



**Drug Utilization Review (DUR) Meeting**

May 11, 2016

**Members Present**

Chaitanya Anand, MD, Matthew Beatty, PA-C, Ryan Femming, Pharm.D., James MacNutt, DO, Pierre Rioux, M.D, Allyson Schlichte, Pharm.D., MBA, and Abigail Stoddard, Pharm.D.

**DHS Staff Present**

Mary Beth Reinke, Pharm.D., Sara Drake, RPh, Dave Hoang, Pharm.D., and Liz Schiller.

**Other attendants**

Larry Dent, Pharm.D., Xerox

**Public Comments:** None

**Approval of Minutes:** Moved to next meeting.

**Old Business:**

**RetroDUR – population based**

**Metabolic monitoring of Medicaid children and adolescents receiving antipsychotic medications Proposal**

Dr. Reinke presented a change in the criteria from what was proposed at the March 2016 meeting which was one or more second generation antipsychotic (SGA) prescription in the last 30 days to two SGA Rxs within the most recent 90 days. Rationale was to be more certain the children was receiving SGA ongoing. This change results in more recipients from Table 1 in previous proposal to Table 1, version 2 using new criteria.

**Table 1. Recipients in Fee-for-service Medicaid**

<b>Increased Risk of ADE – AA MONITOR KIDS</b>	<b>2,344</b>
Lack of SGA Antipsychotic Blood Glucose Monitoring within last year	1,134
Lack of SGA Antipsychotic Lipid Monitoring within last two years	1,210

**Table 1. Recipients in Fee-for-Service Medicaid----version 2**

<b>Increased Risk of Adverse Drug Event – Recommended SGA Monitoring in Children &amp; Adolescents (&lt;18 years of age)</b>	<b>Number of Individuals</b>
Lack of SGA Blood Glucose/A1c Monitoring within Last Year	3,182
Lack of SGA Lipid Monitoring within Last Two Years	1,528
Lack of SGA Blood Glucose/A1c Monitoring within the Last Year AND Lipid Monitoring within the Last 2 Years	1,379

The criteria change was approved by the DUR Board.

**New Business:**

**RetroDUR – population based interventions**

**Stimulants exceeding FDA approved doses per day prescriber notification letter.**

Dr. Reinke explained that this intervention is similar to what was sent to prescribers regarding high dose opioids exceeding 120mg MED (morphine equivalent dose) per day. This consensus recommendation originated through the Universal Pharmacy Policy Workgroup (UPPW) comprised of a pharmacy representation from each contracted Minnesota Medicaid prepaid health plans (PPHP). While PPHP or managed care plans can be more restrictive, the minimum criteria is FDA approved dose per day. From analysis of November and December fee-for-services claims, there were n=73 recipients under the age of eighteen years and n=163 eighteen years and older that would be effected. While not a large number, this intervention is recommended as another way to notify prescribers of this point-of-service edit that will take effect July 5, 2016. The letter will include a link to the corresponding DHS Provider Update. The prescriber packet includes drug profiles showing the stimulant drugs per each recipient that will exceed the existing threshold. There are two instances, dexamethylphenidate 50mg and methylphenidate 108mg, where the thresholds established for recipients under the age of eighteen years are higher than the FDA approved limits. These off-label doses were established through the drug threshold workgroup in conjunction with formation of a psychiatric consultation service back in 2010 are also supported by the American Academy of Child Adolescent Psychiatry (*J Am Acad Child Adolescent Psychiatry* 2007;46:894-921). Prior authorization approval criteria will these allow these exceptions.

The DUR Board approved as presented.

**Benzodiazepine Anxiolytics and Sedative/Hypnotics**

The purpose is to promote the safe and cost-effective prescribing of benzodiazepine anxiolytics and sedative/hypnotic medications. The drugs within each classification for this intervention are found in Table 2 below:

**Table 2: Benzodiazepine Anxiolytics and Controlled Sedative/Hypnotic Medications**

Benzodiazepine Anxiolytic Medications	Controlled Sedative /Hypnotics
Alprazolam	Estazolam
Chlordiazepoxide	Eszopiclone
Clonazepam	Flurazepam
Clorazepate dipotassium	Quazepam
Diazepam	Suvorexant
Lorazepam	Temazepam
Oxazepam	Triazolam
	Zaleplon
	Zolpidem tartrate

Population includes all FFS recipients. Potential number of “hits” were broken down in those under the age of eighteen years and those eighteen years and older.

The proposed intervention was comprised of the following eight performance indicators.

Performance Indicator #1: Concurrent Use of Opioids or Buprenorphine Agents with Carisoprodol and Benzodiazepine Anxiolytics “Triple Threat” n=37 adults.

The DUR Board approved as presented.

Performance Indicator #2: Concurrent Use of Opioids or Buprenorphine Agents with Carisoprodol n=25 adults.

The DUR Board recommended addition cyclobenzaprine to both Performance Indicator #1 & #2.

Performance Indicator #3: Concurrent Use of Opioids or Buprenorphine Agents with Benzodiazepine Anxiolytics n=2,040. Note: only anxiolytics are included in this indicator.

The DUR Board approved as presented.

Performance Indicator #4: Chronic Use of Benzodiazepine Anxiolytics or Controlled Sedative/Hypnotics > 4 months n=3,389. Both anxiolytics and sedatives are included.

Data presented from an ad hoc report containing only alprazolam, clonazepam, and lorazepam showed 48% of alprazolam users, 34% of clonazepam users, and 28% of lorazepam users had a GAD diagnosis in the last two years. Overall, there was about 37% of adults with a GAD diagnosis for these most commonly used benzodiazepines. The DUR Board asked if specific GAD diagnosis code was used or if a more general range of anxiety codes were used which may account for the difference. Additionally, it was noted that it may show up in claims in the last two years even though the recipient still has the condition and is being treated for it.

The DUR Board recommendation was to change the one indicator into four separate indicators.

- Chronic use of a benzodiazepine anxiolytic > 4 months with a diagnosis of Generalized Anxiety Disorder (GAD) and not receiving first-line drug therapy. 26% of recipients from an ad hoc report containing only alprazolam, clonazepam, and lorazepam.
- Chronic use of a benzodiazepine anxiolytic > 4 months with a diagnosis of GAD and receiving first-line drug therapy. 11% of recipients from an ad hoc report containing only alprazolam, clonazepam, and lorazepam.
- Chronic use of a benzodiazepine anxiolytic > 4 months with no diagnosis of GAD nor first-line drug therapy. 63% of recipients from an ad hoc report containing only alprazolam, clonazepam, and lorazepam.
- Chronic use of a controlled sedative/hypnotic > 4 months as originally presented for those that do not fall into one of the categories above.

Performance Indicator #5: Use of a Benzodiazepine Anxiolytic in Individuals with a History of Substance Abuse or Dependence n=894

Performance Indicator #6: Use of a Controlled Sedative/Hypnotic in Individuals with a History of Substance Abuse or Dependence n=479

Performance Indicator #7: Duplicate Therapy: Anti-Anxiety Medications n=223

Performance Indicator #8: Duplicate Therapy: Sedative/Hypnotic Agents n=20

The DUR Board approved criteria for indicator #5, #6, #7, and #8 as presented.

DUR Board recommendations for changes in the intervention paragraph wording and tables, and references in the prescriber letter are listed below:

- *Substance Use Disorder* should be used to replace *Substance Abuse or Dependence* language according to new DSM-5 terminology in indicator #5 and #6.
- Remove pregabalin from table 2 in the proposed letter, which requires a PA to prescribe. Change the title of the table to: *Minnesota Preferred Alternatives to Benzodiazepines for Chronic Anxiety Disorders*.
- Add buspirone to table 2 with the following footnote: \*Buspirone should be reserved as second-line therapy for individuals who are intolerant or fail to respond to SSRIs or SNRIs. It may have limited efficacy in individuals previously treated with a benzodiazepine.<sup>32</sup>
- Replace table 3 in the prescriber letter, “Non-pharmacological Intervention Proven Effective for Insomnia”, which is worded for parents to provide non-pharmacologic intervention to their children, with a table geared towards psychological and behavioral interventions for insomnia in adults. Dr. Rioux provided the following reference “Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline from the American College of Physicians” *Ann Intern Med.* 2016; 165(2):125-133. DOI:10.7326/M15-2175 written by Qaseem A, Kansagara D, Forcica MA, Cooke M, and Denberg TD for the Clinical Guidelines Committee of the American College of Physicians. Information can be found at <http://annals.org/data/Journals/AIM/0/AIME201607190-M152175.pdf>

**ProDUR – POS Edits for Benzodiazepines**

**UPPW Topic: High Dose and Young Age Limits on Benzodiazepines**

The next drug category that the UPPW will be discussing is benzodiazepines both high dose (considered to above FDA approved maximum) and age limits. Recommendations where consensus is reached will be presented at the DUR Board for approval.

In Table 3, November and December 2015 FFS claim analysis showed five benzodiazepines drugs comprise 97% of all benzodiazepine prescriptions, of which clonazepam accounted for 35% followed by lorazepam at 27%. To gauge the impact of enforcing the FDA approved threshold at the pharmacy POS, the analysis shown in Table 3, found only 400 prescriptions or 3.4% were over FDA limits. Dr. Reinke noted two benzodiazepines in Table 3 with large therapeutic ranges, the FDA approved range of clonazepam is 4 mg (anxiety) to 20 mg (seizures). Alprazolam’s range is 4 mg (anxiety) to 10mg (off label for panic disorders).

**Table 3. FFS Benzodiazepine Utilization Nov-Dec 2015 with High Dose Rxs**

HICLDescription	Rxs ALL Nov Dec FFS 2015	% Rxs	Paid	FDA Max	Rxs Over	% Rxs over	
CLONAZEPAM	4,323	35%	\$ 56,810	anxiety 4mg;	144	3.33%	Allow n=144 if they have seizures
				seizure 20mg	1	0.02%	
LORAZEPAM	3,264	27%	\$ 79,307	10 mg	43	1.32%	n=23 solution
ALPRAZOLAM	2,065	17%	\$ 26,396	4mg	157	7.60%	
				10mg off label panic	4	0.19%	Allow n= 157 if they have panic
DIAZEPAM	1,857	15%	\$ 127,102	40mg all 4 indications	26	1.40%	n=3 are solution rxs
TEMAZEPAM	375	3%	\$ 6,329	30mg	25	6.67%	
Total	11,884	97%					
				<b>Rxs over FDA</b>	<b>400</b>	<b>3.4%</b>	

A POS edit could be managed by prior authorization of doses over 4 mg daily of clonazepam and allowing up to 20mg per day for those with seizure diagnoses. Likewise with alprazolam, doses over 4 mg daily would be prior authorized allowing up to 10 mg per day if a diagnosis of panic disorder.

**Table 4: Benzodiazepines and FDA Approved Age Thresholds**

<b>Benzodiazepine Anxiolytic Medications</b>	<b>Controlled Sedative /Hypnotics</b>
Alprazolam – no pediatric indication	Estazolam – no
Chlordiazepoxide (> 6 years)	Eszopiclone
Clonazepam (pediatric indication)	Flurazepam (> 15 years)
Clorazepate dipotassium (> 9 years)	Quazepam – no
Diazepam (> 6 months)	Temazepam – no
Lorazepam – no pediatric indication	Triazolam – no
Oxazepam (> 6 years)	

For those benzodiazepines with no pediatric indications, alprazolam had n=34 recipients under the age of eighteen years (Nov-Dec 2015); lorazepam had n=153 with n=37 using the oral concentrate and n=116 using tablets; and temazepam had n=6 recipients. Therefore, there was a total of n=195 recipients using these drugs where there was no pediatric indication. One DUR Board member commented that lorazepam could be used when undergoing cancer treatment.

The DUR Board recommendation was to bring back young age recommendations from the Child and Adolescent Psychiatrists who under a DHS contract to provide psychiatric consultations.

**DHS Pharmacy Program 2015 Overview – Sara Drake, R.Ph., Deputy Director, PSD**

The Medicaid FFS pharmacy is governed by title 1927 of the social security act and Minnesota Statute 265B.0625. All FDA-approved legend drugs are covered with an exception of those who doesn't participate in the CMS rebate program, drugs without federal funding, hair growth, weight loss, fertility, impotence or erectile dysfunction and DESI products. There are also selected OTC (with the exception of smoking cessation products), cough and cold products covered. Medical foods, investigational drugs and drugs for dual-eligible beneficiaries are not covered by Medicaid and appear to be a source of confusion. All this is reviewed by the Drug Formulary Committee (DFC) that is governed by the MN statute 256B.0625, subd. 13. All the roles of DFC were listed and discussed.

2015 Pharmacy Program highlights were:

- Implementation of the nation's first Basic Health Plan, MinnesotaCare, effective January 1, 2015
- Uniform Pharmacy Policy Work Group: Collaboration with contracted MCOs to develop uniform policy for high risk and high impact drugs. Uniform opioid criteria implemented January 1, 2015
- Formation of the Opioid Prescribing Work Group
- Statewide competitive bid procurement of managed care for families and children

- Implementation of unique and identifiable BIN/PCN combinations for managed care MA and MinnesotaCare
- New copay structure for MinnesotaCare

Summary program statistics were presented for calendar year 2015.

- Total MHCP fee-for-service enrollment (average monthly): 300,178– down 3%
- Dual eligibles in fee-for-service (average): 46,059 – down 1.5% from last year
- Average number of utilizers each month: 74,211 –down 4.3% from last year
- Total annual drug reimbursements to pharmacies: \$261,327,350– down 1.7%
- Total fee-for-service rebates from drug manufacturers: \$150M – up 13% from last year
- Total managed care drug rebates: \$319M
- Total number of prescriptions: 3,340,250 – down 5% from last year
- Specialty drugs account for 29% of pharmacy spend.

During 2015, the Prior Authorization (PA) Program received a total of 53,300 PA's. A provider must obtain a PA for 1.5% of prescriptions paid for through MHCP.

- No action taken on 25% of the PA's since the majority sent to DHS by mistake.
- 36% of the requests were approved.
- 21,000 (39%) were denied.

The top 10 most commonly requested prior authorized drugs (33% of PA requests) were Intuniv/Guanfacine ER, Suboxone, Lyrica, Oxycontin, Vimpat, Lidocaine, oxycodone, Fentanyl, gabapentin tablets, and eszopiclone.

Drugs billed via medical claims were \$12.46 per member per month (pmpm). The combined pharmacy claims and medical drug claims pmpm was \$84.20. The following trends were reported:

- Per member per month (pmpm) pharmacy spending continues to decline.
- Per user per month pharmacy spending is around \$140.
- Rebates have continued to keep net prices down in 2015.

2016 priorities include a new pharmacy payment methodology to comply with CMS' covered outpatient drug rule, implementation of new PA contract and ePA capability, implementation of UPPW stimulant thresholds, continued work on opioid prescribing and access to opioid treatment, planning for new managed care final rule: increased DUR coordination between fee-for-service and managed care, and ongoing efforts to improve prescribing of mental health medications for children, particularly children in foster care.

**2016 meeting dates will be:**

- August 10, 2016
- November 2, 2016