

**Minnesota Department of Human Services
DUR Board Meeting**

FINAL

August 9, 2017

Members Present

Daniel Jude, Pharm.D., Ryan Fremming, Pharm.D., Pierre Rioux, MD., Allyson Schlichte, PharmD., and Abigail Stoddard, Pharm.D.,

DHS Staff Present

Mary Beth Reinke, PharmD., Dave Hoang, PharmD., Chad Hope, PharmD, and Amy Tran, PharmD. student.

Other Attendants

Larry Dent, PharmD., Conduent

Public Comments: There were no public comments.

Approval of Minutes: Minutes from May 10, 2017 were approved.

Old Business: none

New Business:

Recent mailings included (1) Psychotropic Drugs in Youth mailed to 689 prescribers regarding 2,300 patients on May 12, 2017 and (2) Diabetes mailed to 2,577 prescribers regarding 5,770 patients on May 26, 2017.

RetroDUR-population based interventions

This has been a successful intervention that has been mailed on in the past. Last mailing was November 30, 2016. It hasn't been long enough to report on outcomes yet but in the past Dr. Dent noted that last calculated cost avoidance was over \$1.7 million over a one year period for the intervention September 30, 2015.

Polypharmacy 2017 Proposal

The purpose of this intervention is to increase prescriber awareness of patients on polypharmacy regimens and to encourage review of the identified therapy. This may result in discontinuation of drug therapy that is no longer necessary.

The proposed intervention was comprised of the following performance indicator:

Performance Indicator #1: Polypharmacy N=3,899.

Criteria:

- All patients who have had ≥ 10 medications filled within the most recent 30 days of therapy based on claims activity, excluding antibiotics.

Table 1. Total Minnesota Medicaid FFS Specific Data for 2017

Polypharmacy Indicator Summary	Number of Patients with Opportunities*	
	< 18 years	≥ 18 Years
Receipt of 10 or more medications (excluding antibiotics) with history of cancer, HIV, chronic renal failure, or transplant within the most recent 30 days of therapy	21	693
Receipt of 10-14 medications (excluding antibiotics) within the most recent 30 days of therapy	266	2,229
Receipt of 15-19 medications (excluding antibiotics) within the most recent 30 days of therapy	35	514
Receipt of 20 or more medications (excluding antibiotics) within the most recent 30 days of therapy	7	134

*Based on data through 6/23/17

The number of hits per criteria are very similar to 2016. N=3,778.

Table 2. Total Minnesota Medicaid FFS Specific Data for 2016

Polypharmacy Indicator Summary	Number of Patients with Opportunities*	
	< 18 years	≥ 18 Years
Receipt of 10 or more medications (excluding antibiotics) with history of cancer, HIV, chronic renal failure, or transplant within the most recent 30 days of therapy	17	686
Receipt of 10-14 medications (excluding antibiotics) within the most recent 30 days of therapy	218	2,148
Receipt of 15-19 medications (excluding antibiotics) within the most recent 30 days of therapy	36	545
Receipt of 20 or more medications (excluding antibiotics) within the most recent 30 days of therapy	4	124

*Based on data through 5/13/16

Each of the four medication count categories above, there are messages five possible messages. These messages reflect the following criteria:

- Dr. Shopper Opiates: received X different medications from more than 2 prescribers and filled them at more than 2 pharmacies within a 30 day period. This medication list also includes opioids and/or tramadol.
- 3 or more Prescribers and Pharmacies: received X different medications from more than 2 prescribers and filled them at more than 2 pharmacies within a 30 day period.
- 3 or more Prescribers: received X different medication from more than 2 prescribers within a 30 day period.
- 2 Prescribers: received X different medication from more than 1 prescriber within a 30 day period.
- 1 Prescriber: It appears that your patient has received X different medication within a 30 day period.
- Receipt of 10 or more medications (excluding antibiotics) with history of cancer, HIV, chronic renal failure, or transplant within the most recent 30 days of therapy

There was discussion about the last indicator. It was recommended to add cystic fibrosis. The second recommendation was to include antibiotics in this group with the rationale that these patients take several different antibiotics chronically and would benefit from a medication review. Antibiotics will continue to be excluded from the other four groups.

Management of Psychotropic Drugs in Youth Proposal

The purpose of this intervention is to promote the safe and cost-effective use of psychotropic drugs in youth. This issue was selected because:

- The use of second generation antipsychotics (SGA) and attention-deficit hyperactivity disorder (ADHD) medications at doses above recommended maximums are associated with an increased in adverse outcomes and associated costs.
- Individuals who receive multiple psychotropic medications are at an increased risk of drug-drug or drug-disease interactions, duplicate or unnecessary therapy, non-adherence, and hospitalizations. Moreover, the use of multiple SGAs has not been shown to improve efficacy or outcomes.
- The management of metabolic side effects of SGAs in children & adolescents should include regular monitoring of BMI, blood pressure, fasting blood glucose or hemoglobin A1c and fasting lipid profiles.

Summary of Management of Psychotropic Drugs in Youth Indicators	Exceptions
• High Dose: Second Generation Antipsychotics (SGA)	191
• High Dose: ADHD Medications	127
• Multiple (2 or more) Oral SGAs	132
• Polypharmacy: ≥ 3 Psychotropic Medications	1,879
• Monitoring of SGAs: Glucose and/or Hemoglobin A1c	1,425
• Monitoring of SGAs: Lipids	1,533

The May 12, 2017 mailing did not include the high dose SGA and ADHD medications which will be discussed tonight. The high dose thresholds were originally established in 2012 in connection with M.S. 245.4862 and 256B.0625.

Background information

M.S. 245.4862 required an interdisciplinary work group establish appropriate medication and psychotherapy protocols to guide the consultative process including consultation with the Drug Utilization Review Board, as provided in section 256B.0625, subdivision 13j. M.S. 256B.0625, Subd. 13j. describes that the initially established thresholds is in consultation with the DUR Board and actively practicing pediatric mental health professions. The original workgroup consisted of pediatrician, family practice, three child adolescent psychiatrists (CAPs). June 2014 first contract ended along with mandatory psych consult for those that exceeded the thresholds and the point-of-service edits for the thresholds that rejected a claim unless a prior authorization which required a consult was obtained.

Currently, the PAL is operated by PraireCare under a grant with the DHS Children and Mental Division and all consultation are voluntary. Besides the four quarterly required RetroDUR FFS mailings per year, two additional annual RetroDUR mailings were added specifically to address the use of psychotropic drugs in youth. Because of the large number of exceptions for lack of monitoring in SGA, the first mailing, August 16, 2016, highlighted only this issue. The second mailing, May 12, 2017, added and highlighted issue of multiple psychotropic drugs. The two new indicators were (1) three or more concurrent psychotropic drugs and (2) greater than one SGA concurrently. Then, in preparation of DUR Board's discussion of high dose thresholds for SGA and drugs to treat ADHD at the August 9, 2017 meeting, the DUR Board Coordinator interviewed three of PraireCare's child and adolescent psychiatrists (CAPs) regarding differences in the 2012 high dose thresholds FDA maximum allowed thresholds per age.

SGA Thresholds Changes, Impact, and Discussion

Dr. Reinke stated that changing to FDA labeling for SGA thresholds will have a small impact. There would be a net increase change of 56 recipient from 191 to 247. Ziprasidone and clozapine will increase exceptions by 80 recipients since the threshold will change to zero. For the newer drugs, Saphris® and Latuda®, labeling has expanded since 2012 with increased indications at a younger age which reduces the number of exceptions for these two drugs. PraireCare CAP feedback regarding use of ziprasidone in children under the age of 18 years was that this drug may be used where significant weight gain is an issue. While they do not start patients on these drugs, if a patient is transferred to their practice, they would not change the medication if the patient is going well. They all agreed to change the threshold to "0" for both ziprasidone and clozapine. The DUR Board approved these changes as presented.

Drugs to Treat ADHD Thresholds Changes, Impact, and Discussions

A five-month average of the number of FFS recipients under the age of eighteen uses with ≥ 1 prescription ADHD drug per month is 7,893. For May 2017, the four drugs based on the count of distinct recipients are methylphenidate, guanfacine, mixed amphetamine and lisdexamfetamine. Dr. Reinke stated that moving to FDA labeling thresholds would result in lower thresholds for most stimulant drugs. Since there are different thresholds for long and short formulations, these will be reflected in the updated table. Except for a few limited stimulants, FDA labeling is typically for ≥ 6 years of age. This change will result in an increase of $n=247$ exceptions for the ≤ 3 years and 4-5 years age groups. The long acting mixed amphetamine in the 13-17 years group warrants a longer discussion.

Analysis of increase in exceptions per drug

- Methylphenidate which included short and long acting formulations, except Concerta® where the FDA max is 72mg and Daytrana® patches where the max is 30mg, showed a 4.4% or $n=52$ of which $n=20$ is under the age of six years.
- Concerta was an increase of 3.5% or $n=43$ of which $n=13$ is under the age of six years.
- Dexmethylphenidate (short and long acting combined) where Focalin threshold is > 20 mg and Focalin XR threshold is > 30 mg increased by 26% or $n=374$.
- Amphetamine mixed salts, short acting formulations, exceptions increased by 3.31% or $n=20$.
- Amphetamine mixed salts, long acting formulations, was further discussed based on the different FDA approved labeling for 6-12 years old to be seemingly higher compared to the 13-17 years old.

The DUR Board recommendation was to use > 30mg as the threshold for both groups. This will increase exceptions by 12% increase or n=180.

Stimulants in Young Age Discussion

The proposed thresholds would be per FDA labeling. Most stimulants are approved for ≥ 6 years of age. The two exceptions where the drug is approved at ≥ 3 years of age (1) dextroamphetamine (Zenzedi® and Procentra®) and (2) mixed amphetamine (Adderall® short acting and Evekeo®) which are both approved for up to 40mg per day for ADHD.

In summary, the DUR Board approved all changes in ADHD threshold to correspond to FDA approved max per age per drug. The high dose threshold tables in this mailing will be updated accordingly.

Dr. Reinke noted that the current DUR Student from the University of Minnesota's Doctor of Pharmacy program is working on an analysis to determine at the recipient level who would exceed the threshold using only the line level compared to who would *additionally* exceed the threshold if the total ADHD drug mg/day was employed.

The last scheduled meeting is October 11, 2017.