Idaho DUR Board Meeting Minutes

Date: April 14, 2016 **Time:** 9am-12:30pm

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

Moderator: Mark Turner, M.D.

Committee Member Present: Mark Turner, M.D., Matthew Hyde, Pharm.D., Paul Cady, Ph.D., Lane Deitchler, DNP, Wayne Baures, R. Ph., Elaine Ladd, Pharm.D.

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

[☆]Magellan Rx Management

AGENDA ITEMS	PRESENTER	OUTCOMES/ACTIONS
Committee Business ➢ **Call to Order**	Mark Turner, M.D.	Dr. Mark Turner, Chairman, called the meeting to order.  DUR_4_14_2016_Final.pdf
➢ **Review of Minutes from January 21, 2016**	Mark Turner, M.D.	Minutes were approved as written
➢ **Follow-up to Previous Reviews** • Buprenorphine and Benzodiazepine DUR	Jane Gennrich, Pharm.D.	**Slides 2 - 9**

		Dr. Gennrich shared results of her review on Buprenorphine and Benzodiazepine concurrent 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. Letters were sent out ahead of time to affected prescribers.
		
		Additional visual data was presented via graphs and tables.
		• Total number of participants on oral buprenorphine remained consistent this past quarter while those paying cash for an opioid slightly decreased.
		• Two new subsets of recipients were added to the graphs.
		  ○ Patients on concomitant benzodiazepines while on buprenorphine
		  ○ Patients paying cash for opioids AND also on concomitant benzodiazepines while on buprenorphine.
		
		Clonazepam and alprazolam accounted for the majority of benzodiazepines use with indications mainly for anxiety and sleep. On outreach to some mid-level prescribers, they related that they were unaware that the recipient was on buprenorphine and information about the PMP was shared.

• **Ongoing reviews** ○ Glucocorticoids, Inhaled	Mark England, Pharm.D.	**Slides 11 – 15** On March 1, 2016, changes were made to the Idaho Enhanced Prior Authorization Program (EPAP) and changes were instituted in the POS System. On February 24, 2016, letters were sent to 635 prescribers regarding 1,339 patients who had been receiving either Pulmicort Flexhalers or Flovent. An example of the actual letter was provided to the Board members. Utilization data of this class was presented and reviewed. It was noted that additional changes were made to the system later in the month to provide additional denials of all claims to ensure the appropriate switch in therapy is happening. Additional monitoring of this change will take place.
○ Hepatitis C Update	Chris Johnson, Pharm.D.	**Slides 16 - 31** Dr. Johnson presented the quarterly Hepatitis-C Outcomes Report for 1st Quarter 2016 (1/1/2016-3/31/2016) A total of 36 requests for treatment were submitted and 16 were approved, 17 denied, and 3 were pending additional information for review. A total of 9 males and 7 females were approved for which 12

		patients were approved for Harvoni, 3 patients for Sovaldi, and 1 patient for Sovaldi/Daklinza. The most prevalent genotype of approved patients was Genotype-1 (12 patients). Genotype-2 (1 patient) and Genotype-3 (3 patients) made up the remainder of approved patients. For approved requests, there were 6 patients with F3 staging and 10 with F4. Patients with documented cirrhosis accounted for 69% of the approved patients. A total of 17 patients were denied for not meeting criteria. Dr. Johnson reported 6 males and 11 females did not meet criteria for approval. The hepatitis-C agents denied were Harvoni (6), Sovaldi (6), Viekira Pak (2), and Sovaldi/Daklinza (3). Liver fibrosis data submitted for denied patients for the following stages were reported: F0 staging (2), F1 staging (6), F2 staging (5), and F3 staging (2). Two denied requests did not report liver staging. The requests were denied for not meeting criteria (13), active substance abuse (3), and Medicare coverage (1). Dr. Johnson reported a total of 109 patients had completed treatment since January 2014. Of these patients, 41 had a documented cure based upon SVR12 achieved after therapy and 29 of these patients had an SVR24 achieved after therapy. Three patients did not achieve an SRV12 after therapy. In patients for which a SVR12 was not obtained reasons were: • Patient died of other causes before

		an SVR12 could be obtained (5), • Treatment failure due to noncompliance (3), and • 7 patients were approved but the provider decided to hold treatment or not treat for clinical reasons. Dr. Johnson noted the difficulty of obtaining SVR12 reports from providers because the patients are lost to follow up or the providers did not schedule follow up appointments for SVR12 testing. Dr. Johnson reported that 34 denials for hepatitis C agents were appealed by patients. Of the 27 going to hearing, the Department's decision was either affirmed or won by default. Seven appeals submitted by a non-authorized third-party (usually the prescriber did not go to hearing). Four appeals did not meet the deadline for submission and three appeals are pending review. Total costs for the 1st quarter reported $1,789,707for Hepatitis C agents.
➢ **ADURS Annual Meeting**	Chris Johnson, Pharm.D.	**Slides 32 – 45** Dr. Johnson presented an overview of the ADURS (American Drug Utilization Review Society) meeting held in Scottsdale, AZ on February 25-27, 2016. Forty-two states were represented at the meeting. Dr. Johnson reported that the major theme of the meeting revolved around proposed Managed Care

		regulations from CMS. States reported on the challenges of meeting these regulations, including communication difficulties with Managed Care Organizations (MCOs) and meeting specific quality metrics. Hepatitis-C treatment was a major topic for Medicaid States at ADURs because of the cost of medications and the extra staffing required monitoring outcomes of treatment. Key points with the introduction of new direct acting antivirals for the treatment of hepatitis-C report that cure rates are >95% after 12 weeks of treatment and current studies are reporting cure rates within 6 weeks of treatment. Current studies are focusing on agents that have expanded activity to all known hepatitis genotypes. A discussion with John M. Coster., RPh, Director of the Division of Pharmacy for CMS concerning the Hepatitis-C letter submitted to State Medicaid agencies and its impact on state Medicaid resources and enforcement was debated. Dr. Johnson reviewed the state of Oklahoma's experience with their prior authorization (PA) program and comparisons from pre and post PA requirements for Hepatitis C. They concluded that a PA program improved non-adherence without higher overall cost. Challenges to their PA program included prescriber and pharmacy involvement and patient follow up monitoring. Dr. Johnson reviewed the "New Drugs 2016" and the "Pipeline Preview 2016"presented at the ADURs meeting. Some examples of newer agents reported

		were Enteresto® (sacubitril/valsartan)-Novartis, Praluent ® (alirocumab)-Regeneron, Repatha ® (evolocumab)-Amgen, Jardiance ® (empagliflozin)-Boehringer Ingelheim, and Corlanor ® (ivabradine)-Amgen. The pipeline review reported current trends of agents submitted to the FDA are predominately oncology drugs. In 2014 there were 9 oncology FDA drug approvals and in 2015 there were 13 and it continues to increase. Most of the oncology agents are for the treatment of multiple myeloma and lung cancer and with a high price tag. Another common theme with the development of newer agents is "Priority Review Vouchers". Developers of treatments for a neglected disease receive a voucher for priority review from the FDA to be used with a product of its choice or can be sold to another developer. Dr. Johnson gave examples of how the vouchers are sold to other pharmaceutical manufacturers for up to a quarter of a million dollars or more. Dr. Johnson reported issues concerning the introduction of biosimilars and the multiple biologicals losing patent protection in the near future. The FDA process for the submission of biosimilars is geared to foster negotiations and agreements between reference and biosimilar manufacturers without litigation. Unfortunately, the varying interpretations of requirements between the parties involved presently does leads to litigation.

➢ **Current Interventions/Outcomes Studies** ○ Cystic Fibrosis (CF) Kalydeco and Orkambi	Jane Gennrich, Pharm.D.	**Slides 47 – 56** Dr. Gennrich reviewed Kalydeco and Orkambi utilization in CF. Dr. Gennrich provided background information on the cystic fibrosis transmembrane conductance regulator (CFTR) gene and mutations involved in CF. She reviewed FDA indications, mechanisms of activity and annual cost of Orkambi and Kalydeco. Thirteen patients were identified with paid claims for either Kalydeco or Orkambi between 11/01/15 and 01/31/16. • Orkambi - 10 • Kalydeco - 3 ***NOTE: Pricing info for Kalydeco and Orkambi was unfortunately incorrectly switched on the slides. Annual cost for Kalydeco $318,727 and $259,161 for Orkambi.***
○ Second-Generation Antipsychotic Use in Children	Tami Eide, Pharm.D.	**Slides 57 – 86** Dr. Eide briefly reviewed the March 2015 Office of the Inspector General report on Second-Generation Antipsychotic Drug Use Among Medicaid-Enrolled Children and their Quality-of-Care Concerns. Based on these findings, the Department is reviewing utilization and targeting improvement efforts in this area.

		Dr. Eide presented Idaho Specific Data in regards to reviewed medication profiles of children that were 5 years or younger during the calendar year 2015 and had at least one claim for a second generation (atypical) antipsychotic. The study identified 49 children that met these criteria. The majority (82%) were male and none were identified as foster children. Current prior authorizations, mainly for age were in place for 19 or the children. Twenty-nine of the children (59%) were 5 years old during the study period, 16 (33%) were 4 years old, 3 (6%) were 3 years old and only 1 was 2 years old. Age at the time of the original antipsychotic start showed approximately an equal 1/3 split between 3, 4, and 5 years olds. The majority of children received the antipsychotic risperidone (80%) followed by aripiprazole (12%), quetiapine (6%) and olanzapine (2%). Based on claim records, the presumed indication for the majority of children was autism (39%), but concerning was the fact that 14% had no indication listed in their medical profiles. Dr. Eide reviewed the FDA indications in children for each of the second generation antipsychotics (SGAs). If the FDA indication was not met for a child then they were evaluated based on CMS approved

		compendia indications and if those indications were not met then they were evaluated on evidence from the Drug Effectiveness Review Project review or from the American Academy of Child and Adolescent Psychiatry Practice parameter guideline supported indications. Meeting any one of these indications was considered a "supported" indication. Only 27% met the criteria of a supported indication. An additional 37% met the use indication, but were below the age of that indication. The indication was not supported in 22% and as previously stated, the indication was unknown in 14%. Prescribers for these children were evaluated with 29% of them being specialists, 27% generalists and 45% being mid-level (NP or PA) providers. When the prescribers were evaluated for meeting best practice parameters, child and adolescent psychiatrists met this parameter 60% of the time. Psychiatrists met best practice 43% or the time and pediatricians 38% of the time. Physician assistants met only 20% of the time and Nurse Practitioners 18%. Length of therapy and medication dosage was also reviewed. It was noted that 17 children had additional mental health diagnoses and 38 children had a least one other concurrent class of psychotropic.

		• Next Steps: ○ Send out survey to prescribers to gather more detailed information ○ Provide resources to the prescribers
○ Antibiotic/Steroid Ophthalmics	Chris Johnson, Pharm.D.	**Slides 87 - 96** Dr. Johnson reviewed the utilization of combination steroid/antibiotic ophthalmic agents. There has been concern because chronic use can lead to cataracts, glaucoma, secondary infections, or delayed healing. Both the DUR Board and the P&T Committee have expressed concerns of who is prescribing these agents and at what frequency. Best practice is that a specialist in ocular medicine should be prescribing most of these agents for chronic use. Antibiotic/Steroid Ophthalmic Idaho Data for 1st Quarter of 2016 was reviewed. Females accounted for 168 of the 275 unique patients and males 107. There was a total of 331 claims for these patients. The mean age was 17 years with a range of 0 to 81 years. Dr. Johnson reviewed the number of claims by agent, number of providers and provider specialty, patients with two or more claims and the total number of claims and costs associated with them. In conclusion, the majority of antibiotic/steroid combinations appear to be prescribed by ophthalmologists and optometrists. Neomycin/

		Polymyxin/Dexamethasone and Tobramycin/ Dexamethasone are most often prescribed. It was decided by the Board that no further action is needed at this time for this particular class of medications.
○ Skeletal Muscle Relaxants DUR	Chris Johnson, Pharm.D.	**Slides 97 - 112** Dr. Johnson reviewed the drug utilization of skeletal muscle relaxants. Studies for muscular pain or spasms from peripheral musculoskeletal conditions are limited to short term use for acute low back pain. Extended courses of medications should be reserved for patients clearly showing continued benefits from therapy without major adverse effects. Dr. Johnson reported skeletal muscle relaxant drug claims for the 1st quarter of 2016. A total of 9,050 claims and 4,614 unique recipients were reported. Total cost was $157,860.72. Dr. Johnson noted that 48% of patients had at least 1 claim/quarter and 64% of claims were for a 26 to 30 day's supply suggesting chronic use. The majority of claims was for preferred agents of methocarbamol and cyclobenzaprine with an average 21 days supply. It was noted by the Board the days supply can be misleading with this class of agents due to manipulated pharmacy data entry. Additional follow up DUR reporting included chronic skeletal muscle relaxant used concurrently with narcotic agents and/or benzodiazepines was suggested. It will need to be determined if data can

		be collected for specific diagnosis for the chronic treatment of spasticity versus chronic back or other musculoskeletal pain.
➢ **Study Proposals for Next Quarter**	Mark England, Pharm.D.	Dr. England presented the following topics: • Opioid and benzodiazepine concomitant use • Low dose quetiapine • Multiple dosage forms of quetiapine prescribed concomitantly **Questions/Comments** • Albuterol Review – On albuterol and no Steroid – consider sending out letters • Dr. Gennrich will provide review of the 2015-16 Synagis Season.
➢ **ProDUR Quarterly Report**	Mark England, Pharm.D.	Dr. England reviewed the quarterly ProDUR trends. No significant changes in trends were noted.
➢ **Medicaid Update**	Tami Eide, Pharm.D.	Dr. Eide gave an update as to the changes that will be occurring with Idaho Medicaid Administration. Dr. Eide gave a brief introduction to the Antipsychotic Drug Affinity Work Group. o Goal – To improve the Quality of Care in Children. Dr. Eide gave an overview of the Smart-D Study (State Medicaid Entities will be involved) o A 3 year study broken down into 3 phases looking at alternative based pricing of drugs On 6/1/2016 a new edit will be put in place and

		claims will start denying if the prescriber is not enrolled with Idaho Medicaid.
➢ **Adjourn, 12:30pm**	Mark Turner, M.D.	

Next Meeting: July 21, 2016