Idaho DUR Board Meeting Minutes

Date: February 16, 2017 **Time:** 9am-12:15pm

Location: Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D-West

Moderator: Perry Brown, M.D.

Committee Member Present: Matthew Hyde, Pharm.D., Perry Brown M.D., Paul Cady, Pharm.D., Ryan Heyborne M.D.

Others Present: Tami Eide, Pharm.D., Christopher Johnson, Pharm.D., Jane Gennrich, Pharm.D., Mark England, Pharm.D.[☆], Jeanie Armstrong[☆]

[☆]Magellan Rx Management

AGENDA ITEMS	PRESENTER	OUTCOMES/ACTIONS
Committee Business ➢ **Call to Order**	Perry Brown, M.D.	Dr. Perry Brown called the meeting to order.  DUR_2_16_2017_Final.pdf
➢ **Review of Minutes from October 20, 2016**	Perry Brown, M.D.	Minutes were approved as written.
➢ **Current Interventions/Outcomes Studies** • Codeine and Tramadol Use in Children	Jane Gennrich, Pharm.D.	**Slides 60 – 80** Dr. Gennrich presented information from the American Academy of Pediatrics (AAP) and

		specifically from a report in the October 2016 issue of Pediatrics, Codeine: Time to Say "NO". The AAP is urging parents and health providers to stop giving codeine to children, calling for more education about its risks and restrictions on its use in patients under age 18. Per the report, codeine is still commonly prescribed to children after surgical procedures such as tonsil and adenoid removal. In the last 5 years, various U.S. and international organizations and regulatory bodies have promulgated warnings regarding adverse responses associated with codeine. Dr. Gennrich referred to 6 specific examples in her presentation. Dr. Gennrich then presented data specific to the Idaho Medicaid Population: Between August 1 and October 21, 2016, there were 287 claims with 274 unique patients identified. (13 patients with two paid claims each) with a total cost of $3723 paid to pharmacies. This is a safety issue not a cost issue. In looking at the paid claims for patients: • 1% for 0-6 years of age • 24% for 7-11 years of age • 47% for 12-15 years of age and

		• 28% for 16-17 years of age. Focusing on children less than 12 years old, 68 paid claims for 67 unique patients were identified. There were 58 prescribers. In looking at the taxonomy of these prescribers, there were 14 Dentists, 14 Physician Assistants, 10 Family Practice physicians, 9 Nurse Practitioners, 8 Surgeons, 8 Emergency physicians, 2 Ophthalmologists, 1 Pediatrician and 1 Internal Medicine physician. Discussion on how to proceed: Currently codeine/acetaminophen products are preferred agents and pay at the pharmacy with no prior authorization required. It was recommended by the DUR Board to: • Provide education including options other than codeine with appropriate doses. • Institute an age limit of 18 and older. • Move codeine and combinations with codeine to non-preferred status.

		Tramadol Use in Children: Dr. Gennrich then went on to present information on tramadol and its use in children. Per the package insert, the safety and efficacy of Ultram (tramadol) in patients under 16 years of age have not been established. The use of Ultram in the pediatric population is not recommended. On 9/21/2015 the FDA issued a Drug Safety Communication. It stated that the FDA was investigating the use of tramadol in children aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. Dr. Gennrich presented the Mechanism of Action, Metabolism, Pharmacogenomics, and risk of Serotonin Syndrome with tramadol. Dr. Gennrich then presented Idaho Medicaid specific data: Between November 1, 2015 and October 31, 2016 there were 1158 claims for 803 unique patients at a payment to pharmacies of $12,688 for those less than 18 years of age. • 0-6 years of age, none • 7-11 years of age = 6% • 12-15 years of age = 48%

		• 16-17 years of age =46% Looking at the taxonomy of prescribers the highest groups were surgeons, physician assistants, family practice physicians, ER physicians and pediatricians followed by OB and Urologists and the lowest number of prescribers were among dentists, podiatrists, students, a medical examiner and "other." Discussion on how to proceed: Currently tramadol and tramadol/acetaminophen are preferred agents and pay at the pharmacy with prior authorization not needed for patients ≥ 10 years of age. In was recommended by the DUR Board to institute an age limit of 18 and older similar to codeine restrictions.
➢ **Current Interventions/Outcomes Studies** • Ophthalmic Antibiotic/Steroid Combinations	Jane Gennrich, Pharm.D.	**Slides 90 – 98** This DUR Review was requested by the P&T Committee to look at the prescribers for pediatric patient prescriptions.

		The concern was the risk of cataract formation, glaucoma, or worsening infection with long-term use. Risks Associated with Use of Ophthalmic Steroids: • Prolonged use: risk for increased intraocular pressure (glaucoma) and secondary infections. *Micromedex Solutions – online database accessed 12/22/16* • Cataracts can develop in patients with uveitis as a result of chronic ocular inflammation or secondary to the chronic use of steroids. *American Academy of Pediatrics "Pediatric Cataracts: An Overview" Nov 11, 2015* Dr. Gennrich reviewed Idaho specific claims data between 9/1/2016 – 11/30/2016. • 169 claims in patients less than 18 years of age. In a breakdown of age of those less than 18, no pattern was observed, the first year of life and age 15 had the highest number with 19 members having paid claims during this time period. • 96 claims in patients greater than or equal to 18 years of age. • Of the 169 claims for patients less than 18, only 8 patients had 2 claims each, and looking back 2 years at these 8 patients' profiles, none of them had more than 2 paid claims.

		And of these 8, 7 were prescribed by an ophthalmologist/optometrist and 1 by a surgeon. • Breaking down the taxonomy of prescribers for the 169 claims there were 108 by an ophthalmologist or optometrist, 18 Family Practice, 15 PA/NP, 9 Pediatrics, 6 Surgery, 5 Student, 3 Internal Medicine, 5 other. Discussion: Since most prescriptions were written by ophthalmologists and optometrists a limit of one fill per 60 days has already been instituted. The Department will also reach out to a Pediatric Ophthalmologist to discuss the data and their recommendations.
➢ **Study Proposals for Upcoming Quarters** • Paroxetine Use in Children	Jane Gennrich, Pharm.D.	**Slides 100 – 109** The P&T Committee in November 2016 expressed concern about the usage of paroxetine in children < 18 years old due to both lack of efficacy and incidence of side effects. Dr. Gennrich reviewed an FDA Statement Regarding Anti-Depressant Paxil for Children from June 19, 2003 and the current package insert. Dr. Gennrich then presented Idaho Medicaid specific data:

		• Currently prior authorization in not required for patients ≥ 6 years old.
		• Paid claims for paroxetine in children < 18 years of age between 7/1/2016 – 12/31/2016 was reviewed and 86 patients were identified.
		• Breakdown by age was provided
		  ○ Age 9 = 1
		  ○ Age 10= 0
		  ○ Age 11 =2
		  ○ Age 12= 5
		  ○ Age 13= 5
		  ○ Age 14=6
		  ○ Age 15 =16
		  ○ Age 16 =26
		  ○ Age 17 =25
		Of the 86 patients with paid claims between 7/1/16 – 12/31/16, only 46 had paid claims between 11/1/16 – 12/31/16 showing a discontinuation rate of 47%.
		Next steps for next quarter:
		Change minimum age at which prior authorization is not needed to 18 years of age for new patients.

		Currently paroxetine immediate release is a preferred antidepressant with no other criteria for use. Send out DUR letter to current patients on paroxetine who are < 18 years. Include educational information on efficacy and safety concerns. The DUR Board recommended to not send a letter to patients who are currently 16 years or older. The DUR Board recommended a 30-day response time to the letter for current patients prior to implementing the age change.
➢ **Ongoing Reviews** • Foster kids	Tami Eide, Pharm.D.	**Slide 57** Dr. Eide updated the Board on the ongoing work with the IDHW Division of Family and Community Services. Dr. Eide also informed the Board that the data was just received from Magellan Rx Management for the 2016 reports.
➢ **Ongoing Reviews** • Atypical (Second Generation) Antipsychotics in Children < 6 years	Tami Eide, Pharm.D.	**Slide 58**

		Dr. Eide provided a handout and went over the suggested Prior Authorization Criteria for Second Generation Antipsychotics in Children 5 Years Old and Younger. The DUR Board had no additional recommendations and felt the criteria was put together well.
➢ **Ongoing Reviews** • Narcotic Prescribing Improvement Project ▪ Top 150 Utilizers	Tami Eide, Pharm.D.	**Slide 3** Dr. Eide informed the Board that the reviews have been completed and letters created; however, with the departure of the Idaho Medicaid Medical Director these letters have been put on hold for the time being.
➢ **Ongoing Reviews** • Narcotic Prescribing Improvement Project ▪ Top 150 Narcotic Utilizers Treatment of Opioid Induced Constipation	Chris Johnson, Pharm.D.	**Slides 4 – 9** Idaho Medicaid was asked by the Deputy Director of Health and Welfare about the frequency of emergency room visits for abdominal pain due to opioid induced constipation. It is difficult to gather medical billing information and data to determine if emergency room visits for

		abdominal pain are related to opioid induced constipation. Since pharmacy data can determine prescribing patterns for medications to treat or prevent opioid induced constipation the Department reviewed the number of patients and claims for the treatment/prevention of opioid induced constipation in the previously determined top 150 narcotic utilizers (based on claims volume). Dr. Johnson reviewed Idaho specific data related to the review of the top 150 narcotic utilizers. Total number of patients prescribed an agent for constipation: 21 o Male=7 Female=14 o 6 patients were prescribed more than 1 agent • Claims o ClearLax 1 o Amitiza 18 o Movantik 20 o Linzess 33 o PG 3350 41 In conclusion, most patients from the top 150 narcotic utilizers are not treated for opioid induced constipation. 21 patients (14%) have active

		prescription history for agents to treat constipation. Multiple factors can be involved in constipation including diet, exercise, and comorbid illnesses. Limitations exist for data collection for medical admissions to the emergency room and diagnoses to determine opioid induced constipation prevalence in the Medicaid population.
➢ **Ongoing Reviews** • Narcotic Prescribing Improvement Project ▪ Methadone	Chris Johnson, Pharm.D.	**Slides 10 – 21** Dr. Johnson presented background data on methadone nationally. He then presented both the Methadone Initial Request PA form and the Methadone Reauthorization PA form and reviewed the details for each of them. Dr. Johnson then presented comparative data for Idaho Medicaid from 4th Qtr. 2015 to 4th Qtr. 2016. In conclusion, methadone utilization continues to decrease since designation of non-preferred status and institution of prior authorization requirements. Total providers, total patients, and total claims overall have decreased. No change was noted though with the percentage of patients on greater than 40 mg/day of methadone.
➢ **Ongoing Reviews**		

• Buprenorphine and benzodiazepine concomitant use	Jane Gennrich, Pharm.D.	**Slides 22 – 35** Dr. Gennrich presented an update on buprenorphine and benzodiazepine concomitant use. A payment block went in to effect 1/6/16 requiring prior authorization for payment for either buprenorphine or benzodiazepine with overlapping days of service. Dr. Gennrich reported that PDMP Interconnect now includes a total of 19 states including Idaho. New Federal regulations increased the limit rule to 275 buprenorphine patients per prescriber effective 8/8/2016. Physicians who have prescribed buprenorphine to 100 patients for at least one year can now apply to increase their patient limits to 275 under new federal regulations. On November 16, 2016 HHS Press Office released additional information stating: The U.S. Department of Health and Human Services (HHS) is taking additional steps to address the U.S. opioid epidemic by further expanding access to medication-assisted treatment (MAT) for opioid use disorders. Administered by the Substance Abuse and Mental Health Services Administration (SAMHSA), today's announcement enables nurse practitioners (NPs) and physician assistants (PAs) to immediately begin taking the 24 hours of required training to prescribe the opioid use disorder treatment, buprenorphine. NPs and PAs who complete the required training and seek to prescribe buprenorphine for up to 30

		patients will be able to apply to do so beginning in early 2017. Previously, only physicians could prescribe buprenorphine. Once NPs and PAs receive their waiver they can begin prescribing buprenorphine immediately. HHS also is announcing its intent to initiate rulemaking to allow NPs and PAs who have prescribed at the 30-patient limit for one year, to apply for a waiver to prescribe buprenorphine for up to 100 patients. For NPs and PAs in Idaho to prescribe: The new language must be added to the federal controlled substances act (DEA). There is no time estimate yet on when this will happen. This was through personal communication with the Idaho Board of Pharmacy on 1/19/2017. Additional visual data was presented via graphs and tables. • Total number of participants on oral buprenorphine increased this past quarter while those paying cash for an opioid slightly decreased again this quarter. • Patients on concomitant benzodiazepines while on buprenorphine increased slightly. • Patients paying cash for opioids AND on concomitant benzodiazepines while on buprenorphine decreased from 10 to 7.
➢ **Ongoing Reviews**		

• Opioid and Benzodiazepine Concomitant Use	Mark England, Pharm.D.	**Slides 36 – 41** The FDA is requiring boxed warnings for all opioid analgesics and benzodiazepines with information about the serious risks associated with concomitant use of opioids and benzodiazepines. This is part of the FDA Opioid Action Plan to combat the growing epidemic of opioid abuse, dependence and overdose in the United States. Language has been added to the Package Insert of products warning of the risks involved with the concomitant use of these products. Dr. England included in the packet the FDA Drug Safety Communication and FDB response. A ProDUR report was run for 1/2017 for drug-drug interactions between long-acting or short-acting opioids and benzodiazepines and long-acting opioids and Sleep Drugs- Tranquilizers. It returned 5,236 claims and 1,925 unique recipients. With the large number of claims involved and unique recipients, the Board recommended that this be an educational issue only at this time. With the current focus on the opioid epidemic, it was suggested to monitor and potentially follow up later to see if the publicity and education around opioids will have had any impact on the prescribing of the combination therapy.
➢ **Ongoing Reviews**		

• Hepatitis C	Chris Johnson, Pharm.D.	**Slides 42 – 56** Dr. Johnson presented the quarterly Hepatitis-C Outcomes Report for 4th Quarter 2016 (10/1/2016-12/31/2016) A total of 40 requests for treatment were submitted and 22 were approved, 12 denied, and 6 were pending, waiting for additional information for review to be submitted. A total of 9 males and 13 females were approved for which 13 patients were approved for Harvoni, 7 for Epclusa, 1 Viekira XR, and 1 for Sovaldi/Daklinza. The most prevalent genotype of approved patients was Genotype-1 (14 patients). Genotype-3 (4 patients), Genotype-2 (3 patients), and Genotype-4 (1 patient) made up the remainder of approved patients. For approved requests, there were 9 patients with F4 staging, 5 with F3 staging, and 8 with F2. Patients with documented cirrhosis accounted for 50% of the approved patients. A total of 12 patients were denied for not meeting criteria. Dr. Johnson reported 6 males and 6 females did not meet criteria for approval. The hepatitis-C agents denied were Harvoni (3), Epclusa (6), Sovaldi (1), Viekira Pak (1) and Technivie (1). Liver fibrosis data submitted for denied patients for the following stages were reported: F0 staging (5), F1 staging (3), F2 staging (2) and F3 staging (2). The requests were denied for not meeting liver fibrosis criteria (8), active substance abuse (3), and Medicare (1).

		Total costs for the 3rd quarter were $1,510,841 for Hepatitis C agents.
➢ **Current Interventions/Outcomes Studies** • Low dose quetiapine	Jane Gennrich, Pharm.D.	**Slides 81 – 89** Dr. Gennrich presented on low dose quetiapine. She discussed the package insert dosing for approved indications and what the initial recommended and maximum doses were. Also discussed was the titration schedule per the package insert. Dose titration is quick – by day 3, the daily dose is > 100mg regardless of diagnosis Concern – Likely that low dose quetiapine (especially doses < 100mg/day) is being used off-label as a sedative-hypnotic as these doses are not therapeutic for treatment of either bipolar disease or schizophrenia. A report of paid claims for quetiapine 25mg and 50mg tablets between 11/1/2016-12/31/2016 was run. In children < 18 years there were 218 patients and 372 claims identified. In adults ≥ 18 years there were 472 patients and 819 claims. Most these patients are filling prescriptions for the 25mg and 50mg strengths monthly and for at least 30 tablets so these tablet strengths are NOT being used for initial dose titration.

		Looking specifically at the claims for those < 18 years, 176 patients were on only 25mg and 50mg tablets and 42 on 25mg and/or 50mg tablets plus larger strength tablet. The daily dose breakdown for the 176 patients was as follows: 48 – 25mg, 4 - 37.5mg, 78 – 50mg, 21 – 75mg, 16 – 100mg, 7 – 150mg, 2 – 200mg. Discussion on how to proceed: It was recommended to limit 25mg and 50mg tablets to no more than 6 per month which is the maximum amount needed to titrate up to a minimally therapeutic dose per package insert dosing. There was concern expressed that this will affect hundreds of current patients and we are not currently staffed to handle increased number of phone calls and PA requests. Suggestions were to consider grandfathering current patients and sending out an educational DUR letter. The Board also recommended exploring methodology to stop new starts on low dose quetiapine.
➢ **Study Proposals for Upcoming Quarters** • Temazepam – No longer a preferred sedative	Jane Gennrich, Pharm.D.	**Slides 110 – 112** Per Idaho Medicaid's Pharmacy & Therapeutics Committee recommendation, temazepam 15mg and

		30mg capsules have switched from preferred to non-preferred status effective 1-18-17. The other strengths of temazepam are already non-preferred. The current preferred agents are zolpidem immediate release (unchanged for years) and Rozerem (ramelteon). The P&T Committee wanted to have a non-controlled sedative available as a preferred agent that would not require prior authorization. Current patients who have a paid claim between 9-1-16 and 12-31-16 were identified: 398 unique recipients with 1203 paid claims. Most patients are filling their prescription monthly with 30 capsules monthly being the most common quantity. Next steps: Send out DUR letter to current temazepam patients: Emphasize concerns about safety and efficacy of a long-term benzodiazepine, especially if the patient is concurrently on an opioid. Prescribers will need to fill out a prior authorization form if they want the patient to continue temazepam, including medical necessity justification, reason an alternative sedative cannot be used, and

		documentation of screening for substance abuse. The Board discussed how long was reasonable to grandfather current patients, but no consensus was arrived at.
➢ **ProDUR Quarterly Report**	Mark England, Pharm.D.	**Slides 113 – 114** Dr. England reviewed the quarterly ProDUR trends. No significant changes in trends were noted.
➢ **Medicaid Update**	Tami Eide, Pharm.D.	**Slides 115** Dr. Eide did not have any updates at this time.
➢ **Adjourn, 12:15pm**	Perry Brown, M.D.	

Next Meeting: April 20, 2017 at the Holiday Inn 2970 Elder Street Boise, Idaho