Idaho DUR Committee Meeting Minutes

Date: January 17, 2013 **Time:** 9am-12noon.

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

Moderator: Mark Turner, M.D.

Committee Member Present: Perry Brown, M.D., Wayne Baures, R. Ph., Paul Cady, Pharm.D, Mark Turner, M.D., Myrna Olson-Fisher, FNP, Matthew Hyde, Pharm D.

Others Present: Tami Eide, Pharm.D., Chris Johnson, Pharm.D., Jane Gennrich, Pharm.D., Mark England, Pharm.D., Jeanie Armstrong

Committee Members Absent: Suzette Cooper, Pharm.D.

AGENDA ITEMS	PRESENTER	OUTCOMES/ACTIONS
Committee Business ➢ **Call to Order**	Mark Turner, M.D.	
➢ **Review of Minutes from October 18, 2012**	Mark Turner, M.D.	Minutes were approved as written.
➢ **Follow-up Studies – Updates** o Immune Globulin (IV and SC)	Jane Gennrich, Pharm.D.	Additional responses received since the last DUR meeting requesting chart notes for patients who had received immune globulin: • One doctor's office had charged Idaho Medicaid for immune globulin (brand name **Privigen**) 500mg as a single dose for four separate patients. The patients had actually received **promethazine** 50mg injectable. The doctor's office has been asked to correct the

		billing error. • Adult male patient receiving immune globulin 1000mg/kg monthly for chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). This patient is also a poorly controlled diabetic patient who has gained more than 100 pounds over the past year, requiring significantly higher dosages of IVIG. The standard of care is to use either ideal body weight or adjusted body weight (defined as ideal body weight plus 50% of the difference between actual and ideal body weight) in obese patients. The dose for December 2012 was reduced from 128 Gm ($14,930) to 100 Gm ($11,664). In addition, an early refill request for patient convenience was denied for December 2012. • Pregnant woman whose first child died secondary to congenital hemochromatosis (2008). Second child survived (2010) – mother had been treated with IVIG weekly from Weeks 14-37. Third pregnancy (due date February 2013) – mother is being treated with IVIG weekly starting at week 14 (September 2012). Medicaid has approved IVIG to continue throughout this third pregnancy. **Follow up to discussion/decisions on recommendations from October 2012 DUR meeting:** • Require prior authorization for this expensive therapy on both the Medical side and the Pharmacy side. • Check for a FDA approved diagnosis and verify clinical benefits as well as monitor periodic IgG levels (if applicable to diagnosis, such as hypogammaglobulinemia).

		• Initially approve for 3-6 months with additional documentation required after that time period to renew the authorization. • Implementation date of 01/01/2013 **Review of Medical Claims for IVIG** Claims paid as a medical benefit between 8/01/2011 and 7/31/2012 • $288,410 • 116 claims • 24 patients • Average cost per prescription: $2486 <u>Actions</u> • Prior authorization requirement for applicable J-codes effective 01/01/2013 • Notification of new prior authorization requirements published in MedicAide • Pharmacy Unit will be processing these prior authorization requests. **Review of Pharmacy Claims for IVIG** Reviewed outpatient prescription claims paid between 8/01/2011 and 7/31/2012 • $279,527 • 79 claims • 14 patients • Average cost per prescription: $3538 <u>Actions</u>

		• Prior authorization requirement effective 01/01/2013 • A notification letter was sent out to current prescribers and pharmacies of patients receiving immune globulin between September and November 2012(letters sent second week of December) and to new patients receiving immune globulin in December 2012 (letters sent early January 2013). **References for Prior Authorization Criteria:** Intravenous Immune Globulin in Autoimmune and Inflammatory Disease. NEJM 2012;367:2015-25 which is a review article published in November 2012 **Other Payer Information:** Medicare or a commercial insurer has approved reimbursement for such therapy [autoimmune conditions], often conditionally, requiring documentation of contraindications to or a lack of response to conventional therapies.
○ Atopic Dermatitis	Jane Gennrich, Pharm.D.	The P&T Committee requested a DUR on this drug class to include patterns of use, presence or absence of step up therapy from steroids, specialty of prescribers and geographical region differences in prescribing patterns. The DUR was to include an educational piece on risks of these agents compared to risks from steroids since many practitioners seem to be using these agents to spare patients from steroid exposure.

		The DUR was completed April 2012 and the DUR Board determined that the medications were being used appropriately based on the data presented and these findings were shared with the P&T Committee.
		
		The P&T Committee asked at their October 2012 meeting for the DUR Board to look at cases where there is no treatment history of a corticosteroid and/or refill history greater than three months in a given year. Paid claims between 10/01/2011 and 10/01/2012 were reviewed.
		
		Standard of Care Treatment Overview
		
		• Emollients are considered mainstay of maintenance therapy
		• Topical corticosteroids are the standard of care to which other treatments are compared and are considered first-line treatments for flare-ups.
		  • Local side effects include striae, atrophy, and telangiectasia.
		  • Systemic side effects include hypothalamic-pituitary-adrenal axis suppression, reduced linear growth in children, and bone density changes in adults. There is no conclusive evidence that appropriately used topical steroids cause significant systemic adverse effects.
		  • Topical corticosteroids should be used for the shortest duration possible to control the flare-up.
		• Sedating antihistamines are useful when

		patients have sleep disturbances and concomitant allergic conditions.
		• Antibiotics should be reserved for patients with acutely infected lesions.
		• Topical calcineurin inhibitors should be second-line treatment for flare-ups and maintenance.
		  • Local side effects include skin burning and irritation. Patients should also be counseled on proper sun protection.
		
		<u>Concerns with Elidel and Protopic</u>
		
		In March 2010, the FDA issued a public health advisory about the potential cancer risk associated with the use of Elidel (pimecrolimus) and Protopic (tacrolimus) products applied to the skin.
		
		This was based on information from animal studies, case reports in a small number of patients, and knowledge of the drugs' mechanisms of action.
		
		The FDA recommends that healthcare providers, patients, and caregivers consider the following:
		
		  • Use these products only as second-line agents for short term and intermittent treatment.
		  • Avoid the use in children under the age of 2.
		  • Use for a short period of time, not continuously.
		  • Children and adults with a weakened or compromised immune system should not use these products.

		• Use the minimum amount of the products needed to control the patient's symptoms. <u>Conclusions/Discussion Questions</u> • Overall only 13 of the 436 patients (3%) filled their Elidel or Protopic more than once every other month. • Of those 13 patients, 7 were filling prescriptions for topical steroids at least as often as prescriptions for Elidel or Protopic. Most of these patients were seeing a dermatologist. • For the 6 patients with no or infrequent topical steroid fills over the same time period, the DUR board recommended sending educational information on the treatment of atopic dermatitis (a one page handout). • The DUR Board did not feel that it was necessary to place additional limits of how often Elidel or Protopic could be prescribed (current quantity limits are one tube monthly). • The DUR board also recommended requiring that the patient have a diagnosis of atopic dermatitis in their electronic profile prior to allowing a claim to pay at the pharmacy. <u>Next Steps</u> • The DUR Board suggested to consider prior authorization for Elidel and Protopic with

		consideration of diagnosis codes and prior use of a corticosteroid. • Develop an educational piece that discusses appropriateness of steroid use in kids including use on trunk vs. face. This educational piece would be sent back to prescriber as an attachment with the PA decision. • Re-evaluate individual providers for any prescribing patterns that would benefit from a physician-to-physician contact. • Publish an article in Idaho AAP and IMA Newsletters.
➢ **Current Interventions/Outcomes Studies** o P&T Committee Narcotic Analgesic Studies o National Summit on Opioid Safety	Jane Gennrich, Pharm.D.	National Summit on Opioid Safety, October 31-November 1, 2012 Seattle, Washington Dr. Gennrich attended this conference and gave a summary of the principles that were discussed at this meeting. These principles were written by the faculty of the National Summit for Opioid Safety **Principles for All Chronic Non-Cancer Pain Patients** 1. Self-care is the foundation for effective chronic non-cancer pain care 2. Your relationship with the patient supports effective self-care 3. Guide care by progress toward resuming activities 4. Prioritize long-term effectiveness over short-term pain relief **Principles When Considering Long-term Use of Opioids**

		5. Put patient safety first 6. Think twice before prescribing long-term opioids for axial low back pain, headache and fibromyalgia 7. Systematically evaluate risks 8. Consider intermittent opioid use 9. Do not sustain opioid use long-term without decisive benefits 10. Keep opioid doses as low as possible **Principles for Patients Using Opioids Long-term** 11. Clearly communicate standardized expectations to reduce risks 12. Adhere to recommended precautions 13. Avoid prescribing opioids and sedatives concurrently 14. Revisit discontinuing opioids or lowering dose 15. Identify and treat prescription opioid misuse disorders The National Summit had support from the Group Health Foundation. It was co-sponsored by Group Health Research Institute; Project ROAM (Dept. of Family Medicine, University of Washington); and Physicians for Responsible Opioid Prescribing (PROP).
○ Update on Department Activities for Improving Narcotic Analgesic Use	Tami Eide, Pharm.D.	Dr. Eide discussed an action plan for improvement in the use of long-acting narcotic analgesics. Initiatives will be phased in over the next year and a half. ○ Beginning within the next month, all new starts of Fentanyl and Oxycodone ER will be manually reviewed by the clinical call center.

		○ Beginning March 2013 the Department will limit to one long acting and one short acting opioid. ○ Beginning in October, urine screens and pain contracts will be required for new patients receiving continuous narcotics for more than three months. ○ Beginning in January 2014, annual renewal of Prior Authorizations will require progress notes, documentation of non-drug measures tried, a functionality assessment and pain contract and urine screen. The Board asked that prescribers be given lead time well in advance of which patients would be subject to extra requirements as it would add an additional burden to workload, particularly pain specialists. It was also suggested that we review Board of Pharmacy records for cash payments after we have limited to one long-acting and one short-acting agent.
○ Psychotropic Medications in Foster Children ○ Two (2) or more concomitant antipsychotics	Tami Eide, Pharm.D.	**Foster Children Psychotropic Drugs Red Flags** • Five (5) or more psychotropic medications prescribed concomitantly (reviewed August 2012) • Two (2) or more concomitant antidepressants (reviewed October 2012) • Two (2) or more concomitant antipsychotic medications (current DUR) • Two(2) or more concomitant stimulant medications ○ One long-acting plus one short-acting is ok

		• Three (3) or more concomitant mood stabilizer medications
		• Psychotropic polypharmacy (2 or more agents) for a given mental disorder prescribed before utilizing psychotropic monotherapy
		
		Foster Children Receiving Two or More Concurrent Antipsychotics
		
		Study Parameters and Results
		• Children in Foster Care ages 0-17 years
		• Time Period 4/1/2012 through 9/30/2012
		• 49 patients were identified with fills for two or more different antipsychotics during time period
		  ○ 26 patients received > or = 60 days concurrently
		  ○ Other patients received two antipsychotics concurrently for only limited time period (1-2 fills) or sequentially
		
		The DUR Board recommended creating a hard stop (requiring prior authorization) when the overlap between two antipsychotics is greater than 60 days.

○ Synagis Update	Jane Gennrich, Pharm.D.	Idaho Medicaid's outpatient prescription drug program authorized payment for eligible patients for the 2012-2013 RSV season as of December 1, 2012. Many hospitals started dosing Synagis in November 2012. Doses given in the hospital are subtracted from the total doses approved by the Idaho Medicaid outpatient prescription drug program. AAP recommends a maximum of five monthly doses.

		Idaho Medicaid utilizes Idaho specific epidemiology to maximize drug benefit over the timeframe when RSV is most prevalent Please refer to the slides for the historical start and end dates of RSV in Idaho for the last 12 RSV seasons. After the fifth dose of Synagis, most patients will have adequate RSV antibody titers for six to seven weeks. The antibody levels do not plummet to zero thirty days after the fifth Synagis dose. In Idaho, Respiratory Syncytial Virus (RSV) season officially began the week ending December 8, 2012. The definition for season onset is adapted from the National Respiratory and Enteric Virus Surveillance System (NREVSS). RSV is considered widespread in Idaho in the first of two consecutive weeks during which the reported total percent of specimens testing positive for antigen is ≥ 10%. A follow-up review of the 2012-1013 RSV season and Synagis use will be completed following the end of the RSV season.
○ Revatio Use in Children	Jane Gennrich, Pharm.D.	On August 30, 2012, the U.S. Food and Drug Administration (FDA) sent out a safety announcement recommending against the use of Revatio in children with pulmonary hypertension. Revatio claims in Idaho Medicaid patients were reviewed prior to and after the announcement for comparison. Revatio Use in Children **6/1/2012- 8/31/2012** • 12 claims • 5 patients • $11,368

		10/1/2012 – 12/31/2012 • 5 claims • 3 patients • $4,015 The three patients receiving drug from 10/1/2012 through 12/31/2012 were all patients who had received drug prior to the safety announcement. No new patients have started on drug post-announcement. It was noted that Revatio became available generically as sildenafil 20mg tablets in November 2012.
➢ **Study Proposals for Next Quarter** o P&T Committee Narcotic Analgesic Studies – Next Steps o Use of Psychotropic Medication in Foster Children - Next Steps o Two (2) or more concomitant stimulant medications - Long-acting plus short acting ok	Mark England, Pharm.D./Tami Eide, Pharm.D. Mark England, Pharm.D./Tami Eide Pharm.D.	Background information on this ongoing initiative was presented. The next red flag for review is two (2) or more concomitant stimulant medications. The Board directed the Department to include all ADHD drugs and not limit to stimulants. The Board asked that the following be reviewed in the evaluation • Patients receiving more than one long-acting or more than one short-acting stimulant • Therapy with different classes of ADHD drugs • Excessive dosing • Type (specialty) of prescribers • Number of prescribers per patient

○ Migraine Prevention ○ Prophylaxis Utilization in Chronic Triptan Utilizers	Mark England, Pharm.D./ Chris Johnson, Pharm.D.	A summary handout was provided for discussion and review.
○ Botulinumtoxin Products	Mark England, Pharm.D./ Jane Gennrich, Pharm.D.	Botulinumtoxin products are excluded from coverage by the outpatient pharmacy prescription drug program since these medications are only administered by health care professionals and not self-administered. Botulinumtoxin products are currently payable without prior authorization on the medical side using J codes. Current usage and expenditures were evaluated. Paid botulinumtoxin claims from 12/1/201-11/30/2012 • Botox : 478 claims, $405,615 • Dysport : 21 claims, $14,286 • Myobloc :23 claims, $11,133 • Xeomin -:3 claims, $647 Total: 525 claims, $431,681 For the April 2012 DUR meeting, the electronic profiles of patients with paid claims on the medical side will be reviewed to assess what the botulinum toxin is most likely being used for (e.g. cervical dystonia, migraines). Even though Botox does not require prior authorization at this time, the department has been receiving prior authorization requests for Botox for migraines. The Department needs to develop criteria

		for Botox's place in therapy as it is not first-line therapy. Botox is FDA approved for chronic migraines for patients with at least 15 days of migraines per month with each migraine lasting at least four hours.
○ Testosterone enanthate/testosterone cypionate	Mark England, Pharm.D. Chris Johnson, Pharm.D.	Medicaid requires prior authorization for topical androgens. Injectable testosterone does not currently require a prior authorization. Preliminary reports from 2012 found 532 claims for which 113 participants had a diagnosis for testicular dysfunction and 39 participants did not have a diagnosis. The age range was 0 to 75 years with mean of 41 years. A high abuse potential is possible with injectable testosterone so a DUR will evaluate the appropriate use of injectable testosterone and appropriateness of participant selection. Dr. Cady asked if J-code medical billing reports are available to evaluate the frequency of its use in medical office procedures. Dr. Gennrich stated she was in the process of evaluating J-code billing and would provide the information to Dr. Johnson.
○ Zolpidem Safety	Mark England, Pharm.D.	Dr. England informed the Board of a new FDA safety announcement recommending zolpidem doses be reduced. This is based on data showing morning blood levels in some patients high enough to impair activities requiring alertness, such as driving. Driving simulation and laboratory studies showed that in some individual's zolpidem blood levels the morning after use were high enough to impair driving to a degree that increased the risk of a motor vehicle accident. FDA Recommendations:

Future Reviews On Hold o Antipsychotic Indication evaluation o AAP and DVT's		o The dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien, Edular, and Zolpimist) and from 12.5 mg to 6.25 g for extended-release products (Ambien CR). o For men, the lower dose of 5 mg for immediate-release zolpidem and 6.25 mg for extended – release should be considered. The number of Medicaid claims for the last quarter show that the higher doses of 12.5 mg and 10 mg are the most common strengths prescribed and the majority of prescriptions are for women. Discussion/Recommendations: The Board felt there were gaps in the FDA evidence that did not necessarily support immediate changes to program coverage. It was suggested that Medicaid consider a 2 week supply limit similar to other insurance products. It was agreed that the FDA safety announcement should be submitted in the next DUR letter.
➢ **ProDUR Quarterly Report**	Mark England, Pharm.D.	Dr. England reviewed the quarterly report. No specific actions taken.
➢ **DUR Newsletter**	Mark England, Pharm.D.	Current Newsletter was provided via hard copy. For the next newsletter the Board suggested including the percentage of drug spend of total Medicaid spend, update on zolpidem, and information on appropriate treatment of atopic dermatitis.
➢ **Medicaid Update**	Tami Eide, Pharm.D.	Dr. Eide discussed recent OIG (Office of the Inspector General) audits on physician administered drugs and rebates.

		Legislative Audit also looking at the rebate process. OIG security audit PASSED PERM audit, 1 recommendation – defect eligibility process. Jan. 2013 – Medicare Part D will begin covering benzodiazepine and barbiturates for certain indications.
➢ ***Adjourn, 12:00noon***	Mark Turner, M.D.	
Next Meeting: **April 18, 2013 – 9:00 AM**	Mark England, Pharm.D.	