DHCS Quality Strategy

Quality improvement is a key component in helping DHCS to achieve the Triple Aim: Improving the patient experience; improving the health of populations; and reducing the per capita cost of health care. DHCS' commitment to quality improvement is summarized in the DHCS Strategy for Quality Improvement in Health Care (Quality Strategy), which describes the goals, priorities, and program activities. The Quality Strategy also aligns with the National Quality Strategy.

The mission of the Medi-Cal Drug Utilization Review (DUR) Program is to facilitate the appropriate and cost effective delivery of health care to all beneficiaries. By aligning with the DHCS Quality Strategy, and collaborating with QIPs, we are creating the synergism that leads to improving DUR program

effectiveness. This requires ongoing and sustaining efforts, and we are excited to see some very positive results in our collaborative efforts with the Foster Care Psychotropic Medication QIP.

Illinois

Illinois (IL) Medicaid Fee For Service (FFS) – Psychotropic Medication Use in Children January 2016

The IL Medicaid FFS Pharmacy Program has had the Atypical Antipsychotic drug class on the Preferred Drug List since October 2005, requiring prior authorization (PA) for non-preferred and special formulations (injectable, orally disintegrating, liquid) of preferred agents. In October 2006, the UIC Prior Authorization (UIC-PA) Group was contracted to develop criteria and adjudicate PA requests for IL Medicaid. The UIC-PA Group is made up of 10 Clinical Pharmacist FTEs, 1 Technician FTE, and 1 Medical Director FTE. In August of 2009, edits were put in place to require PA for all medications in this class for children <8 y/o. A specific PA form was developed and criteria created; requests are all evaluated by a clinical pharmacist in the UIC-PA Group and escalated to a UIC-PA Medical Director if necessary. The form is available at: http://www.illinois.gov/hfs/SiteCollectionDocuments/hfsweb006.pdf . Currently, approvals are given for a 1-year period.

Since September 2008, a Child and Adolescent Behavior Health Consultation Program has been available for prescribers who want to consult with a child and adolescent psychiatrist regarding their patients. This service is available at no charge. The website is: www.psych.uic.edu/DOCASSIST . IL DocAssist is funded by the IL Department of Healthcare and Family Services (HFS), and the IL Department of Human Services, Division of Mental Health (DMH). In FY15 DocAssist provided 2,694 consultations to 562 unique providers and conducted 41 workshops where they trained 723 providers.

Children in Foster Care:

Children in foster care in IL are required to get consent for all psychotropic medications through the Department of Children and Family Services (DCFS). DCFS established the Centralized Psychotropic Medication Consent Program in the Office of the Guardian to provide consent for the prescription of psychotropic medications. Requests are submitted electronically by prescribers through DCFS and reviewed by independent experts. Since 1993, The University of Illinois at Chicago's Clinical Services Psychopharmacology (CSP) Group has been contracted to provide independent review of psychotropic medication requests through collaboration with DCFS. Their website is: http://www.psych.uic.edu/csp/.

The CSP Group is made up of 4 Psychiatrist FTEs, 2.5 RN FTEs, and 5 Research Technician FTEs. Consent is required for alpha agonists, antidepressants, anti-enuretics, antihistamines, anti-parkinson agents, 1st and 2nd generation antipsychotics, benzodiazepines/anxiolytics, hypnotics, beta-blockers (propranolol), mood stabilizers/anticonvulsants, psychostimulants and some miscellaneous agents. Information on the medications CSP provides consultation for and criteria is available at http://www.psych.uic.edu/csp/medication-info/medical-professionals .

Prescribers submit psychotropic medication consent requests electronically through the DCFS website. The form is available at: http://www.illinois.gov/dcfs/aboutus/notices/Documents/cfs431a.pdf . Once the CSP Group has determined the status of the consent, their recommendations are sent to DCFS for final approval. Approximately 1,200 consent requests are processed monthly. Consent is granted for a

maximum of 180 days at a time. Data analysis is done on a monthly, quarterly, and annual basis by CSP consultants.

UIC-PA Group collaboration with DCFS:

Prior to 2013 the UIC-PA Group relied on prescribers to inform them if DCFS Consent had been received for a psychotropic medication request for a child in foster care. Very few consent forms were voluntarily submitted. Primarily, DCFS consent information was communicated to UIC-PA as a result of a PA request for a medication being denied for a client and the prescriber contacting UIC-PA to appeal the decision and supplying the consent at that time. UIC-PA began working in conjunction with the CSP Group to ensure consents were being obtained by prescribers and to streamline the process so that once a DCFS consent was received the medication would not reject for needing a PA at the pharmacy. Through collaboration with the CSP Group, UIC-PA updated the CSP Group's medication lists, educated them on IL Medicaid preferred vs. non-preferred options, and determined which eligibility codes in the IL Medicaid system required consent through DCFS.

UIC-PA began checking client eligibility on every request for a psychotropic medication in children <18y/o. This process allowed UIC-PA to inform prescribers that consent was necessary from DCFS for the medications they were prescribing if they had not already done so. To further streamline the process and ensure patients would be able to get their prescriptions filled, UIC-PA instituted a program where DCFS/CSP forwards a list of their daily consents to the UIC-PA group and PA approvals are entered into the system proactively.

Current Issues:

Although this process has been an improvement in ensuring that appropriate DCFS consents are obtained in this population, there are unavoidable flaws in the process:

1. System limitations allow for patients to fill medications without consent. Currently, the Pharmacy Point of Sale (POS) system cannot edit against eligibility codes. Therefore preferred medications can still be filled for patients ≥ 8 y/o whether consent has been obtained or not.

2. CSP consents a dosage range for the requested medication. When UIC-PA receives the list of consents, it is not always apparent what the prescriber's intended starting dose is. This can result in the actual prescription rejecting at the pharmacy if the PA was entered for the wrong starting dose.

Future Considerations:

1. IL Medicaid is getting a new pharmacy point-of-sale (POS) system in 2016, which will allow psychotropic medication prescriptions to edit at the pharmacy POS for children coded as being in foster care to ensure a DCFS consent/PA is on file. This will eliminate the current issue of preferred medication prescriptions bypassing the consent process.

2. Expanding the age range requiring PA for psychotropic medications for all children. This would allow increased monitoring for duplicate therapy, inappropriate dosing, and adverse events/safety issues. Currently with many preferred options, it is not possible to deter polypharmacy, inadequate dosing, etc.

3. Metabolic monitoring is not currently required in the non-foster care population. This is an area UIC-PA should expand into and offer education for providers and patients on dealing with these effects.

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Indiana

Indiana Psychotropic Medication Initiative

4/12/13 Summary

The use of psychotropic medications among children in state custody has come under increasing scrutiny in recent years. A number of published studies have demonstrated that children in foster care are prescribed psychotropic medication at a rate that is three to four times greater than other Medicaid-insured youth (Naylor et. al., 2007; Zito, et. al., 2008). In addition, these youth typically experience abuse, neglect or other traumatic stressors at rates that are significantly higher than the general population.

To address these concerns, the Department of Child Services (DCS) is in the process of launching a comprehensive initiative, in collaboration with the Office of Medicaid Policy and Planning (OMPP), the Department of Mental Health and Addiction (DMHA) and the Indiana University School of Medicine (IUSM) Department of Psychiatry, to provide oversight, monitoring, education and consultation for youth in state care who are prescribed psychotropic medications. Components of the Indiana psychotropic medication protocol will include the following:

a. Informed and Shared Decision Making

DCS Policy 8.30 – Psychotropic Medication – addresses current procedures for handling of psychotropic medication for DCS wards and youth in foster care who are in out-of-home placement. By policy, DCS requires that informed consent be obtained from the parent, guardian, or custodian and from the appropriate DCS Local Office Director or designee before a child in out-of home care is placed on psychotropic medication. DCS provides an exception to the requirement to obtain parental consent, if:

1. The parent, guardian, or custodian cannot be located;
2. Parental rights have been terminated;
3. The parent, guardian, or custodian is unable to make a decision due to physical or mental impairment; or
4. Prior court authorization has been obtained.

If the parent, guardian, or custodian denies consent, a Child and Family Team Meeting (CFTM) is convened immediately to determine if DCS will seek a court order for authorization of the recommended medication. Medication can be administered without prior consent if it is needed to address an emergency condition in which the child is a danger to himself or herself or others, and no other form of intervention will mitigate the danger. Consent must be obtained within 24 hours of administering the initial dose of medication on the weekends or holidays. DCS has the right to request a second opinion, if there are questions surrounding the need for and/or use of psychotropic medication.

Information about all medications is maintained in child's Medical Passport. In addition to the information maintained in the paper Medical Passport, DCS is collaborating with OMPP to design a technical framework for sharing relevant medical data electronically. A regularly scheduled electronic

exchange will include information regarding prescription medications. This will allow for oversight as well as the opportunity for enhanced case management to improve health outcomes for wards, foster and adoptive children.

b. Psychotropic Medication Advisory Committee (PMAC)

The Indiana Psychotropic Medication Advisory Committee (PMAC) was initiated in January, 2013 to review the psychiatric treatment of DCS-involved youth, with a specific focus on psychotropic medication utilization patterns. This committee includes representatives from IUSM Department of Psychiatry, DCS, OMPP, DMHA, pediatricians, social workers, psychologists, pharmacists, child advocates and other identified stakeholders (see attached and labeled 2013 PMAC Members). The advisory committee will monitor Federal legislation, review best-practice guidelines for psychotropic medication use, monitor Indiana prescription patterns, review formularies and make policy recommendations to DCS. Specific responsibilities of the committee include the following:

- Review the literature on psychotropic medication best practice [e.g., American Academy of Child and Adolescent Psychiatry (AACAP)] and provide guidance to DCS, OMPP, IUSM and prescribing providers;
- Provide assistance to DCS in establishing a consultation program for youth in state care who are prescribed psychotropic medications;
- Publish guidelines for the utilization of psychotropic medications among DCS-involved youth, with revisions made on a semi-annual basis, as needed;
- Publish a DCS Approved List of Psychotropic Medications that contains a comprehensive listing of medications (generic and brand) approved for use with DCS-involved youth;
- Review DCS policies for requesting and obtaining consent to treat DCS-involved youth with psychotropic medications and make recommendations for change to DCS Permanency and Practice Support Division; and
- Identify non-pharmacologic, evidence-based mental health treatments for DCS-involved youth.

In 2013, the PMAC will publish DCS Psychotropic Medication Protocols, with revisions made on a semi-annual basis. The guidelines will contain suggested baseline and follow up labs and other monitoring interventions that are based on the latest in evidence-based practice and research literature. Prescribing providers will be requested to utilize the guidelines and may be asked to provide clinical information and follow up based on this document.

The PMAC will also work with OMPP to publish the DCS Approved List of Medications that will contain a comprehensive listing of medications (generic and brand) approved for use with DCS children and adolescents. Requests for medications that are not listed on the formulary will require review and approval by the PMAC. Note: DCS will utilize the current OMPP formularies until such time as the PMAC can review and revise, as necessary.

c. Mental Health/Trauma Screening

All DCS youth are screened using the CANS upon entry into the system and at critical case junctures thereafter. The CANS identifies mental health needs, and a placement algorithm is used to generate a level of care recommendation. In addition, all youth entering the foster care system receive a

comprehensive mental health evaluation within the first 30 days of placement.

To identify trauma-related needs associated with a child's maltreatment and removal from the home, DSC will screen all youth entering the system using the CANS-Trauma Module. Youth who score a "2" or a "3" on the CANS "adjustment to trauma" item may be referred for a trauma assessment with one of our contractual providers, or the case may be staffed with a member of the Clinical Resource Team to determine the best course of treatment. Recommendations from these clinical assessments will be incorporated into the DCS case plan, including any recommendations for specific, trauma-informed services. Training materials have been developed regarding the reliable rating of trauma needs using the CANS, and all DCS Family Case Managers will be trained on these measures in 2013.

d. Assessment

All children receive a comprehensive health evaluation and identification of acute medical problems prior to the administration of psychotropic medications. The physical evaluation is performed by a physician or other healthcare professional qualified to provide this service. ***Except in the case of an emergency, consent for psychotropic medication will not be provided until the child has received a thorough health history, psychosocial assessment, mental status exam and physical exam.*** In some cases, medical problems mimic and/or occur co-morbidly with psychiatric disorders. In those instances, the identification of target symptoms will be critical. When pharmacologic intervention is identified as part of the treatment plan, considerations such as diagnostic medical evaluations, drug-drug interactions, polypharmacy, treatment compliance, informed consent, and the safe storage and administration of medications will need to be documented.

The assessment of a medication trial is facilitated by the initial identification of target symptoms and the regular evaluation of those target symptoms. Secondly, the consideration of ongoing life events, particularly in children and adolescents, is essential in assessing benefits of medication. Removal from the home, a change in living situation, physical illness, parental functioning, traumatic events, etc. can all impact functioning and can confound the evaluation of a medication trial. Thirdly, compliance may need to be investigated through pharmacy records or medication administration records in order to clearly assess efficacy of a medication trial. Once an informed decision is made about a particular medication, changes in the treatment plan may be necessary, including changes in medication regime, adjustment in non-pharmacologic treatment strategies, and re-evaluation of the diagnosis.

In children and adolescents, re-evaluation of the working diagnosis is critical not only when there is a lack of treatment response, but in other situations as well. By nature, children and adolescents are developing and changing during treatment. Longitudinal information may become available revealing temporal patterns of functioning that may alter the initial diagnosis. In addition, the successful treatment of one disorder may then expose an underlying co-morbid disorder that requires treatment. Ultimately, the resolution of a disorder or the ineffectiveness of a medication requires the medically supervised discontinuation of medications. Because withdrawal or discontinuation effects may arise and confound the clinical picture, ongoing assessment is vital to sort out the illness from the medication effects.

e. Psychotropic Medication Consultation

The IUSM Department of Psychiatry has agreed to serve as the consultation entity for DCS. The PMAC

considered consultation models from several other states and determined that the model currently being used in Illinois would be the best fit for Indiana. In this model, the prescribing provider will complete a web-based consent and medical information form and forward to the IU Consultation Team – all Board Certified child and adolescent psychiatrists. Once a referral has been generated, the IU psychiatrist will review the information, and if necessary, will staff the case with the prescribing provider "physician to physician."

Once the IU Consultation Team has approved the request, the web-based form will be forwarded to DCS Central Office for final consent. Copies of the consent form will then be distributed to the family, DCS Family Case Manager and prescribing provider. The IU Consultation Team will also review any case that meets one or more of the "red flag" indicators listed in Table 1. Again, this consultation will take place "physician to physician" with the prescribing provider. The DCS Family Case Manager may be asked to provide background case information, including health records, treatment summaries, family histories, etc. In those instances where the IU Consultation Team member and the prescribing physician cannot agree on a course of treatment, the case may be referred to another provider, or the IU Consultation Team member may agree to staff the case on a monthly basis with the prescribing physician. It should be noted that IU is the sole training program for psychiatrists in the state of Indiana, and as such, the IUSM faculty have longstanding relationships with most psychiatrists and behavioral health programs in the state.

f. Guidelines for Safe Utilization of Psychotropic Medications with Children and Adolescents

In order to safeguard the health and welfare of DCS youth who are prescribed psychotropic medications, the following guidelines have been adopted from the Texas Psychotropic Medication Utilization Parameters for Youth in State Care and the AACAP Practice Parameters for Psychotropic Medication Use in Children and Adolescents:

- A DSM-IV-TR diagnosis should be made before the prescribing of psychotropic medications.
- Clearly defined target symptoms and treatment goals for the use of psychotropic medications should be identified and documented in the medication record at the time of or before beginning treatment with a psychotropic mediation. These target symptoms should be assessed each clinic visit with the child and caretaker(s).
- Except in the case of emergency, informed consent should be obtained from the appropriate party(s) prior to beginning psychotropic medication.
- During the course of psychotropic medication therapy, the presence or absence of medication side effects should be documented in the child's medical record at each visit.
- Appropriate monitoring of indices such as height, weight, blood pressure or other laboratory findings should be documented.
- Monotherapy regimens for a given disorder or target symptoms should be tried before polypharmacy.
- Doses should usually be started low and titrated carefully as needed.
- Only one medication should be changed at a time, unless a clinically appropriate reason to do

otherwise is documented in the medical record.

- The frequency of clinician follow up with the patient should be appropriate for the severity of the child's condition and adequate to monitor response to treatment, including symptoms, behavior, function and potential medication side effects.
- In depressed children and adolescents, the potential for emergent suicidality should be carefully evaluated and monitored.
- If the prescribing clinician is not a child psychiatrist, referral to or consultation with a psychiatrist should occur if the child's clinical status has not experienced meaningful improvement within a timeframe that is appropriate for the child's clinical status and medication regimen being used.
- When medication changes are warranted within the same class of medications, a 60 day crossover period of titration of the new agent and taper of the agent to be discontinued is appropriate unless the agent to be discontinued is causing adverse effects.
- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, accuracy of the diagnosis, the occurrence of comorbid disorders (including substance abuse and general medical disorders), and the influence of psychosocial stressors.
- If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-IV-TR nonpsychiatric diagnosis (e.g., conduct disorder, oppositional defiant disorder, intermittent explosive disorder), and the behavior disturbance has been in remission for six months, then serious consideration should be given to slow tapering and discontinuation of the medication. If the medication is continued in this situation, the necessity for continued treatment should be evaluated at a minimum of every six months.
- The prescribing provider should clearly document care provided in the child's medical record, including history, mental status assessment, physical findings (where relevant), impressions, adequate laboratory monitoring specific to the drug(s) prescribed at intervals required specific to the prescribed drug and potential known risks, medication response, presence or absence of side effects, treatment plan and intended use of the prescribed medications.

g. Data Management

DCS has completed an MOU with OMPP to share Medicaid claims data (see attached and labeled DCS/OMPP Data Sharing MOU). As part of the MOU, OMPP will provide DCS with monthly utilization reports for their wards on psychotropic medication(s). The Medicaid claims database captures psychotropic medication prescriptions on a "real time" basis, allowing for identification of cases that fall outside of best practice parameters. The ward psychotropic utilization reports will identify outliers (see Table 1 below), including prescribing physicians. In addition, the ward psychotropic utilization reports will include utilization statistics that can be used to benchmark against other states. Report formats will include the following:

1. Percentage of children prescribed psychotropic medication by age: 0-5 years old, 6-12 years old, 13-17 years old, 0-17 years old. DCS Wards vs. Non-DCS Medicaid Youth. (GAO). Within DCS Wards – In-home vs. out-of-home placements.

2. Children age 0-17 prescribed five or more psychotropic medications concomitantly. DCS Wards vs. Non-DCS Medicaid Youth. (GAO). Within DCS Wards – In-home vs. out-of-home placements.
3. Children 0-17 with a dosage exceeding maximum guidelines based on FDA-approved labels. DCS Wards vs. Non-DCS Medicaid Youth. (GAO). Within DCS Wards – In-home vs. out-of-home placements.
4. Children under age one year prescribed a psychotropic drug. DCS Wards vs. Non-DCS Medicaid Youth. (GAO). Within DCS Wards – In-home vs. out-of-home placements.
5. Children 0-17 with a dosage exceeding maximum standards published in the medical literature (i.e., medications for which there are no FDA-recommended dosages for the child's age – see Texas guidelines). DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
6. Children 0-17 prescribed a psychotropic medication without a DSM IV diagnosis. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
7. Children 0-17 prescribed a psychotropic medication that is not consistent with the listed DSM-IV diagnosis (e.g., Seroquel with ADHD). DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
8. Children age 0-17 prescribed two or more antidepressant medications concomitantly. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
9. Children age 0-17 prescribed three or more mood stabilizers concomitantly. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
10. Children age 0-17 prescribed two or more antipsychotic medications concomitantly. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
11. Children age 0-17 prescribed two or more stimulant medications concomitantly. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
12. Children age 0-3 prescribed an antidepressant medication. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
13. Children age 0-3 prescribed an antipsychotic medication. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.
14. Children age 0-2 prescribed a stimulant medication. DCS Wards vs. Non-DCS Medicaid Youth. Within DCS Wards – In-home vs. out-of-home placements.

h. "Red Flag" Indicators

The Indiana PMAC has established "red flag" indicators based on the American Academy of Child and Adolescent Psychiatry practice parameters (AACAP, 2009) and the Texas Psychotropic Medication Utilization Parameters for Foster Children (2010). DCS "red flag" indicators are listed in Table 1. Any youth who meets one or more of these criteria will be automatically referred to the IUSM Department of Psychiatry Consultation Team for case review and follow up.

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Table 1. DCS "Red Flag" Indicators

Absence of a DSM-IV diagnosis in the child's medical record
Prescription of psychotropic medication that is not consistent with the child's listed diagnosis
Prescription for five (5) or more psychotropic medications
Prescription for two (2) or more antidepressant medications
Prescription for three (2) or more mood stabilizers
Prescription for two (2) or more antipsychotic medications
Prescription for two (2) or more stimulant medications
Prescription of an antidepressant to a child less than four (4) years old
Prescription of an antipsychotic medication to a child less than four (4) years old
Prescription of a stimulant medication to a child less than three (3) years old
Psychotropic polypharmacy for a given mental disorder is prescribed before utilizing psychotropic monotherapy.
Prescription of a psychotropic medication above the FDA or literature-based maximum dosage level

i. Ongoing Monitoring for Individual Youth in Foster Care

DCS facilitates ongoing communication, through the Child and Family Team Meetings, case staffing, Permanency Roundtables and other venues, between the youth, parent/guardians and others who understand the youth's behavioral/emotional needs best. This communication is intended to ensure a) that psychotropic medication effectiveness is monitored, b) that treatment is appropriate to the youth's needs, c) that treatment includes the family and/or other essential connections, d) that treatment builds upon the youth's strengths, and e) that permanency planning is incorporated into treatment.

j. Education and Training

DCS will develop a training curriculum for DCS staff and for key stakeholder groups at the local and state level. Target audiences will include residential, foster care and community-based providers, as well as parents and child advocates (e.g., CASA, Guardian ad Litem). The training curriculum will include information about best practice guidelines, current psychotropic utilization trends and issues unique to

you in the foster care system. DCS will establish mechanisms for sharing training with staff and other stakeholders, including computer-based, "train the trainer" and in-service formats.

k. Information Portal

DCS will develop a "psychotropic medication" information portal through the www.dcs.in.gov website. The information portal will include an overview of the DCS psychotropic medication initiative, contact information, summary performance data (e.g., quarterly utilization reports), and links to relevant research, resources and Federal legislation. The information portal will also include a list of answers to frequently asked questions for consumers.

Louisiana

Louisiana Medicaid Psychotropic Medication Utilization in Children: Pharmacy Initiatives and Overview

Introduction

Behavioral health initiatives addressing antipsychotic utilization among Medicaid-enrolled children and Medicaid-enrolled foster children are a priority for Louisiana Medicaid. The Louisiana Medicaid Pharmacy Program monitors antipsychotic utilization in Fee-for-Service Medicaid and five Managed Care Organizations (MCOs). The Pharmacy Program has reviewed access to anti-psychotic medications, appropriate diagnoses, multiple psychotropic usage, prior authorizations, clinical pre-authorizations, age limits, therapeutic duplications, overutilization, combination drug therapy, prescriber specialty, metabolic monitoring, and best practice guidelines.

Clinical Edits

The Louisiana Medicaid Pharmacy Program in collaboration with the Drug Utilization Review Board has established clinical edits for antipsychotic medication utilization in children.

Clinical Pre-Authorization

Behavioral health medications in children less than 6 years old require an approved Clinical Pre- Authorization. Clinical Pre-Authorization is a prescriber initiated request in which certain criteria and best practice guidelines must be met before a medication is approved for payment. Prescribing providers must complete the Behavioral Medication Therapy Clinical Pre-Authorization Form. The Behavioral Medication Therapy Clinical Pre-Authorization Form requests information such as previous medication therapy and outcome, patient clinical evaluation and assessment, select lab values, and physical assessment. A manual Clinical Pre-Authorization review is performed by a clinical pharmacist.
If a more extensive clinical review is needed, the Clinical Pre-Authorization request is reviewed by a child psychiatrist.

Drug Utilization Review (DUR)

Behavioral health is addressed by the Louisiana Drug Utilization Review (LADUR) Program. Behavioral health initiatives are a part of prospective and retrospective DUR. Prospective

DUR for behavioral health initiatives include Point of Sale (POS) edits such as therapeutic duplication, overutilization, polypharmacy, maximum daily dosage limit, age limits, and appropriate diagnosis code utilization.
Retrospective DUR for behavioral health initiatives include profile reviews for select behavioral health members where the prescriber is contacted when a possible intervention is identified.

The following is a summary of the Behavioral Health Initiatives in LADUR.

1. Retrospective DUR focus on children (all children including children in foster care)

Retrospective Drug Utilization Review Program (LADUR)

Focus Studies- Behavioral Health

Year-Month	Drug/Disease focus	Population focus	Intervention	Profiles reviewed	Interventions	Responses
2006-03	Antipsychotic agents	Age < 4y, exclude PDD, autism	ANTIPSYCHOTIC RX FOR CHILD < 4 YEARS: RECOMMEND REVIEW OF MEDICATION REGIMEN	43	38	11
			Request for information: diagnosis, laboratory, monitoring, re-evaluation plan, pertinent literature			
2007-02	ADHD agents	Age < 6y	REEVALUATE ADD/ADHD & DRUG TREATMENT IN CHILDREN	800	688	384
2007-03				662	560	286
			Request for information: diagnostic tools, specific evaluation & intervention, specific behavioral techniques-strategies, re-evaluation plan, pertinent literature			
2008-09	Antipsychotic agents	Age < 4y, exclude PDD, autism	ANTIPSYCHOTIC RX FOR CHILD < 4 YEARS: RECOMMEND REVIEW OF MEDICATION REGIMEN	24	26	8
2009-02		Age 4 - 5 y, exclude PDD, autism	ANTIPSYCHOTIC RX FOR CHILD < 6 YEARS: RECOMMEND REVIEW OF MEDICATION REGIMEN	244	245	129
			Evaluation of medical profile for efficacy, severity of condition, potential for side effects			
2010-01	Antidepressants	Age < 6y	ANTIDEPRESSANT PRESCRIPTION FOR CHILD AGE <6 YEARS	117	113	45
			Request for diagnostic information			
2014-07	ADHD agents	Age < 4y	ADHD AGENT PRESCRIPTION FOR CHILD AGE < 4 YEARS	93	99	34
			Recommend review of medication profile and condition			
2014-10	ADHD agents	Age = 4 y	ADHD AGENT PRESCRIPTION FOR CHILD AGE < 4 YEARS	282	267	148

			Recommend review of medication profile and condition			

2. Retrospective DUR focus on behavioral health drugs, rotated on an annual basis (all recipients including children in foster care)

Behavioral health

- Concurrent use of antipsychotic agents
- Antipsychotic prescriptions for greater than maximum recommended dose
- Patient non-adherence to antipsychotic agents

Depressive disorders

- Concurrent use of antidepressants prescribed by different prescribers.
- Concurrent use of same-class antidepressants (prescribed by the same or different prescribers).
- Patient non-adherence to antidepressant therapy.
- Citalopram above maximum recommended dose (general and elderly)

Sleep disorders

- Prolonged, continuous use of sedative-hypnotic agents.
- Potential for additive adverse CNS effects when using sedative-hypnotic agents concurrently.
- Use of sedative-hypnotic agents above the recommended adult dose.
- Use of ramelteon with fluvoxamine (manufacturer's safety information)
- Possibility of stimulant-induced insomnia. Dose adjustment may be considered.
- Concurrent cholinesterase inhibitor use with anti-cholinergic agent
- Use-precaution for modafinil (Provigil) or armodafinil (Nuvigil) for patients with psychosis, stimulant or drug abuse

3. Prospective Drug Utilization Review- point-of-sale edits and implementation dates

2001 Duplication of drug therapy

- Prescriptions for therapeutic duplicates of drugs in these drug classes are payable only after discussion with and approval from the prescriber
    - Tricyclic antidepressants
    - Selective serotonin reuptake inhibitors

2005 Behavioral health

- A focus on behavioral health issues resulted in the implementation of prospective edits addressing appropriate drug use, polypharmacy, and overutilization of antipsychotic agents.
    - Prescriptions for antipsychotic agents are payable only when a valid diagnosis code

indicating the use of the drug is supplied.
    - A prescription for a third antipsychotic agent is not permitted without discussion and approval from the prescriber. An emergency override provision is allowed for this edit.

    - Prescriptions for antipsychotic agents prescribed above the maximum recommended dose are payable only after discussion and approval from the prescriber.
    - Prescriptions for therapeutic duplicates of anti-anxiety agents are payable only after discussion and approval from the prescriber.

2008 Duplication of drug therapy

- Prescriptions for therapeutic duplicates of drugs in these drug classes are payable only after discussion with and approval from the prescriber.
    - Sedative-hypnotic agents

2013 Sleep disorders

- Prescriptions for selected sedative hypnotic agents are subject to a maximum daily dosage limit.

2014 Behavioral health

- Additional initiatives were implemented for specified anti-anxiety drugs:
    - Prescriptions for alprazolam ER and alprazolam ODT require appropriate diagnosis code for payment. Payment is not allowed for patients who are 17 years of age or younger.
    - Prescriptions for specified anti-anxiety drugs are subject to a quantity limit.
- Additional initiatives were implemented for antipsychotic agents:
    - Prescriptions for antipsychotic agents are payable only when an appropriate diagnosis code indicating the use of the drug is supplied.

Sleep disorders

- Additional initiatives were implemented for specified narcolepsy agents:
    - Prescriptions for modafinil and armodafinil require appropriate diagnosis code for payment. Payment is not allowed for patients who are 16 years of age or younger.
    - Duplication of therapy is not allowed for these agents, with stimulants, and with sedative hypnotic drugs.

2015 Behavioral health

- Clinical pre-authorization is required for all behavioral health medications for patients less

than 6 years old.

Fee-for-Service Reports

Fee-for-Service Medicaid generates Behavioral Health reports monthly. The reports include drug utilization in children prescribed attention deficit hyperactivity disorder (ADHD) medications, atypical antipsychotics, typical antipsychotics, antidepressants, and antianxiety agents. The reports have age identifiers and foster child identifiers. The reports show drug utilization grouped by age range and foster child status.

Managed Care Organizations (MCO) Reports

Managed Care Organizations also implement behavioral health initiatives. A MCO may have clinical edits and prior authorizations as a component of their behavioral health initiatives. MCOs generate Behavioral Health reports monthly for review by the Louisiana Medicaid Pharmacy Program. The behavioral health reports submitted include the same parameters as Fee-for-Service Medicaid.

The reports also include drug utilization in children prescribed ADHD medications, atypical antipsychotics, typical antipsychotics, antidepressants, and antianxiety agents. The report shows drug utilization grouped by age range and foster child status.

Conclusion

Appropriate utilization of antipsychotic medications in Medicaid-enrolled children and Medicaid-enrolled foster children is an ongoing priority for Louisiana Medicaid. Current best practice guidelines are reviewed and clinical expert consults are sought to ensure safe and effective utilization of psychotropic medications. The Louisiana Medicaid Pharmacy Program is dedicated to the continued monitoring and implementation of behavioral health initiatives to improve healthcare outcomes of all patients.

Maryland

ANTIPSYCHOTIC REVIEW PROGRAMS

Antipsychotics are FDA approved for a variety of diagnoses including but not limited to: Schizophrenia, Schizoaffective Disorder, Bipolar Disorder, Major Depression (as adjunct treatment) and Autistic Disorder (to treat associated irritability). However, there are situations in which a clinician may prescribe an antipsychotic "off-label".

In the public and health care arena concerns have been raised, not only about the "off-label" prescribing, but also about the lack of side effect (including weight, body mass index and blood glucose and lipid levels) monitoring of antipsychotics.

Federally, a Government Accountability Office (GAO - http://www.gao.gov/assets/590/586906.pdf) report has outlined concerns about antipsychotic use in Medicaid recipients in Foster Care.

Published guidelines addressing some of the above issues include, but are not limited to, the American Academy of Child and Adolescent Psychiatry Practice Parameters for Atypical Antipsychotics (http://www.aacap.org/galleries/PracticeParameters/Atypical_Antipsychotic_Medications_Web.pdf)

and The American Diabetes Association/American Psychiatric Association consensus statement issued in 2004 recommending monitoring body mass index and blood glucose and blood lipid levels on patients taking atypical antipsychotics.

To support providers who prescribe this drug class, the Maryland Medicaid Pharmacy Program (MMPP) has established three (3) programs. These are the Peer Review Program (PRP), the Tier 2 & Non Preferred (Tier 2 & NP) Antipsychotic Review Program and Antipsychotic Prescription Review Program (APRP).

The Peer Review Program

This program was established to address the concerns that an increasing number of children are being prescribed antipsychotics and there is a lack of laboratory monitoring of those children. The goal of the program is to ensure that children and adolescents receive optimal treatment in conjunction with appropriate non-pharmacologic measures in the safest manner possible. (https://mmcp.dhmh.maryland.gov/pap/docs/Antipsychotic-Peer-review-Project-Narrative.pdf)

This program began in October 2011 and initially addressed the use of antipsychotics in Medicaid patients under five years of age. In July 2012, it expanded to encompass children under 10 years of age. **In January 2014, the program expanded to include any Medicaid recipient 17 years or younger who is prescribed any antipsychotic.**

The program works in partnership with the Mental Hygiene Administration (MHA) and the University of Maryland (UMD) School of Pharmacy and Division of Child and Adolescent Psychiatry.

The MMPP and the MHA hosted a webinar to discuss the PRP and answer questions regarding this program on September 15, 2011.

The Tier 2 & Non-Preferred Antipsychotic Review Program

This program was launched in September 2012. It was designed to address a variety of concerns, including the off-label use of antipsychotics. The goal of the program is to have prescribers, whenever appropriate, prescribe antipsychotics using FDA guidelines for diagnosis, dose and frequency in the most cost-effective manner.

To meet this goal, the program has established a prior authorization (PA) process. As always, a PREFERRED antipsychotic (see Preferred Drug List at:http://www.providersynergies.com/services/documents/MDM_PDL.pdf) does not require a prior authorization, if prescribed within the FDA guidelines for the dose and frequency. Clinical criteria have been established which must be met before a Tier 2 & Non-preferred (Tier 2 & NP) antipsychotic is approved. (See Clinical Criteria on the right side bar or clickhttp://mmcp.dhmh.maryland.gov/pap/SitePages/Clinical%20Criteria.aspx)

When seeking a PA for a Tier 2 or NP antipsychotic, remember that it could take up to 1 business day after all requested information is received before a decision is rendered.

Antipsychotic Prescription Review Program

The Maryland Medicaid Pharmacy Program (MMPP) with assistance of University of Maryland, School of Pharmacy had developed a program that performs a retrospective analysis of antipsychotic prescribing data and the use of this data to promote more evidence based and cost-effective prescribing. The

Antipsychotic Prescription Review Program (APRP) reviews antipsychotic use through Medicaid and offer a Psychopharmacology Review Panel to review cases with outlying prescribing practices as agreed upon with MMPP.

MMPP has established a Preferred Drug List (PDL) which has resulted in consistent savings. The APRP analyzes compliance with the PDL, quantity limits, maximum dose guidelines, specific standards of practice and determine cost trends for clients and prescribers.

Minnesota

Minnesota Department of Human Services (DHS), Children's Mental Health Division (CMHD), and Child Safety and Permanency Division efforts to ensure appropriate use of psychotropic medications in children in foster care. January 2016.

Child Safety and Permanency Division

Minnesota's child welfare system is state-supervised, county-administered. For this reason, child welfare practice in the state can vary widely from county to county. In Minnesota, children considered to be in out-of-home placement include not just children who are placed for child protection, but children in voluntary placement for treatment, or children placed by a court under a juvenile delinquency order in a county with a Title IV-E agreement between the social service and corrections agencies.

Target Population

Coverage parameters regarding the use of psychotropic medications in children apply whether in foster care or not. During 2013, there were 449,394 enrollees under the age of eighteen years, of which 45,980 recipients received ≥ 1 psychotropic prescription paid for by the Minnesota Medicaid Program which includes fee-for-service and six different Prepaid Health Plans (PPHP).
Within this group, using the criteria of being in foster care for ≥ 30 days, there were 9,328 foster care children, of which 3,296 received ≥ 1 psychotropic prescription.

Of these, 413 recipients met DHS Multiple Psychotropic Drugs in Children criteria of ≥ 4 psychotropic drugs for at least 53 days out of 60 day span.

Attachment C contains the steps in the analysis leading to the development of this criteria.

Minnesota sent a state team to the ***Because Minds Matter: Collaborating to Strengthen Psychotropic Medication Management for Children and Youth in Foster Care*** **Summit** in August 2012. This core group represented counties, children's mental health, child safety and permanency, the court system, health care/pharmacy, and the Minnesota Medicaid program. The group developed a state plan and convened the State team for Psychotropic Medication Management and Oversight.

The state plan set forth goals for implementation related to:

- Providing psychiatric consultation to prescribers treating children
- Developing screening and assessment protocols for children in foster care

- Training mental health professionals across the state to assess for, and treat traumatic stress in children utilizing evidence-based treatments
- Training county court staff on court oversight of psychotropic medication use
- Training child welfare staff and foster families in trauma-informed care and treatment
- Developing data collection/management systems to track the utilization of psychotropic medications with children across the state

Minnesota Collaborative Psychiatric Consultation Service

The Minnesota Collaborative Psychiatric Consultation Service (required under Minnesota Statutes, sections 245.4862 and 256B.0625, subd. 13j. – Attachment A) was developed in 2010. For the first 2 years, second generation antipsychotics and drugs to treat ADHD exceeding an established threshold per age would reject the FFS point-of-service. A peer-to-peer psychiatric consultation was required and upon approval, a prior authorization was issued.

The program was changed in 2014 so that the hard edits and mandatory consultations were discontinued. This was due to a number of factors including, but not limited to, change of staffing at the contractor level, lack of acceptance in the provider community, and minimal changes in high-dose regimens as a result of the program (86% of regimens were not changed).

The Minnesota Collaborative Psychiatric Consultation Service in its current form is voluntary and administered by a contract with a single provider agency (www.mnpsychconsult.com). In addition to providing psychiatric consultations, the contractor also provides quarterly training for primary care providers and other prescribers across the state. The trainings are based upon the "flowcharts" developed by the Minnesota Protocols Workgroups (facilitated by Children's Mental Health) for primary care physicians treating children with mental health issues. These protocols are available at consultation service site at: http://www.mnpsychconsult.com/treatment-protocols.html.

Recognizing and treating trauma using non-pharmacologic approaches was something that the original psychiatric consultation child and adolescent psychiatrists did not address or consider during their consultations. As this is such a critical component of caring for all children in the foster care system, the Children's Mental Health Division has now hired a full-time consultation facilitator who has a master's degree in clinical psychology to complete individual case reviews to assure that children taking psychotropic medications are also receiving the appropriate evidence-based psychosocial treatments.

The recent changes to the psychiatric consultation process will better allow for the realization of the overall goals of 2010 legislation which are:

- Improve the quality of mental health treatment by encouraging the use of evidence-based treatments in addition to, or in place of medication where appropriate.
- Improve access and quality of care by making more efficient use of both primary care and specialty mental health services.
- Improve collaboration between primary care and behavioral health services.

The DUR Coordinator will continue to work with CMHD to further develop this endeavor.

Screening and Assessment Protocols for Children in Foster Care

The Child Safety and Permanency Division at the Department of Human Services is currently piloting a trauma screening that will pull indicators from a risk assessment tool that is completed on all children entering the child welfare system. This process will provide "flags" to ensure that children who need assessments for trauma are identified early in the process.

Training Initiatives

The Children's Mental Health Division has a long-standing relationship with the Ambit Network at the University of Minnesota. The Ambit Network is a National Child Traumatic Stress Network Site funded by SAMHSA. Since 2007, this partnership has provided training in Trauma-focused Cognitive Behavior Therapy (TF-CBT) to over 500 mental health professionals across the state of Minnesota. Funding continues to provide training to approximately 50-75 new clinicians every year.
http://www.cehd.umn.edu/fsos/projects/ambit/tfcbt.asp

The Child Safety and Permanency Division and the Children's Mental Health Division have partnered with the state Children's Justice Initiatives to train court personnel across the state. This initiative is led by the Commissioner of the Department of Human Services and the Chief Justice of the Supreme Court, and has provided training to approximately 800 judges, county attorneys, public defenders, social services managers, guardians ad litem and child welfare supervisors.

The Child Safety and Permanency Division has developed a trauma-informed practice model for child welfare services. The Minnesota Child Welfare Training System is currently developing a new Training Academy model to improve training to all workers and supervisors and to provide resources for parents throughout the state.

Developing Data Collection/Management Systems

As part of the Retrospective Drug Utilization Review process, the Health Care Administration of the Department of Human Services maintains a contract with Xerox.

Contract deliverables now include (1) two mailings each year specific to psychotropic drug use in children and (2) multiple reporting requirements regarding the use of psychotropic drugs in children. When the Child Safety and Permanency Division supplies foster care children recipient identification numbers, a report can be generated specific to children in foster care.

Monthly the contractor will provide a separate online publication using Minnesota specific psychotropic drugs in children criteria.

MINNESOTA ATTACHMENT A

Subd. 13j.**Antipsychotic and attention deficit disorder and attention deficit hyperactivity disorder medications.**

(a) The commissioner, in consultation with the Drug Utilization Review Board established in subdivision 13i and actively practicing pediatric mental health professionals, must:

(1) identify recommended pediatric dose ranges for atypical antipsychotic drugs and drugs used for attention deficit disorder or attention deficit hyperactivity disorder based on available medical, clinical, and safety data and research. The commissioner shall periodically review the list of medications and

pediatric dose ranges and update the medications and doses listed as needed after consultation with the Drug Utilization Review Board;

(2) identify situations where a collaborative psychiatric consultation and prior authorization should be required before the initiation or continuation of drug therapy in pediatric patients including, but not limited to, high-dose regimens, off-label use of prescription medication, a patient's young age, and lack of coordination among multiple prescribing providers; and

(3) track prescriptive practices and the use of psychotropic medications in children with the goal of reducing the use of medication, where appropriate.

(b) Effective July 1, 2011, the commissioner shall require prior authorization and a collaborative psychiatric consultation before an atypical antipsychotic and attention deficit disorder and attention deficit hyperactivity disorder medication meeting the criteria identified in paragraph (a), clause (2), is eligible for payment. A collaborative psychiatric consultation must be completed before the identified medications are eligible for payment unless:

(1) the patient has already been stabilized on the medication regimen; or

(2) the prescriber indicates that the child is in crisis.

If clause (1) or (2) applies, the collaborative psychiatric consultation must be completed within 90 days for payment to continue.

(c) For purposes of this subdivision, a collaborative psychiatric consultation must meet the criteria described in section 245.4862, subdivision 4.

Mississippi

MISSISSIPPI DIVISION OF MEDICAID

POS CHANGES AND OTHER DUR ACTIONS TO ADDRESS APPROPRIATE USE OF ANTIPSYCHOTIC MEDICATIONS IN CHILDREN

January 28, 2016

Foster care children

In December 2012, the Mississippi Department of Human Services (MDHS) "opted in" children in custody-foster care children- into the MississippiCAN program and chose only one of the two Coordinated Care Organization (CCO) in which to enroll the children.

When this occurred, this CCO developed an intensive care management team especially for foster care children consisting of registered nurses, LCSWs and beneficiary advocates. This intensive care management team collaborates with the Mississippi Division of Medicaid quality improvement team and the Nurse Manager for the MDHS to provide resources, education, and reporting for the case worker for each foster care beneficiary. These resources and education includes reports on all children in foster care receiving antipsychotics, concurrent psychotropic medications, the prescribing practitioner and where the child is receiving therapy services. In addition, the care manager for the CCO assists the beneficiary's case worker when a beneficiary is hospitalized for an acute psychiatric admission.

Information provided includes the child's current medication regimen, education of the beneficiary's the case worker on any new medications prescribed by the practitioner during the hospitalization

encompassing a drug utilization review related to new medications and beneficiaries medication regime.

The CCO's pharmacy director obtains a monthly report for review of all children in foster care that are receiving antipsychotics and/or psychotropic medications and other medications and performs a drug utilization review. If any areas of concern are noted, the pharmacy director will notify the CCO case manager to discuss with the case worker, and the CCO will notify all prescribing practitioners of the areas of concern. The CCO notifies DOM and the MDHS of all reports, findings and a monthly list of all foster care children on antipsychotics and/or concurrent psychotropic medications.

DOM has developed a collaborative Quality Improvement Plan with the CCOs to address foster care children receiving anti-psychotics and/or concurrent psychotropic medications and is partnering with the Office of Pharmacy and the Office of Mental Health Programs to address this area of concern.

MS-DUR actions for antipsychotic use in children

9-2003 DUR Board added therapeutic duplication of Atypical Antipsychotics to monitoring and interventions

9-2008 FDA minimum age limits implemented on all Atypical Antipsychotics

2-2009 DUR Board began a review of Atypical Antipsychotic use in children

9-2010 Changed Quetiapine XR age limit to >/=18 years

2-2011 Added Latuda age limit to >/=18 years

4-2011 Implemented electronic prior authorization criteria for antipsychotics.

12-2011 MS-DUR white paper report "Mental Health Medication Use Among Foster Children and Other Children Enrolled In the Mississippi Medicaid Program" prepared and disseminated in Medicaid and Department of Human Services. A comprehensive analysis of mental health diagnoses and medication use among foster and other children enrolled in Medicaid for the years 2008 - 2011. Included results for quality of care indicators from the Government Accountability Office report, *Foster Care: State Practices for Assessing Health Needs, Facilitating Service Delivery, and Monitoring Children's Care,* and the Medicaid Medical Directors Learning Network and Rutgers Center for Education and Research on Mental Health Therapeutics report, *Antipsychotic Medication Use in Medicaid Children and Adolescents: Report and Resource Guide from a 16-State Study.*

7-2013 Changed Seroquel XR age limit to >/=10

8-2013 Changed Symbyax age limit to >/= 10

10-2014 DUR Board report on state performance with metabolic monitoring for children taking antipsychotics quality measure.

2-2015 DUR Board report on use of multiple antipsychotics in children. Report included analysis using the HEDIS 2+ and the PQA 3+ measure that never was formally reported out of the PQA work group. Board approved recommendation for electronic clinical edit for initiation of 3rd antipsychotic and development of prior authorization criteria. The board was not comfortable with an edit using 2+ since there are times when this might be done for day time and night time meds and be appropriate.

DUR Board report on metabolic monitoring for children taking antipsychotics. Report included analysis using HEDIS measure for annual metabolic monitoring. Board approved recommendations for educational intervention initiative for providers with children not having metabolic monitoring.

3-2015 Changed Saphris age limit to >/=10 for Bipolar I disorder.

5-2015 DUR Board report on metabolic monitoring for children taking antipsychotics. Board approved recommendations for educational intervention initiative for providers with children not having metabolic monitoring.

7-2015 DUR Board report on quality assurance in use of antipsychotics in children. Report examined quality of care criteria identified in the Office of the Inspector General's report "Second-Generation Antipsychotic Drug Use Among Medicaid-Enrolled Children: Quality-of-Care Concerns," the state's performance on quality measures related to these criteria, and current prior authorization criteria and DUR actions addressing these criteria.

8-2015 Electronic prior authorization criteria updated to include check for concurrent therapy with 3 or more atypical antipsychotics.

1-2016 DUR Board report from evaluation of educational intervention related to metabolic monitoring for children taking antipsychotics. The educational intervention conducted in 2015 appears to have had a small positive effect on metabolic monitoring rates. However, the program did not increase rates as much as would be desired, even among the providers who were contacted. Additional educational actions and/or clinical edits or procedures are needed to adequately address metabolic monitoring in children taking antipsychotics. However, when beneficiaries saw prescribers at their offices, rates for metabolic monitoring were higher. The number of children taking antipsychotics and not having office visits during the 8-month observation periods is a concern and may indicate that increased supervision of beneficiaries taking antipsychotics is needed.

The percent of beneficiaries classified as meeting the metabolic monitoring requirement during each observation period are reported in Table 1, which describes whether they had a visit with the provider prescribing their antipsychotic prescription during the observation period. Overall, the percentage of children taking antipsychotics who had metabolic monitoring did not change significantly between the 2014 and 2015 observation periods. It was assumed that prescribers would most likely wait until the next patient visit to perform metabolic monitoring after receiving the educational letter, therefore, we examined changes in the rates for metabolic monitoring for children having office visits and those not having office visits during the two observation periods. Among children having office visits, a slight

increase (+2.9%) in the rate for lipid monitoring was observed

TABLE 1: Percentage of Children Who Are Taking Antipsychotics That Had Metabolic Monitoring Within One Year of a Prescription Fill by Whether The Child Had a Visit With The AP Prescriber During Observation Period
(Prescription fills between April - November 2014 and April - November 2015; FFS and CCOs)

NOTE: Includes all beneficiaries with 3+ prescription fills during each period		# Children on APs	Glucose monitoring[a]	Lipid monitoring[a]	Both lab tests[a]
ALL Children Taking Antipsychotics	2014	5,071	54.2%	32.4%	31.4%
	2015	4,851	49.5%	32.4%	30.6%
	Change 2014 - 2015		-4.7%	0.0%	-0.8%
Children WITH Visit During Observation Period	2014	2,887	57.1%	34.1%	32.9%
	2015	2,540	54.3%	37.0%	34.4%
	Change 2014 - 2015		-2.8%	2.9%	1.5%
Children WITHOUT Visit During Observation Period	2014	2,184	50.5%	30.0%	29.4%
	2015	2,311	44.2%	27.3%	26.4%
	Change 2014 - 2015		-6.3%	-2.7%	-3.0%

[a] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year prior to the prescription fill.*

The rates for children receiving metabolic monitoring by whether the prescribing provider was contacted in the educational initiative are show in Table 2. The educational initiative increased the rate of monitoring among children on antipsychotics prescribed by providers contacted during the intervention by only 1.4%. A decrease was seen in the percentage of children having glucose monitoring. Among prescribers who were not contacted as part of the educational initiative, the percentage of children being prescribed APs that had glucose monitoring went down -7.0% and the percentage having lipid monitoring went down -5.5%. It appears that the initiative had a small beneficial effect among the providers contacted.

TABLE 2: Percentage of Children Taking Antipsychotics Having Metabolic Monitoring Within One Year of a Prescription Fill by Whether The Prescriber Was Contacted During Educational Initiative[a]

(Prescription fills between April - November 2014 and April - November 2015; FFS and CCOs)

NOTE: Includes all beneficiaries with 3+ prescription fills during each period		# Children on APs	Glucose monitoring[b]	Lipid monitoring[b]	Both lab tests[b]
Children With Prescribers CONTACTED in 2015	**2014**	2,925	52.0%	31.4%	30.6%
	2015	3,811	48.5%	32.8%	31.2%
	Change 2014 - 2015		-3.5%	1.4%	0.6%
Children With Prescribers NOT CONTACTED in 2015	**2014**	780	60.1%	36.5%	35.6%
	2015	1,040	53.1%	31.0%	28.4%
	Change 2014 - 2015		-7.0%	-5.5%	-7.2%

[a] *Educational intervention letters were mailed from February 2015 - September 2015. 2014 data are reported as baseline information for the contacted providers.*

[b] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year of the prescription fill.*

As previously noted, providers are not likely to schedule lab tests until the next patient visit. Table 3 compares provider rates for monitoring by whether the prescriber was contacted as part of the educational initiative and whether the beneficiary had an office visit during the observation period. Comparing the two observation periods in this breakdown provides a method of examining whether provider behaviors actually changed with respect to ordering lab tests during office visits. Performance on monitoring actually decreased among providers not contacted through the educational initiative. Among providers who were contacted the rate of monitoring for lipids increased by 5.2% and the rate for glucose monitoring decreased by 2.4% for beneficiaries who had office visits during the observation periods.

TABLE 3: Prescriber Performance Rates For Metabolic Monitoring by Whether The Prescriber Was Contacted During Educational Initiative[a] and Whether Child Visited Prescriber During Observation Period

(Prescription fills between April - November 2014 and April - November 2015; FFS and CCOs)

NOTE: Includes all prescribers with ratings in both years based on 2+ beneficiaries			Average # Children / Prescriber	% With Glucose Monitoring[b]	% With Lipid Monitoring[b]	% With Both Lab Tests[b]
Prescribers NOT CONTACTED in 2015 (n = 119)	**Children WITH VISIT During Observation Period**	**2014**	10.5	52.3%	24.4%	23.9%
		2015	7.9	46.8%	19.3%	18.7%
		Change 2014 - 2015		-5.5%	-5.1%	-5.2%
Prescribers CONTACTED in 2015	**Children WITH VISIT During Observation Period**	**2014**	20.8	53.5%	32.2%	29.6%
		2015	19.8	51.1%	37.4%	34.4%
		Change 2014 - 2015		-2.4%	5.2%	4.8%
	Children	**2014**	14.3	44.6%	25.7%	24.0%
		2015	16.6	35.8%	21.0%	19.0%

(n = 111)	WITHOUT VISIT During Observation	Change 2014 - 2015		-8.8%	-4.7%	-5.0%

[a] *Educational intervention letters were mailed from February 2015 - September 2015. 2014 data are reported as baseline information for the contacted providers.*

[b] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year of the prescription fill.*

Providers were targeted for contact during the educational initiative based on the number of children they had prescribed APs and their rate of metabolic monitoring. Priority was given to contacting providers with high numbers of children without monitoring. As such, few of the providers with only one or two patients were contacted. As shown in Table 4, providers with only a few children on APs had the lowest rates for metabolic monitoring. These providers do not account for a very large percentage of the children on APs, but do continue to present a problem with respect to metabolic monitoring.

TABLE 4: Prescriber Performance Rates For Metabolic Monitoring by Number of Children Prescribed Antipsychotics During 2015 Observation Period
(Prescription fills between April - November 2015; FFS and CCOs)

		Number of Prescribers	Total Number Children on APs	% Children With Glucose Monitoring[a]	% Children With Lipid Monitoring[a]	% Children With Both Lab Tests[a]
Number of Children Prescribed APs in 2015	1 - 2	473	571	46.7%	14.6%	13.8%
	3 - 5	106	399	42.1%	19.8%	18.9%
	6 - 10	47	341	42.8%	27.4%	23.5%
	11 - 20	50	717	62.3%	41.4%	39.7%
	21+	95	5,786	56.0%	43.5%	40.4%

[a] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year prior to the prescription fill.*

Future actions:

Although our existing "Smart PA" clinical electronic PA edits for POS have been fairly effective, **starting in February 2016:**

- SMART PA Point of Sale changes will encompass coding of concurrent therapy check from GCN level to HICL level, to allow dose changes within the same active ingredient.
- Change concurrent therapy criteria "look back" from 15 days of concurrent therapy in the last 45 days to 60 days of concurrent therapy with ≥ 3 atypical antipsychotics in the last 90 days.
- For beneficiaries who do not appear to be in a titration pattern, a manual PA will need to be completed that assesses 1) use of more than 2 antipsychotics and justification, metabolic monitoring, and assessments for TD/EPS adverse effects.

Conclusion:

Based on discussions internally and with the DUR Board, the emerging consensus is that significant improvements may require prior authorization review by experts in child/adolescent psychiatry. We are about to complete an updated white paper on mental health diagnosis and treatment of foster and non-

foster children and plan to review results from that report and information learned from the ADURS/CMS task force to develop new strategies for assuring appropriate utilization of APS in children.

Montana

Montana Medicaid - Psychotropic Medication Utilization in Foster Care Children

Overview

The Department of Health and Human Services (HHS) has become increasingly concerned about the safe, appropriate, and effective use of psychotropic medications among children in foster care. A 16 state study revealed foster children were prescribed antipsychotics at 9 times the rate of other Medicaid recipients. While medications can be an important component of treatment, strengthened oversight of psychotropic medication use is necessary in order to responsibly and effectively attend to the clinical needs of children who have experienced maltreatment. A glaring area of vulnerability for foster children is poly-pharmacy, which may lead to significant drug interactions. Additionally, although clinically effective, psychotropic medications are highly potent agents with the potential for significant adverse effects such as metabolic syndrome. Metabolic syndrome is known to increase the risk of developing cardiovascular disease, particularly heart failure, and diabetes. The purpose of these requirements is to ensure that children in foster care receive high-quality, coordinated medical services, including appropriate medication, even as their placements change.

The purpose of this project is to evaluate the use of psychotropic medications in Montana Medicaid children, with a focus on foster care children, using a Clinical Pharmacist, to evaluate and improve the prescribing and monitoring of psychotropic medication through educational and clinical interventions.

Review Process

1. Monthly we receive a list of all children ≤18 Years of Age that are in the custody of Child and Family Services for the particular month requested.
    a. The list generally has about 2000-2500 children
        i. Placements include:
            1. Family Foster Care
            2. Kinship Foster Care
            3. Therapeutic Group Home
            4. Residential Treatment Center
            5. Foster Care Group Homes
    b. This list of names are then sent to HID to be matched against the following predetermined criteria:
        i. Child Well Check- This category will check to see if the recipient has had a well check visit within the last 365 days

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ii. ≥ 1 Antipsychotic- This category includes all the atypical antipsychotics and the typical antipsychotics

iii. ≥ 2 Atypical Antipsychotic

iv. ≥ 3 Psychotropics- This category includes all psychotropic medications, including; anti-anxiety/sedatives, ADHD treatments, antidepressants, antipsychotics.

v. > 1 AHDH Treatment- This category includes stimulant medications, as well as non-stimulant medications.

vi. ≥ 2 Psychotropic Prescriber- This category will check to see if patients are receiving medication from more than two prescribers.

vii. ≤ 6 YOA on Atypical- This checks to see if a patient 6 years of age receiving an Atypical Antipsychotic. (See below for a description of an adjunctive Medicaid program that goes along with this search parameter.)

c. For those ID's that hit against the above criteria, we then review the claims data for the following:

i. Indication/Diagnosis: Medications are consistent with the diagnosis in database

ii. Dosage: Appropriate for age and started with lowest effective dose

iii. Laboratory Monitoring: Baseline and ongoing metabolic monitoring labs being monitored.

iv. Polypharmacy: Single drugs should be tried before multiple drug regimens are started.

v. Multiple Pharmacies/Physicians: Checking to see if patients are receiving duplicate drug therapy from different prescribers or pharmacies.

vi. Medication Compliance: Monitoring for medication compliance and monthly fills of maintenance medications.

vii. Drug-drug interactions: Monitoring for any potential drug interactions.

viii. Medication Misuse/Abuse: Monitor for early refill requests on controlled substances or drugs with potential for abuse.

2. If any of the above conditions are present, we reach out to the provider with a phone call or a letter requesting a telephone conference to discuss and/or additional information to be submitted back to us via fax. We are then able to:

a. Share case-specific medication, lab monitoring and side effect information with prescribers to improve prescribing and quality of care.

b. Create and share psychotropic medication education resources with prescribers

c. Serve as a medical resource on medication information for prescribers /CPS workers

d. Continue to identify quality improvement opportunities

e. Establish a collaborative working relationship between Montana Child Psychiatrists, the Montana Child and Family Services Department, and Montana Medicaid

Successes and Barriers

Since our program began in July 2012, we have found many opportunities for interventions with providers. In 2013, 75% of Medicaid foster care children had not had metabolic syndrome lab monitoring performed, per claims data. Through clinical pharmacist interventions, we had a 34% success rate in obtaining metabolic lab monitoring in these children. With the help of our clinical pharmacists, we have also seen a reduction in atypical antipsychotic medications by 23%, either by dose reduction or drug discontinuation. Our interactions with the providers and their staff promote the development of a strong and positive working relationship with Montana Child Psychiatrists, Montana Child and Family Services Department and Montana Medicaid. This has allowed us to educate the providers and notify them of missing medication history information, identify cases of medication abuse with stimulants, missing lab monitoring, compliance in filling medications and being an education resource. These relationships that we have built and the awareness of our program have led to even greater successes in subsequent years. In our most recent year, looking at a 6 month snapshot, we have seen an even greater success in our program. The percentage of patients without metabolic syndrome lab monitoring has decreased to 22% and when a provider is contacted about missing laboratory data, we have a 67% success rate in obtaining completed labs. Also, when contacted about an intervention (i.e. labs, drug-drug interaction, dosage), providers respond and resolve the issue 82% of the time. In addition, we have also developed educational resources for providers, foster parents and CPS workers, including:

1. Atypical antipsychotic brochure for foster care parents and providers
2. Medication History Magnet with the clinical pharmacists contact information for providers in need of medication histories or case reviews
3. Presentations as requested for CFSD and foster care parent conferences
4. Prescriber newsletters on Pediatric Psychopharmacology by stakeholder Child Psychiatrists; distributed to 1000 prescribers/pharmacies across Montana
5. Presented at the Big Sky Psychiatric Conference in January 2015 to the Montana Chapter of the American Academy of Child and Adolescent Psychiatrists
6. Email/Phone correspondence with CPS workers to answer psychotropic medication and side effect questions

In lieu of all of our successes, there are some barriers to the program. We are sometimes unable to see the full picture of each child due to the inability and the lack of access to provider chart notes. We also are unable to view database claims for children who are institutionalized, so it is hard to follow a timeline when it comes to dosages, medication trials and labs. Some prescribers refuse to follow lab monitoring guidelines, but continue to prescribe atypical antipsychotics. We also do not have a Child Psychiatrist on staff to perform high level case reviews or peer reviews when needed.

Prior Authorization Program: ≤6 Years of Age on Atypical Antipsychotic

We have also created a created a secondary review program that goes hand in hand with our foster care psychotropic program. This program requires all children ≤6 years of age, being prescribed an atypical antipsychotic by a non-fellowship trained pediatric psychiatrist to fill out a consent form and obtain baseline laboratory requirements, prior to initiating the medication and receiving approval. The provider and legal guardian must review the medication together, the side effects, and both consent before initiating the medication, as well as obtain the necessary laboratory monitoring requirements. They must also continue to follow continued laboratory monitoring requirements, as well as form renewal. This enables us to improve the oversight of prescribing, as well as medication and lab monitoring education and compliance with the providers. We currently have around 90 children in this program and all of these interventions are also followed by our case management staff.

Conclusion

Montana Medicaid has made the evaluation and monitoring of psychotropic medications a priority since the inception of this project. Our program has shown to be very successful and we are able to impact the lives of many children and make a difference in their care. The success of increased metabolic syndrome monitoring alone may lead to a decreased long term risk of obesity, diabetes, heart disease, and joint problems, which will lead to substantial decreases in long term health care costs. Metabolic syndrome can be costly; for example:

1. Diabetes: According to the American Diabetes Association: People with diagnosed diabetes incur average medical expenditures of about $13,700 per year and have approximately 2.3 times higher medical expenditures.
2. Heart disease: According to the Centers for Disease Control (CDC): People with heart disease can incur average medical expenditures nearing $121,200 over 20 years. For those needing surgery or procedures and ongoing care, heart disease and stroke can cost more than $4.8 million over a lifetime.
3. Obesity: According to the Harvard School of Public Health, the cost of obesity for an individual can be an additional $1,429 (42%) -$2,741 (150%) higher compared to individuals of normal weight.

Our case management staff strive to make a difference in the lives of our children through educational and clinical interventions, which will improve healthcare outcomes and decrease overall healthcare costs.

North Dakota

State law prohibits prior authorization on:

- Antipsychotics
- Anticonvulsants
- Antidepressants
- Stimulants for ADHD

Multi-department team reviews utilization

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- Human Services
- Children and Family Services
- Juvenile Services
- Foster Care
- Psychologists
- Court System

Given inability to confirm appropriate prescribing through prior authorization or peer-to-peer consultations, ND Medicaid utilizes a broad amount of quantity limits, duplicate therapy edits, and a variety of first fill edits (e.g. 14 day supply for the first fill of a given strength on extended release ADHD medications) to attempt to impact this area.

Oklahoma

In 2012 Oklahoma (Pharmacy Management Consultants & Oklahoma Health Care Authority) joined 5 other states in a collaborative effort to improve the quality of care for children experiencing mental health difficulties. The program is referred to as MEDNET and was supported by a grant from AHRQ. You can see all the details in the attachment below which also have examples of the letters we mailed for education and intervention. The second attachment below is the MEDNET overview (rather lengthy). The 3rd attachment is a description of our mailings (screening dates and letter dates), dates, and changes made along the way. To access the attachments below please click this link.


SoonerCare Atypical Rx Program Update.c


mednetresourcedgui de.pdf


MEDNET 2012 Providers and Recipie

In the following attachment you can see an evaluation of our first two mailings which includes a summary of the responses received. On the last page you will see the plans for the next mailing in Jan 2013.


SoonerCare Atypical Rx Program Update D

In the following attachment you can see the remaining mailings of the MEDNET program with results tabulated.


Program Update August 2013 Finall.dc

In the following attachment you can see the overall summary of the results for Oklahoma for the MEDNET program. There are 4 tabs on the bottom with results of the interventions and mailings broken out.


OK intervention summary results - 06:

After the MEDNET project ended Pharmacy Management Consultants continued the program and

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renamed it the SoonerPsych Program. Below are examples of the current interventions and mailings we continue to perform. You will see examples of letters to providers explaining the intervention and also an attachment with a scoring gauge to give a more visual description of where the provider ranks among the other Oklahoma Medicaid providers for the same medications. We rotate interventions for Adherence, Metabolic Monitoring, Polypharmacy (patient using 2 or more atypical antipsychotic medications concurrently for 90 days or more), and Diagnosis. In July 2015 we switched to a letter with the gauge on the attached documents so there are 2 documents for the 3 most recent mailings.


SP Metabolic attachment - Jan 201


SP Metabolic letter - Jan 2016.docx


SP Adherence attachment - Oct 201


SP Adherence letter - Oct 2015.docx


SP polypharmacy attachment July 2015


SP polypharmacy letter July 2015.docx


2015-04 SoonerPsych Diagnos

adherenceMailingSummary_20150930.pd

Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care

Introduction and General Principles

The use of psychotropic medications by children and youth is an issue confronting parents, other caregivers, and health care professionals across the United States. Children and youth in foster care, in particular, have multiple needs, including those related to emotional or psychological stress. They typically have experienced abusive, neglectful, serial or chaotic caretaking environments. Birth family history is often not available. These children often present with a fluidity of different symptoms over time reflective of past traumatic events that may mimic many psychiatric disorders and result in difficulties with attachment, mood regulation, behavioral control, and other areas of functioning. Establishment of rapport may be difficult. These multiple factors serve to complicate diagnosis. Foster children may reside in areas of the state where mental health professionals such as child psychiatrists are not readily available. Similarly, caregivers and health providers may be faced with critical situations that require immediate decisions about the care to be delivered. For these and other reasons, a need exists for treatment guidelines and parameters regarding the appropriate use of psychotropic medications for children and youth in foster care.

Because of the complex issues involved in the lives of foster children, it is important that a comprehensive evaluation be performed before beginning treatment for a mental or behavioral disorder. Except in the case of an emergency, a child should receive a thorough health history, psychosocial assessment, mental status exam, and physical exam before prescribing a psychotropic medication. The physical assessment should be performed by a physician or another healthcare professional qualified to perform such an assessment. It is recognized that in some emergency situations, it may be in the best interest of the child to prescribe psychotropic medications before a physical exam can actually be performed. In these situations, a thorough health history should be performed to assess for significant medical disorders and past response to medications, and a physical evaluation should be performed as soon as possible. A thorough psychosocial assessment should be performed by an appropriately qualified mental health clinician (masters or doctoral level), a psychiatrist/child psychiatrist, or a primary care physician with experience in providing mental health care to children and youth. The child's symptoms and functioning should be assessed across multiple domains, and the assessment should be developmentally age appropriate. It is very important that information about the child's history, including history of trauma and current functioning be made available to the treating physician in a timely manner, either through an adult who is well-informed about the child or through a comprehensive medical record. It is critical to meet the individual needs of patients and their families in a culturally competent manner. This indicates a need to address communication issues as well as differences in perspective on issues such as behavior and mental functioning. Interpretation of clinical symptoms and decisions concerning treatment should, whenever possible, be informed by the child's developmental history of trauma, neglect or abuse and the timing of these stressors. At present there are no biomarkers to assist with the diagnosis of mental disorders, and imaging (e.g., MRI) and other tests (e.g., EEG) are not generally helpful in making a clinical diagnosis of a mental disorder.

The role of non-pharmacological interventions should be considered before beginning a psychotropic medication, except in urgent situations such as suicidal ideation, psychosis, self-injurious behavior, physical aggression that is acutely dangerous to others, or severe impulsivity endangering the child or others; when there is marked disturbance of psychophysiological functioning (such as profound sleep disturbance), or when the child shows marked anxiety, isolation, or withdrawal. Given the history of trauma, unusual stress and change in environmental circumstances associated with being a child in foster care, psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication. Referral for trauma-informed, evidence based psychotherapy should be considered when available and appropriate. Patient and caregiver education should be provided about the condition to be treated, treatment options (non-pharmacological and pharmacological), treatment expectations, and potential side effects that may occur during the prescription of psychotropic medications.

It is recognized that many psychotropic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. The FDA has a statutory mandate to determine whether pharmaceutical company sponsored research indicates that a medication is safe and effective for those indications that are listed in the approved product labeling. The FDA assures that information in the approved product labeling is accurate, and limits the manufacturer's marketing to the information contained in the approved labeling. ***The FDA does not regulate physician and other health provider practice. In fact, the FDA has stated that it does "not limit the manner in which a practitioner may***

prescribe an approved drug." Studies and expert clinical experience often support the use of a medication for an "off-label" use. Physicians should utilize the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what is best for each individual patient.

Role of Primary Care Providers

Primary care providers play a valuable role in the care of youth with mental disorders. Not only are they the clinicians most likely to initially interact with children who are in distress due to an emotional or psychiatric disorder, inadequate numbers of child psychiatrists are available to meet all children's mental health needs. Primary care clinicians are in an excellent position to perform screenings of children for potential mental disorders, and they should be able to diagnose and treat relatively straightforward situations such as uncomplicated ADHD, anxiety, or depression. Primary care providers should provide advice to youth in foster care and their care givers about handling feelings and behaviors, recognizing the need for help, making decisions regarding healthy life styles, and the available treatments for childhood mental disorders. As always, consideration should be given regarding the need for referral for counseling, psychotherapy, or behavioral therapy. Primary care providers vary in their training, clinical experience, and confidence to address mental disorders in children. Short courses and intensive skills oriented seminars may be beneficial in assisting primary clinicians in caring for children with mental disorders. Active liaisons with child psychiatrists who are available for phone consultation or referral can be beneficial in assisting primary care clinicians to meet the mental health needs of children. A useful toolkit (American Academy of Pediatrics Task Force on Mental Health Addressing Mental Health Care in Primary Care: A Clinicians Toolkit) can be found at: www.aap.org/pcorss/demos/mht.html

General principles regarding the use of psychotropic medications in children include:

- A DSM-5 psychiatric diagnosis should be made before the prescribing of psychotropic medications.
- Clearly defined target symptoms and treatment goals for the use of psychotropic medications should be identified and documented in the medical record at the time of or before beginning treatment with a psychotropic medication. These target symptoms and treatment goals should be assessed at each clinic visit with the child and caregiver in a culturally and linguistically appropriate manner. Whenever possible, standardized clinical rating scales (clinician, patient, primary caregiver, teachers, and other care providers) or other measures should be used to quantify the response of the child's target symptoms to treatment and the progress made toward treatment goals.
- In making a decision regarding whether to prescribe a psychotropic medication in a specific child, the clinician should carefully consider potential side effects, including those that are uncommon but potentially severe, and evaluate the overall benefit to risk ratio of pharmacotherapy.
- Except in the case of an emergency, informed consent should be obtained from the appropriate party(s) before beginning psychotropic medication. Informed consent to treatment with psychotropic medication entails diagnosis, expected benefits and risks of treatment, including common side effects, discussion of laboratory findings, and uncommon but potentially severe adverse events. Alternative treatments, the risks associated with no treatment, and the overall potential benefit to risk ratio of treatment should be discussed.
- Youth, as well as caregivers, should be involved in decision-making about treatment, in accordance with their developmental level.
- During the prescription of psychotropic medication, the presence or absence of medication side effects should be documented in the child's medical record at each visit.
- Appropriate monitoring of indices such as height, weight, blood pressure, or other laboratory findings should be documented.
- Monotherapy regimens for a given disorder or specific target symptoms should usually be tried before polypharmacy regimens. While the goal is to use as few psychotropic medications as can be used to appropriately address the child's clinical status, it is recognized that the presence of psychiatric comorbidities may affect the number of psychotropic medications that are prescribed. When polypharmacy regimens are needed, It should occur in a systematic orderly process, accompanied by on-going monitoring, evaluation, and documentation. The treatment goal is to minimize polypharmacy while maximizing therapeutic outcomes.
- Medications should be initiated at the lower end of the recommended dose range and titrated carefully as needed.
- Only one medication should be changed at a time, unless a clinically appropriate reason to do otherwise is documented in the medical record. (Note: starting a new medication and beginning the dose taper of a current medication is considered one medication change).
- The use of "prn" or as needed prescriptions is discouraged. If they are used, the situation indicating need for the administration of a prn medication should be clearly indicated as well as the maximum number of prn doses in a day and a week. The frequency of administration should be monitored to assure that these do not become regularly scheduled medications.
- The frequency of clinician follow-up

with the patient should be appropriate for the severity of the child's condition and adequate to monitor response to treatment, including: symptoms, behavior, function, and potential medication side effects. At a minimum, a child receiving psychotropic medication should be seen by the clinician at least once every ninety days.

- The potential for emergent suicidality should be carefully evaluated and monitored, particularly in depressed children and adolescents as well as those initiating antidepressants, those having a history of suicidal behavior or deliberate self-harm and those with a history of anxiety or substance abuse disorders.

- If the prescribing clinician is not a child psychiatrist, referral to or consultation with a child psychiatrist, or a general psychiatrist with significant experience in treating children, should occur if the child's clinical status has not experienced meaningful improvement within a timeframe that is appropriate for the child's clinical response and the medication regimen being used.

- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, accuracy of the diagnosis, the occurrence of comorbid disorders (including substance abuse and general medical disorders), and the influence of psychosocial stressors.

- If a medication has not resulted in improvement in a child's target symptoms (or rating scale score), discontinue that medication rather than adding a second medication to it.

- If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-5 nonpsychotic diagnosis (e.g., conduct disorder, oppositional defiant disorder, intermittent explosive disorder), and the behavior disturbance has been in remission for six months, then serious consideration should be given to slow tapering and discontinuation of the medication. If the medication is continued in this situation, the necessity for continued treatment should be evaluated and documented in the medical record at a minimum of every six months.

- The clinician should clearly document care provided in the child's medical record, including history, mental status assessment, physical findings (when relevant), impressions, adequate laboratory monitoring specific to the drug(s) prescribed at intervals required specific to the prescribed drug and potential known risks, medication response, presence or absence of side effects, treatment plan, and intended use of prescribed medications.

Use of Psychotropic Medication in Preschool Age Children

The use of psychotropic medication in young children of preschool ages is a practice that is limited by the lack of evidence available for use of these agents in this age group. The Preschool Psychopharmacology Working Group (PPWG) published guidelines (Gleason 2007) summarizing available evidence for use of psychotropic medications in this age group. The PPWG was established in response to the clinical needs of preschoolers being treated with psychopharmacological agents and the absence of systematic practice guidelines for this age group, with its central purpose to attempt to promote an evidence-based, informed, and clinically sound approach when considering medications in preschool-aged children.

The PPWG guidelines emphasize consideration of multiple different factors when deciding on whether to prescribe psychotropic medications to preschool-aged children. Such factors include the assessment and diagnostic methods utilized in evaluating the child for psychiatric symptoms/illness, the current state of knowledge regarding the impact of psychotropic medication use on childhood neurodevelopmental processes, the regulatory and ethical contexts of use of psychotropic medications in small children (including available safety information and FDA status), and the existing evidence base for use of psychotropic medication in preschool aged children.

The publication includes specific guidelines and algorithm schematics developed by the PPWG to help guide treatment decisions for a number of psychiatric disorders that may present in preschool-aged children, including Attention-Deficit Hyperactivity Disorder, Disruptive Behavioral Disorders, Major Depressive Disorder, Bipolar Disorder, Anxiety Disorders, Post-Traumatic Stress Disorder, Obsessive-Compulsive Disorder, Pervasive Developmental Disorders, and Primary Sleep Disorders.

The working group's key points and guidelines are similar to the general principles regarding the use of psychotropic medication in children already detailed in this paper. However, the working group's algorithms put more emphasis on treating preschool-aged children with non-psychopharmacological interventions (for up to 12 weeks) before starting psychopharmacological treatment, in an effort to be very cautious in introducing psychopharmacological interventions to rapidly developing preschoolers. The working group also emphasizes the need to assess parent functioning and mental health needs, in addition to training parents in evidence-based behavior management, since parent behavior and functioning can have a large impact on behavior and symptoms in preschool-aged children.

Therapeutic Controversies

Antipsychotic selection

Significant controversy exists regarding the use of 2nd generation versus 1st generation antipsychotics. Most of the data support- ing no difference in efficacy between these two groups of antipsychotics comes from studies conducted in chronically ill adults with schizophrenia. Most of the controlled studies of the use of antipsychotics to treat

behavioral disorders in children have been performed with 2nd generation antipsychotics, with the most evidence for risperidone. The only study comparing a 1st generation antipsychotic versus 2nd generation antipsychotics in youth was conducted in individuals with early onset schizophrenia. The 1st generation agent used in this study was molindone, an antipsychotic, no longer on the market, that is known to be weight neutral or cause weight loss in adults. It is unknown how the results of this study can be extrapolated to the treatment of children with other first generation antipsychotics.

Antipsychotics vary with regard to their side effect profiles, and side effects are the primary basis for individual medication choice. Second generation antipsychotics are prone to cause significant weight gain in many children, but the risk for the development of weight gain in youth varies significantly among the 2nd generation agents. In a systematic review (De Hert 2011) of 31 short-term randomized controlled trials including 3595 youth, the average weight gain was olanzapine (3.78 kg, 3.4 weeks), risperidone (2.37 kg, 7.5 weeks) quetiapine (2.15 kg, 4.5 weeks), aripiprazole (1.04 kg, 6.1 weeks), and ziprasidone (0.49 kg, 5.3 weeks). Significant weight gain was more common in children with autistic disorder who were younger and more likely first-time antipsychotic users. In addition, the most significant effects on glucose and lipids are associated with the 2nd generation antipsychotics known to cause the largest weight gain. Because of the risk of obesity and metabolic dysfunction associated with some of the 2nd generation antipsychotics, particularly olanzapine, clinicians should consider being proactive and implement diet counseling and exercise programs at the same time that antipsychotics are initiated.

First generation antipsychotics are prone to causing extrapyramidal side effects. In particular, youth are especially susceptible to developing acute dystonic reactions from 1st generation antipsychotics. Similarly, 1st generation antipsychotics pose a higher risk for the development of tardive dyskinesia in chronically treated individuals. If antipsychotics are indicated, the clinician should carefully evaluate the individual needs of the child, actively engage the family in decision-making, evaluate overall benefit to risk ratio, and when indicated, choose the antipsychotic that the clinician thinks will be best tolerated by that child.

Psychotropic medication choice in acute mania

Traditionally, because of a lack of research, clinicians have used the same medications to treat mania associated with bipolar disorder in children and adolescents as are used in adults. Recently studies addressing the treatment of mania and mixed mania in children and adolescents have been conducted. The Treatment of Early Age Mania (TEAM) study (Geller 2012) evaluated the relative efficacy and tolerability of risperidone, lithium, and divalproex in 279 medication naïve children and adolescents with either mania or mixed mania. Risperidone was superior in efficacy to either lithium or divalproex. The discontinuation rate was higher with lithium, suggesting better tolerability with risperidone. However, risperidone did have significant adverse effects including weight gain, BMI increase, and hyperprolactinemia.

Depression, Suicidality, and Antidepressants

In October 2003, the FDA released a public health advisory alerting health care professionals to reports of suicidality (suicidal verbalizations and suicidal behaviors) in clinical trials of antidepressants in pediatric populations. These reports provided the impetus for a FDA meta-analytic review of short-term clinical trials of antidepressants in children and adolescents. These analyses involved review, assessment, and reclassification of over 400 case descriptions. This review ultimately resulted in findings of an increased risk of suicidality during the first few weeks of antidepressant treatment. The FDA responded by issuing a black box warning in October 2004. The black box warning describes an increased risk of suicidality (suicidal behavior and ideation) for ALL antidepressants used in individuals under the age of 18. The incidence of suicidal ideations and behaviors in these pooled analyses was about 4% for those youth receiving antidepressants compared with 2% on placebo. It is important to note that no completed suicides (i.e., deaths) were reported in any of these trials.

The mortality risk of depression is from suicide. Other major suicide risk factors that should be assessed include: anxiety, substance abuse, and conduct disorders, life stressors (such as legal or disciplinary/school problems), interpersonal losses, family and peer discord, abuse, lack of support, poor interpersonal problem-solving ability, the tendency to respond with hostility or overt aggression to frustration or stress, hopelessness and cognitive distortions. All youth with depression should be monitored carefully for the potential presence of suicidal thoughts or behaviors. This should occur at the time of initial clinical assessment and upon each visit follow-up until depression is no longer present. Assessment of suicidality should include asking questions about ideation and frequency, plans, intention, means, and potential dangerousness. More frequent visits, combined with follow-up calls as necessary, should be considered along with appropriate review of safety plans. It is noteworthy that in one study, the concomitant use of cognitive behavioral therapy was shown to decrease the incidence of suicidality associated with SSRI use.

Stimulants and growth

Parents and caregivers are often concerned about the possibility that stimulants may adversely affect growth. This is largely related to the fact that, at least short term, stimulants decrease appetite. Although data from different studies are mixed, results from the Multimodal Treatment of ADHD (MTA) study, indicate that weight loss occurred during the first 3-4 months of treatment, but this was followed be a resumption of weight increase. The rate of growth in height decreased by about 1-3 cm/year over the first 1-3 years of medication treatment. These decreases in height were only seen in the youth who were adherent with their stimulant medications. Although both advantages and disadvantag-

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es are associated with medication holidays or vacations, this has been suggested as one mechanism to minimize potential effects on growth. It is questionable whether the use of stimulants has any effect on ultimate adult height(Swanson 2008; Vitello 2008)

Stimulants and cardiovascular side effects

Both stimulants and atomoxetine cause small but statistically significant increases in blood pressure and pulse rate. However, it is unclear whether these changes are clinically significant. Although case reports of sudden death in children taking stimulants have been reported, a causal link has not been proven. A large cohort study using data from a 5-state Medicaid database [1999-2003] and the 14-state HealthCore Integrated Research Database [2001-2006] with 241,417 incident users found no statistically significant difference between incident users and nonusers in the rate of sudden death, ventricular arrhythmia, or death from any cause. One theory is that underlying cardiac disorders such as serious structural abnormalities, cardiomyopathies, serious heart rhythm disturbances, or other serious cardiac problems may place children at increased risk of sudden death when stimulants are administered. The clinician should conduct a careful history of the child and the family regarding potential heart problems. A thorough physical exam should also be conducted. If the history and physical provide suspicion of a cardiac problem, then an electrocardiogram should be considered before beginning a stimulant. Although not routinely required, if the child has a known history of a cardiac problem, then a cardiology consult should be considered before beginning a stimulant- (Cooper 2011, Correll 2011, Perrin 2008, Skelleman 2011).

Distinguishing between Levels of Warnings Associated with Medication Adverse Effects

Psychotropic medications have the potential for adverse effects, some that are treatment-limiting. Some adverse effects are detected prior to marketing, and are included in product labeling provided by the manufacturers. When looking at product labeling, these adverse effects will be listed in the "Warnings and Precautions" section. As well, the "Adverse Reactions" section of the product labeling will outline those adverse effects reported during clinical trials, as well as those discovered during post-marketing evaluation. Many tertiary drug information resources also report information regarding common adverse effects and precautions for use with psychotropic medications.

At times, post-marketing evaluation may detect critical adverse effects associated with significant morbidity and mortal- ity. The Food and Drug Administration (FDA) may require manufacturers to revise product labeling to indicate these critical adverse effects. If found to be particularly significant, these effects are demarcated by a black box outlining the information at the very beginning of the product labeling, and have, in turn, been named black box warnings. Black box warnings are the strongest warning required by the FDA. It is important for clinicians to be familiar with all medication adverse effects, including black box warnings, in order to appropriately monitor patients and minimize the risk of their occurrence.

The FDA has in recent years taken additional measures to try and help patients avoid serious adverse events. New guides called Medication Guides have been developed, and are specific to particular drugs and drug classes. Medication Guides advise patients and caregivers regarding possible adverse effects associated with classes of medications, and include precautions that they or healthcare providers may take while taking/ prescribing certain classes of medications. FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that certain information is necessary to prevent serious adverse effects, that patient decision-making should be informed by information about a known serious side effect with a product, or when patient adherence to directions for the use of a product are essential to its effectiveness. During the drug distribution process, if a Medication Guide has been developed for a certain class of medications, then one must be provided with every new prescription and refill of that medication.

Copies of the Medication Guides for psychotropic medications can be accessed on the FDA website at:

http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

Usual Recommended Doses of Common Psychotropic Medications

The attached medication charts are intended to reflect usual doses and brief medication information for commonly used psychotropic medications. The preferred drug list of medications potentially prescribed for foster children is the same as for all other Texas Medicaid recipients.

These are intended to serve as a guide for clinicians. The tables are not intended to serve as comprehensive drug information references or a substitute for sound clinical judgment in the care of individual patients, and individual patient circumstances may dictate the need for the use of higher doses in specific patients. In these cases, careful documentation of the rationale for the higher dose should occur, and careful monitoring and documentation of response to treatment should be observed.

Not all medications prescribed by clinicians for psychiatric diagnoses in children and adolescents are included below. However, in general, medications not listed do not have adequate efficacy and safety information available to support a usual maximum dose recommendation.

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Criteria Indicating Need for Further Review of a Child's Clinical Status

The following situations indicate a need for review of a patient's clinical care. These parameters do not necessarily indicate that treatment is inappropriate, but they do indicate a need for further review.

For a child being prescribed a psychotropic medication, any of the following suggests the need for additional review of a patient's clinical status:

1. Absence of a thorough assessment for the DSM-5 diagnosis(es) in the child's medical record

2. Four (4) or more psychotropic medications prescribed concomitantly (side effect medications are not included in this count)

3. Prescribing of:

- Two (2) or more concomitant stimulants *
- Two (2) or more concomitant alpha agonists
- Two (2) or more concomitant antidepressants
- Two (2) or more concomitant antipsychotics
- Three (3) or more concomitant mood stabilizers

* The prescription of a long-acting stimulant and an immediate release stimulant of the same chemical entity (e.g., methylphenidate) does not constitute concomitant prescribing.

Note: When switching psychotropics, medication overlaps and cross taper should occur in a timely fashion, generally within 4 weeks.

4. The prescribed psychotropic medication is not consistent with appropriate care for the patient's diagnosed mental disorder or with documented target symptoms usually associated with a therapeutic response to the medication prescribed.

5. Psychotropic polypharmacy (2 or more medications) for a given mental disorder is prescribed before utilizing psychotropic monotherapy.

6. The psychotropic medication dose exceeds usual recommended doses (FDA and/or literature based maximum dosages).

7. Psychotropic medications are prescribed for children of very young age, including children receiving the following medications with an age of:
   - Stimulants: Less than three (3) years of age
   - Alpha Agonists Less than four (4) years of age
   - Antidepressants: Less than four (4) years of age
   - Antipsychotics Less than four (4) years of age
   - Mood Stabilizers: Less than four (4) years of age

8. Prescribing by a primary care provider who has not documented previous specialty training for a diagnosis other than the following (unless recommended by a psychiatrist consultant):
   - Attention Deficit Hyperactive Disorder (ADHD)
   - Uncomplicated anxiety disorders
   - Uncomplicated depression

9. Antipsychotic medication(s) prescribed continuously without appropriate monitoring of glucose and lipids at least every 6 months.

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Stimulants (for treatment of ADHD)

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning**	Warnings and Precautions
Amphetamine mixed salts*	Adderall®	• Age 3-5 years: 2.5 mg/day • Age ≥ 6 years: 5-10 mg/day	>50 kg: 60 mg/day	Approved for children 3 years and older: 40 mg/day	One to three times daily	• Abuse potential • Sudden death and serious cardiovascular events	• Sudden death in those with pre-existing structural cardiac abnormalities or other serious heart problems • Hypertension • Psychiatric adverse event • Long-term suppression of growth • Tics • Decreased appetite • Sleep disturbance
	Adderall®XR	• Age 6-12 years: 5-10 mg/day • Age ≥13 years: 10 mg/day		Approved for children 6 years and older: 30 mg/day	Once daily		
Dextroamphetamine*	Dexedrine®	• Age 3-5 years: 2.5 mg/day • Age ≥ 6 years: 5 mg twice daily	>50 kg: 60 mg/day	Approved for children 6 years and older: 40 mg/day	Once or twice daily		
	Dexedrine Spansule®	• Age ≥ 6 years: 5 mg/day					
Lisdexamfetamine	Vyvanse®	30 mg/day	70 mg/day	Approved for children 6 years and older: 70 mg/day	Once daily		
Methylphenidate*	Ritalin®	• Age 3-5 years: 2.5 mg twice daily • Age ≥ 6 years: 5 mg twice daily	• Age 3-5 years: 22.5 mg/day • >50 kg: 100 mg/day	Approved for children 6 years and older: 60 mg/day	One to three times daily		
	Ritalin®SR	20 mg/day			1-2 X daily		
	Ritalin®LA	20 mg/day			Once daily		
	Metadate®ER	10 mg/day		Approved for children 6 years and older: 60 mg/day	2-3 X daily		
	Metadate®CD	10 mg/day			Once daily		
	Methylin®	5 mg twice daily		Approved for children 6 years and older: 60 mg/day	One to three times daily		
	Methylin®ER	10 mg/day			2-3 X daily		
	Concerta®	18 mg/day	108 mg/day	Approved for children 6 years and older: • Age 6-12 years: 54 mg/day • Age 13-17 years: lesser of 72 mg/day or 2 mg/kg/day	Once daily		
	Daytrana®TD	10 mg/day	30 mg/day	Approved for children 6 years and older: 30 mg/day (largest patch)	Once daily		
Dexmethylphenidate*	Focalin®	2.5 mg twice daily	50 mg/day	Approved for children 6 years and older: 20 mg/day	Twice daily		
	Focalin®XR	5 mg/day		Approved for children 6 years and older: 30 mg/day	Once daily		

* Generic available

** See the FDA approved product labeling for each medication for the full black box warnings.

+ IR, immediate release; SR, sustained-release formulation; CD, combined immediate release and extended release; ER and XR, extended-release; LA, long-acting; TD, transdermal

Other ADHD Treatments

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Baseline/ Monitoring	Black Box Warning	Warnings and Precautions
Atomoxetine	Strattera®	• Weight ≤70 kg: 0.5 mg/kg/day • Weight >70 kg: 40 mg/day	Lesser of 1.8 mg/kg or 100 mg/day	Approved for treatment of ADHD (age 6-17 years): Lesser of 1.4 mg/kg/day or 100 mg/day	Once or twice daily	None	Suicidal thinking in children and adolescents being treated for ADHD	• Severe liver injury • Serious cardiovascular events, including sudden death, particularly in those with pre-existing structural abnormalities or other serious heart problems • Increased blood pressure and heart rate • Psychiatric adverse events • Allergic Events • Priapism • Long-term suppression of growth • Weight gain
Clonidine*	Catapres® (IR)	• Weight <45 kg: 0.05 mg/day • Weight >45 kg: 0.1 mg/day	• Weight 27-40.5 kg: 0.2 mg/day • Weight 40.5-45 kg: 0.3 mg/day • Weight >45 kg: 0.4 mg/day	Not approved for treatment of ADHD in children and adolescents	One to four times daily	Personal and family cardiovascular history	None	• Hypotension • Bradycardia • Syncope • Sedation/Somnolence • Do not discontinue abruptly **CAUTION IF USED WITH ANTIPSYCHOTICS (↓ BP)**
	Kapvay® (ER)	0.1 mg/day	0.4 mg/day	Approved for treatment of ADHD (age 6-17 years): 0.4 mg/day	Once or twice daily			
Guanfacine*	Tenex® (IR)	• Weight <45 kg: 0.5 mg/day • Weight > 45 kg: 1 mg/day	• Weight 27-40.5 kg: 2 mg/day • Weight 40.5-45 kg: 3 mg/day • Weight >45 kg: 4 mg/day	Not approved for children and adolescents	One to four times daily	Personal and family cardiovascular history	None	
	Intuniv® (ER)	1 mg/day	4 mg/day	Approved for treatment of ADHD (age 6-17 years): 4 mg/day	Once daily			
Bupropion*	Wellbutrin®	Lesser of 3 mg/kg/day or 150 mg/day	Lesser of 6 mg/kg/day or 300 mg/day with no single dose >150 mg	Not approved for children and adolescents	One to three times daily	None	Increased risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depres- sive disorder (MDD) and other psychiatric disorders	• Use in combination with MAOIs • Suicidal ideation • Activation of mania/ hypomania • Lowers seizure threshold • Discontinuation syndrome • Caution with cardiac disease
	Wellbutrin®SR	Same as above	400 mg/day		Once or twice daily			
	Wellbutrin®XL	Same as above	450 mg/day		Once daily			
Imipramine*	Tofranil®	Lesser of 1 mg/kg/day or 25 mg/day	Lesser of 4 mg/kg/day or 200 mg/day	Approved for treatment of enuresis in children Age 6-12 years: lesser of 2.5 mg/kg/day or 50 mg/day Age ≥ 12 years: lesser of 2.5 mg/kg/day or 75 mg/day Approved treatment of depression ≥ 12 years: 100 mg/day	Twice daily	• Pulse • ECG		
Nortriptyline*	Aventyl®	0.5 mg/kg/day	Lesser of 2 mg/kg/day or 100 mg/day	Not approved for children and adolescents	Twice daily	• Pulse • ECG		
	Pamelor®							
	Nortrilen®							

* Generic available

\+ IR, immediate release; SR, sustained-release formulation; ER, extended-release; XL, extended-length

Antidepressants, SSRIs

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Citalopram*	Celexa®	• Children: 10 mg/day • Adolescents: 20 mg/day	40 mg/day	Not approved for children and adolescents	Once daily	• Pregnancy test – as clinically indicated • Monitor for emergence of suicidal ideation or behavior • Monitor weight and growth	Increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Use in combination with MAOIs • Suicidal ideation • Activation of mania/hypomania • Discontinuation syndrome • Abnormal bleeding • Weight loss • Serotonin Syndrome or Neuroleptic Malignant Syndrome • Interference with cognitive and motor performance • Lowers seizure threshold • Hyponatremia
Escitalopram*	Lexapro®	• Age 6-17 years (autism): 2.5 mg/day • Adolescents (MDD): 10 mg/day	• Age 6-12 years: 20mg/day • Age ≥ 12 years: 30 mg/day	• Not approved for children • Approved for treatment of MDD in adolescents (age 12-17 years): 20 mg/day				
Fluoxetine*	Prozac®	• Children: 5-10 mg/day • Adolescents: 10 mg/day	60/day	• Approved for treatment of MDD (age 8-18 years): 20 mg/day • Approved for treatment of OCD (age 7-17 years): 60 mg/day				
Paroxetine*	Paxil®	• Children: Not recommended • Adolescents: 10 mg	• Children: Not recommended • Adolescents: 40 mg	Not approved for children and adolescents				
	Paxil®CR	• Children: Not recommended • Adolescents: 25 mg	• Children: Not recommended • Adolescents: 50 mg					
Fluvoxamine*	Luvox®	25 mg/day	• Age 8-11 years: 200 mg/day • Age 12-17 years: 300 mg/day	Approved for treatment of OCD (age 8-17 years): • Ages 8-11 years: 200 mg/day • Ages 12-17 years: 300 mg/day	Daily doses >50 mg should be divided			
	Luvox®CR	100 mg/day						
Sertraline*	Zoloft®	Age 6-12 years: 12.5-25 mg/dayAge 13-17 years: 25-50 mg/day	200 mg/day	Approved for treatment of OCD (age 6-17 years): 200 mg/day	Once daily			

* Generic available

+ CR, controlled-release

From Black Box Warning in product labeling: Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Both patients and families should be encouraged to contact the clinician if depression worsens, the patient demonstrates suicidal behavior or verbalizations, or if medication side effects occur. The appropriate utilization of non-physician clinical personnel who are knowledgeable of the patient population can aid in increasing the frequency of contact between the clinic and the patient/parent.

Antidepressants, SNRIs

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Venlafaxine*	Effexor Effexor®XR	Age 7-17 years: 37.5 mg/day	• Children: 150 mg/day • Adolescents: 375 mg/day	Not approved forchildren and adolescents	IR: Two to three times daily XR: Once daily	• Pregnancy test – as clinically indicated • Monitor for emergence of suicidal ideation or behavior • Blood pressure during dosage titration and as clinically indicated • Monitor weight and growth • Serum cholesterol levels	Increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Use in combination with MAOIs • Suicidal ideation • Abnormal bleeding • Severe skin reactions • Discontinuation syndrome • Activation of mania/hypomania • Hepatotoxicity • Orthostatic hypotension and syncope • Serotonin Syndrome or Neuroleptic Malignant Syndrome • Seizures • Elevated blood pressure • Hyponatremia
Duloxetine	Cymbalta®	• Children: Insufficient Evidence • Adolescents: 40 mg/day	• Children: Insufficient Evidence • Adolescents: 60 mg/day	Not approved for children and adolescents	Once or twice daily	• Pregnancy test – as clinically indicated • Monitor for emergence of suicidal ideation or behavior • Blood pressure prior to initiating treatment, during dosage titration and as clinically indicated • Hepatic function testing – baseline and as clinically indicated		
Desvenlafaxine	Pristiq®	• Children: Insufficient Evidence • Adolescents: 50 mg/day	• Children: Insufficient Evidence • Adolescents: 100 mg/day	Not approved for children and adolescents	Once daily	• Pregnancy test – as clinically indicated • Monitor for emergence of suicidal ideation or behavior • Blood pressure prior to initiating treatment, during dosage titration and as clinically indicated • Hepatic function testing – baseline and as clinically indicated • Serum cholesterol and triglyceride levels		

* Generic Available

\+ XR, extended-release

From Black Box Warning on package inserts: Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Both patients and families should be encouraged to contact the clinician if depression worsens, the patient demonstrates suicidal behavior or verbalizations, or if medication side effects occur. The appropriate utilization of non-physician clinical personnel who are knowledgeable of the patient population can aid in increasing the frequency of contact between the clinic and the patient/parent.

Antipsychotics: Second Generation (Atypical)

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Aripiprazole	Abilify®	2 mg/day	• Children: 15 mg/day • Adolescents: 30 mg/day	• Approved for treatment of Bipolar Mania or Mixed Episodes (age 10-17 years) and Schizophrenia (13-17 years): 30 mg/day • Approved for treatment of irritability associated with Autistic Disorder (age 6-17 years): 15 mg/day	Once daily	• Fasting plasma glucose level or hemoglobin A1c – at baseline, at 3 months, then every 6 months. • Lipid screening [total cholesterol, low-and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides]-at baseline, at 3 months, then every 6 months. • CBC as indicated by guidelines approved by the FDA in the product labeling. • Pregnancy test – as clinically indicated • Blood pressure, pulse rate, height, weight and BMI measurement – when a new antipsychotic is initiated and at every visit • Sexual function inquiry – inquire yearly for evidence of galactorrhea/ gynecomastia, menstrual disturbance, libido disturbance or erectile/ ejaculatory disturbances in males (Priapism has been reported with Iloperidone, Risperidone and Ziprasidone). This inquiry should be done at each visit (quarterly for inpatients) for the first 12 months after starting an antipsychotic or until the medication dose is stable and then yearly. • EPS evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase. • Tardive Dyskinesia evaluation – every 12 months. For high risk patients (including the elderly), every 6 months.. • Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision-yearly. (Cataracts have been reported for Quietapine) • EKG - Baseline and as clinically indicated (QTc prolongation reported for Asenapine, Clozapine, Iloperidone, Paliperidone, Quietapine and Ziprasidone)	Not approved for depression in under age 18. Increased the risk of suicidal thinking and behavior in short-term studies in children and adolescents with major depressive disorder and other psychiatric disorders	• Neuroleptic Malignant Syndrome • Tardive Dyskinesia • Hyperglycemia and Diabetes Mellitus • Weight gain • Dyslipidemia • Orthostatic Hypotension • Leukopenia, neutropenia, and agranulocytosis • Lowers seizure threshold • Cognitive and motor impairment • Hyperthermia • Dysphagia • Hyperprolactinemia (Except not reported with Aripiprazole, Clozapine, and Asenapine) • Extrapyramidal side effects
Quetiapine*	Seroquel® Seroquel®XR (brand only)	• Age ≤ 9 years: 12.5-25 mg/ day • Age 10-17 years: 50 mg/ day	• Age ≤ 9 years: 400 mg/day • Age 10-17 years: 800 mg/day	• Approved for treatment of Bipolar Mania (age 10-17 years): 600 mg/day • Approved for treatment of Schizophrenia (13-17 years): 800 mg/day	Two to three times daily			
Olanzapine*	Zyprexa®	• Age < 6 years: 1.25 mg/day • Age 6-12 years: 2.5 mg/ day • Age ≥ 13 years: 2.5-5 mg/day	Children: 12.5 mg/day Adolescents: 20 mg/day	Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 20 mg/day	Once daily		None related to youth	
Risperidone*	Risperdal®	• Children ○ <20 kg: 0.25 mg/day ○ >20 kg: 0.5 mg/day • Adolescents: 0.5 mg/day	• Children: 3 mg/day • Adolescents: 6 mg/day	• Approved for treatment of Schizophrenia (age 13-17 years) and Bipolar Mania or Mixed Episodes (age 10-17 years): 6 mg/day • Approved for treatment of irritability associated with autistic disorder (age 5-16 years): 3 mg/day	Once or twice daily		None related to youth	
Clozapine*	Clozaril® Fazaclo® (oral disintegrating tablet)	• Children: 6.25-12.5 mg/day • Adolescents: 6.25-25 mg/ day	• Children: 150-300 mg/day • Adolescents: 600 mg/day Target serum clozapine level of 350 ng/mL for optimal efficacy	Not approved for children and adolescents	Once or twice daily		• Risk of life threatening agranulocytosis • Seizures • Myocarditis • Other adverse cardiovascular and respiratory effects	
Asenapine (sublingual)	Saphris®	Insufficient evidence	Insufficient evidence	Not approved for children and adolescents	Insufficient evidence; nothing by mouth for 10 minutes after sublingual adminis-tration		None related to youth	
Iloperidone	Fanapt®	Insufficient Evidence	Insufficient evidence	Not approved for children and adolescents	Insufficient Evidence		None related to youth	
Paliperidone	Invega®	• Children: Insufficient evidence • Adolescents: 3 mg/day	• Children: Insufficient evidence • Adolescents: ○ Weight < 51 kg: 6 mg/day ○ Weight ≥ 51 kg: 12 mg/day	Approved for treatment of Schizophrenia (age 12-17 years): • Weight < 51 kg: 6 mg/ day • Weight ≥ 51 kg: 12 mg/day	Once daily		None related to youth	
Ziprasidone*	Geodon®	• Bipolar Disorder (age 10-17 years): 20 mg/day • Tourette's Disorder: 5 mg/day	• Bipolar Disorder • Weight ≤ 45 kg: 80 mg/day • Weight > 45 kg: 160 mg/day • Tourette's Disorder: 40 mg/day	Not approved for children and adolescents	Insufficient evidence; take with ≥500 calorie meal		None related to youth	
Lurasidone	Latuda®	Insufficient Evidence	Insufficient evidence	Not approved for children and adolescents	Insufficient evidence; take with >350 calorie meal		None related to youth	

* Generic available

+ XR, extended-release

Antipsychotics: First Generation (Typical)

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning	Warnings and Precautions
Chlorpromazine*	Thorazine®	• Age > 6 months: 0.25 mg/lb every 4-6 hours, as needed • Adolescents: 10-25 mg/dose every 4-6 hours	• Age < 5 years: 40 mg/day • Age 5-12 years: 75 mg/day • Age > 12 years: 800 mg/day	Approved for treatment of severe behavioral problems (age 6 months-12 years) • Outpatient Children: 0.55 mg/kg every 4-6 hours, as needed • Inpatient Children: 500 mg/day Approved for the management of manifestations of Psychotic Disorders (age > 12 years): 1 g/day	One to six times daily	None related to youth	• Tardive Dyskinesia • Neuroleptic Malignant Syndrome • Leukopenia, neutropenia, and agranulocytosis • Drowsiness • Orthostatic hypotension • EKG changes • Extrapyramidal symptoms • Ocular changes • Hyperprolactinemia • Anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention) • Antiemetic effect (Reported in Chlorpromazine and Perphenazine)
Haloperidol*	Haldol®	• Age 3-12 years, (15 – 40 kg): 0.025-0.05 mg/kg/day • Age ≥13 years: 1 mg/day	• Children: 0.15 mg/kg/day • Adolescents ○ Acute agitation: 15 mg/dose ○ Psychosis: 15 mg/day ○ Tourette's Disorder: 15 mg/ day	Approved for treatment of Psychotic Disorders, Tourette's Disorder, and severe behavioral problems (age ≥3 years): • Psychosis: 0.15 mg/kg/day • Tourette's Disorder and severe behavioral problems: 0.075 mg/kg/day • Severely disturbed children: 6 mg/day	One to three times daily	None related to youth	
Perphenazine*	Trilafon®	• Children: insufficient evidence • Adolescents: ○ Outpatient: 4-8 mg three times daily ○ Inpatient: 8-16mg twice to four times daily	• Children: insufficient evidence • Adolescents: 64 mg/day	Approved for treatment of psychotic disorders (age ≥12 years): • Outpatient: 24 mg/day • Inpatient: 64 mg/day	Two to four times daily	None related to youth	
Pimozide	Orap®	Age ≥7 years: 0.05 mg/kg	• Age 7-12 years: lesser of 6 mg/day or 0.2 mg/kg/day • Age ≥ 12 years: Lesser of 10 mg/day or 0.2 mg/kg/day	Approved for treatment of Tourette's Disorder (age ≥12 years): Lesser of 10 mg/day or 0.2 mg/kg/day	Once or twice daily	None related to youth	

* Generic available

Mood Stabilizers

Drug (generic)	Drug (brand)+	Initial Dosage	Target Dosage Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Baseline Monitoring	Black Box Warning	Warnings and Precautions
Carbamazepine*	Carbatrol®(ER) Tegretol® Tegretol®XR	• Age < 6 years: 10-20 mg/kg/day • Age 6-12 years: 10 mg/kg/day or 200 mg/day • Age >12 years: 400 mg/day	• Age <6 years: 35 mg/kg/day • Ages 6-12 years: 400-800 mg/day • Age >12 years: 800-1200 mg/day	• Age <6 years: 35 mg/kg/day • Ages 6-12 years: 800 mg/day • Age 12-15 years: 1000 mg/day • Age >15 years: 1200 mg/day	Approved for treatment of Seizure Disorders in all ages • Age < 6 years: 35 mg/kg/day • Age 6-15 years: 1000 mg/day • Age >15 years: 1200 mg/day	Twice daily Two to four times daily Twice daily	• HLA-B*1502 Allele (risk of SJS) • Pregnancy test • CBC • Electrolytes	• Stevens-Johnson Syndrome • Aplastic Anemia/granulocytosis	• Stevens-Johnson Syndrome • Aplastic anemia • Suicidality • Teratogenicity • Neutropenia • Hyponatremia • Induces metabolism of itself and some other drugs • Decreased efficacy of oral contraceptives • Withdrawal seizures
Divalproex Sodium*	Depakote®	10-15 mg/kg/day	30-60 mg/kg/day	Serum level: 125 µg/mL, or 60 mg/kg/day	Approved for treatment of Seizure Disorders (age ≥ 10 years) Maximum dose based upon serum level: 50-100 µg/mL, or 60 mg/kg/day	One to three times daily	• Chemistry Panel • CBC (with platelets) • LFTs • Pregnancy test	• Hepatotoxicity • Teratogenicity • Pancreatitis	• Hepatotoxicity • Pancreatitis • Urea cycle disorders • Teratogenicity • Suicidal ideation • Thrombocytopenia • Hyperammonemia • Multi-organ hypersensitivity reaction • Withdrawal seizures • Polycystic ovaries • Neutropenia
Lithium*	Eskalith® Eskalith®CR Lithobid®(ER)	• Children: Lesser of 15-20 mg/kg/day or 150mg twice per day • Adolescents: Lesser of 15-20 mg/day or 300 mg twice per day	Dose adjustment based upon serum level Serum level: 0.6-1.2 mEq/L	Serum level: 1.2 mEq/L, or 1800 mg	Approved for treatment of manic episodes and maintenance of Bipolar Disorder (age ≥ 12 years) Maximum dose based upon serum level: 1.2 mEq/L	One to four times daily	• Chemistry Panel • CBC (with platelets) • Serum Creatinine • LFTs • Pregnancy test • ECG • Blood for lithium serum levels should be drawn 10-12 hours after the last dose.	Toxicity above therapeutic serum levels	• Toxicity above therapeutic serum levels • Chronic renal function impairment • Special risk patients: those with significant renal or cardiovascular disease, severe debilitation, dehydration, or sodium depletion • Polyuria • Tremor • Diarrhea • Nausea • Hypothyroidism • Teratogenicity
Lamotrigine*	Lamictal®	• Children: 2-5 mg/day • Adolescents: 25 mg/day (increase by 25 mg every2 weeks)	Children • Monotherapy: 4.5-7.5 mg/kg/day • With Valproate: 1-3 mg/kg/day • With Valproate and EIAEDs✦: 1-5 mg/kg/day • With EIAED's: 5-15 mg/kg/day Adolescents • Monotherapy: 225-375 mg/day • With Valproate: 100-200 mg/day • With Valproate and EIAEDs✦: 100-400 mg/day • With EIAEDs✦: 300-500 mg/day		Approved for adjunctive therapy for Seizure Disorders: Age 2-12: 400 mg/day Age >12: 500 mg/day Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established	Once or twice daily		Serious rashes including Stevens-Johnson syndrome	• Dermatological reactions • Potential Stevens-Johnson Syndrome • Multi-organ Hypersensitivity reactions and organ failure • Blood dyscrasias • Suicidal ideation • Aseptic meningitis • Concomitant use with oral contraceptives increases lamotrigine clearance • Withdrawal seizures
Oxcarbazepine*	Trileptal®	8-10 mg/kg/day	Monotherapy (based on weight): • 20-24.9 kg: 600-900 mg/day • 25-34.9 kg: 900-1200 mg/day • 35-44.9 kg: 900-1500 mg/day • 45-49.9 kg: 1200 – 1500mg/day • 50-59.9 kg: 1200-1800 mg/day • 60-69.9 kg: 1200-2100 mg/day • ≥70 kg: 1500-2100 mg/day	• Children: 60 mg/kg/day or 1500 mg/day • Adolescents: 60 mg/kg/day or 2100 mg/day	Approved for treatment of Seizure Disorders as monotherapy (age ≥ 4 years), or as adjunctive therapy in (age ≥ 2 years): 60 mg/kg/day or 1800 mg/day	Twice daily	• CBC • Electrolytes • Pregnancy test		• Hyponatremia • Anaphylactic reactions and angioedema • Patients with a past history of hypersensitivity reaction to carbamazepine • Serious dermatological reactions • Withdrawal seizures • Cognitive/neuropsychiatric adverse events • Multi-organ hypersensitivity • Hematologic events

* Generic Available

✦EIAED's - Enzyme Inducing Anti-Epileptic Drugs (e.g. Carbamazepine, Phenobarbital, Phenytoin, Primidone)

+ ER and XR, extended-release; CR, controlled release

Sedatives/Hypnotics

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning**	Warnings and Precautions
Diphenhydramine*	Benadryl®	• Age 3-5 years: 6.25-12.5 mg (1mg/kg max) • Age 5-12 years: 12.5-25 mg • Age ≥12 years: 25-50 mg	• 25-37 lbs: 12.5 mg • 38-49 lbs: 19 mg • 50-99 lbs: 25 mg • ≥100 lbs: 50 mg	Approved for treatment of insomnia (age ≥12 years): 50 mg at bedtime	Once at bedtime		• Drowsiness • Dizziness • Dry mouth • Nausea • Nervousness • Blurred vision • Diminished mental alertness • Paradoxical excitation • Respiratory disease • Hypersensitivity reactions
Trazodone*	Desyrel®	• Children: Insufficient Evidence • Adolescents: 25 mg	• Children Insufficient Evidence • Adolescents: 100 mg/day	Not approved for children or adolescents	Once at bedtime	Increased the risk compared to placebo of suicidal thinking and behavior (Suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Serotonin Syndrome • Neuroleptic Malignant Syndrome • Use in combination with MAOIs • Suicidal ideation • Activation of mania/hypomania • Discontinuation syndrome • Abnormal bleeding • QT prolongation and risk of sudden death • Orthostatic hypotension and syncope • Abnormal bleeding • Priapism • Hyponatremia • Cognitive and motor impairment
Eszopiclone	Lunesta®	Insufficient Evidence	Insufficient evidence	Not approved for children or adolescents	Once at bedtime		• Psychiatric/physical disorder • Abnormal thinking and behavior changes • Withdrawal effects • Drug abuse and dependence • Tolerance
Melatonin		• Age 3-6 years: 0.5mg • Age ≥6 years: 1mg	• Age 3-6 years: • Lesser of 0.15 mg/kg or 3 mg • Age ≥6 years: Lesser of 0.15mg/kg or 6mg	Not FDA approved	Once at bedtime		• Sedation • May adversely affect gonadal development
Ramelteon	Rozerem®	Insufficient Evidence	Insufficient evidence	Not approved for children or adolescents	Insufficient Evidence		• Hypersensitivity reactions • Need to evaluate for co-morbid diagnoses • Abnormal thinking and behavioral changes • CNS depression • Decreased testosterone • Hyperprolactinemia
Hydroxyzine*	Vistaril®	• Age 3-6 years:25 mg • Age ≥6 years: 50mg	• Age 3-6 years: 25 mg/day • Age 6-12 years: 50 mg • Age > 12 years: 100 mg	Approved for treatment of anxiety and tension: • Age <6 years: 50 mg/day • Age ≥ 6 years: 50-100 mg/day Approved as a sedative when used as a premedication and following general anesthesia: 0.6 mg/kg	Once at bedtime		• Drowsiness • Dry mouth • Involuntary motor activity • Blurred vision, dizziness, diminished mental alertness • Paradoxical excitation

* Generic Available

* Maximum doses for the sedative/hypnotics are based upon night time doses to induce sleep in a child with severe insomnia.

Use of zolpidem in pediatric patients: Safety and effectiveness of zolpidem have not been established in pediatric patients. In an 8-week study in pediatric patients (aged 6-17 years) with insomnia associated with ADHD, zolpidem did not decrease sleep latency compared to placebo. Hallucinations were reported in 7.4% of the pediatric patients who received zolpi- dem; none of the pediatric patients who received placebo reported hallucinations

Glossary

BMI = Body Mass Index. A measure of body fat based upon height and weight.

CBC = Complete blood count. Lab test used to monitor for abnormalities in blood cells, e.g., for anemia.

Serum creatinine = A lab test used to calculate an estimate of kidney function.

ECG = Electrocardiogram

EEG = Electroencephalogram

EPS = Extrapyramidal side effects. These are adverse effects upon movement, including stiffness, tremor, and severe muscle spasm

FDA = U.S. Food and Drug Administration

Hemoglobin A1c = A laboratory measurement of the amount of glucose in the hemoglobin of the red blood cells. Provides a measure of average glucose over the previous 3 months.

LFTs = Liver function tests

MAOIs = Monoamine Oxidase Inhibitors

MRI = Magnetic resonance imaging

PRN = as needed

Prolactin = A hormone produced by the pituitary gland

TFTs = Thyroid Function Tests

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Web Reference for the *September 2013 Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care*

http://www.dfps.state.tx.us/Child_Protection/Medical_Services/guide-psychotropic.asp