Idaho DUR Committee Meeting Minutes

Date: April 18, 2013 **Time:** 9am-2pm

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., Mark Turner, M.D., Matthew Hyde, Pharm D.

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

Committee Members Absent: Suzette Cooper, Pharm.D. Myrna Olson-Fisher, FNP, Paul Cady, Ph.D.

AGENDA ITEMS	PRESENTER	OUTCOMES/ACTIONS
Committee Business ➢ **Call to Order**	Mark Turner, M.D.	 DUR_4_18_2013_Final (2).pptx
➢ **Introductions/Review of Minutes from January 17, 2013**	Mark Turner, M.D.	Minutes were approved as written.  DUR Minutes 2013-01-17 FINAL.pc
➢ **American Drug Utilization Review Society (ADURS) Conference Report** o February 21-23, 2013 Scottsdale, Arizona	Jane Gennrich, Pharm.D.	This conference is held annually in Scottsdale, AZ. Representatives were present from 40 state Medicaid programs, with 109 total attendees. Round Table presentations included presentations from Medicaid representatives from each state. Recurrent issues included: 1. Opioid therapy for non-malignant pain • Limiting fills per month

		• Limiting morphine equivalent dosage 2. Psychotropic medications in children • Require pediatric psychiatric evaluation pre-treatment for certain age groups (e.g. < 6 years, < 12 years) 3. Suboxone therapy • Expense of therapy • Limit dose to maximum of 16mg/day • Limit length of therapy (e.g. 1 year) Opening Session presentation was "Health Care Reform: How States are Responding". The speaker was from the National Conference of State Legislatures. • Provided global view of which states were going to expand their Medicaid programs Continuing Education Topics included: • Collaborative Care – extensive information was provided by psychiatrist M.D. from Delaware on how to safely use psychotropic medications in children and adolescents. • Importance of collaborative care • Extensive online evaluation form used by all members of the healthcare team Committee members expressed interest that this type of documentation would be valuable to rural Idaho areas. Follow-up: Dr. Eide to contact Delaware to see if online evaluation form is proprietary or is available.

		• Hemophilia 101 – speaker from Accredo Specialty Pharmacy
		  • Basic overview
		  • IDHW is currently tracking hemophilia patients and monitoring use of factor products.
		• Medicaid Fraud and Abuse
		  • Discussed two cases which involved (1) fraudulent billing of AIDS drugs for Medicaid patients without AIDS that were then sold and (2) billing for twice as much Synagis as was actually dispensed and administered
		• Managed Care Medicaid
		  • Review of MCO's
		  • Carving the prescription benefit back into Medicaid
		• 340(b) Programs
		• New Drugs 2013 review

➢ **Follow-up to Previous Reviews** o 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 geographic 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 original DUR was completed April 2012 and the DUR Board concluded that the medications were being used appropriately based on the data presented and these findings were also presented to the P&T Committee. • At the October 2012 P&T Committee meeting it was requested that the DUR Board evaluate how frequently these medications were being filled. • Consequently a review of paid claims between 10/01/2011 and 10/01/2012 was completed. Conclusions: • Findings were encouraging. Overall, only 13 of the 436 patients (3%) filled their Elidel/Protopic more than once every other month. • Of those 13 patients, 7/13 were filling prescriptions for topical steroids at least as often as prescriptions for Elidel/Protopic. • For the six (6) patients with no or infrequent topical steroid fills over the same time period, the DUR board discussed whether any action should be taken (e.g. send a DUR letter asking for chart notes)?

P&T Committee Narcotic Analgesic Studies	Tami Eide, Pharm.D.	• The decision was made to send a letter to the prescribers of the six patients mentioned above. An Educational Document was created to be sent along with the DUR letter and is also available for future use. A sample of this educational document is included in the Packet (attached below)  Atopic Dermatitis Educational Documen **Participants Receiving Over 500 mg Morphine Equivalents per Day** Original review : • Profiles for the top 150 recipients by total narcotic claim count from the recipients who had at least one narcotic claim in each of the 24 months of the period ending December 2011 • Time Period: May 1, 2011 through December 31, 2011 • All profiles were manually reviewed by Idaho Medicaid Pharmacists Follow-up on original participants receiving over 500 Morphine Equivalents in 2011 Study • Original study 5/1/2011 – 12/31/2011

		• 30 participants > 500 morphine mg equivalents • Follow-up study of these 30 participants 6/1/2012-11/30/2012 Data on 30 original is as follows; • Six (6) still meeting threshold (> 500 mg/day morphine equivalents) • Two (2) ineligible or inactive for Idaho Medicaid • Five (5) deceased* • One (1) Incarcerated (drug abuse/sales) • Sixteen (16) Current dose < 500 mg morphine equivalents *Committee member requested research of cause of death of five (5) noted above, if available. Follow-up for patients still meeting threshold: • Letter (attached below) sent 2/13/2013 • Included patient medication profile and Board of Pharmacy controlled substance report • Requested chart notes and documentation for most recent 6 months • Evaluation and monitoring of pain relief • Evaluation for improvement in daily function • Potential misuse/abuse • Current treatment plan • Pain contract • Random urine screen results **Five (5) of Six (6) prescribers returned documentation**; Case presentations were presented by Tami Eide, Pharm.D., Chris Johnson, Pharm.D., and Jane Gennrich, Pharm.D., and discussed (due to HIPAA, all presentation documentation details will be kept confidential)

		Discussion for follow up included: • Reporting to DEA and Medicaid Fraud division for further actions when appropriate. • Consider law/rule to not allow cash payment for narcotics above Medicaid covered limits • Require pain contracts Next steps will be limiting use to one (1) long- acting and one (1) short- acting opioid.  Follow up request to participants' prescribe

➢ **Current Interventions/Outcomes Studies** o Zolpidem High Dose	Mark England, Pharm.D.	On January 10, 2013, the United States Food and Drug Administration (FDA) notified the public of new information regarding the safety of certain drugs that contain zolpidem. (See packet for copy of Drug Safety Announcement). The risk of next-morning impairment is highest for women, who may eliminate the medication more slowly. Impairment is also greater in those taking the extended release formulation (Ambien CR/zolpidem ER). • The NEW recommended dose for immediate release zolpidem for women is being lowered from 10 mg to 5 mg. • The NEW recommended dose for extended release zolpidem for women is being lowered from 12.5 mg to 6.25 mg. • For men, the new labeling recommends that the same lower doses be considered (zolpidem immediate release 5 mg or zolpidem ER 6.25 mg). A report was run of paid claims between October 1, 2012, and December 31, 2012, to identify the number of Idaho Medicaid recipients who had received zolpidem. • Patients were selected if they had doses above the NEW recommended doses. • Letters were sent to 877 prescribers about 1,984 patients on 1/18/2013. (attached below) • 246 responses have been received as of 4/16/2013. (28% response rate) Responses received from prescribers included "Comments of Interest" noted below;

		• "Patient is stable" (numerous similar responses) • "Will discuss with patient" • "Chronic sleep disorder. Pt. with chronic sleep problem nightly and does not sleep without zolpidem" • "Dose was initially changed, had worsening of symptoms and strongly favored higher dose" • "Attempts made to lower dosage or taper off without success. The pt listed is a long-term complicated pt and to effectively recess her has been reviewed previously. Thanks" • "Lower doses do not help. I still treat patients not studies." • "I will change my prescribing habits. Have only given 1 dose." • "I'm the physician. Waste of my time." • "I already know." • "Will change dose to Ambien 5mg" • "Patient has not responded to a lower dose" • "Both patients were (are) pregnant" • "Tolerates well, has taken since April 2009" • "The benefits outweigh the risks" • "I will attempt to modify therapy with pts as recommended" • "But the patient is a male, not female" • "He tolerates the current dose without side effects" • "Address at their next visit. Had already heard about the FDA announcement"  Zolpidem letter.pdf

○ Migraine Prevention ○ Prophylaxis Utilization in Chronic Triptan Utilizers	Mark England, Pharm.D.	Idaho Medicaid paid over $770,000 in pharmacy claims for the Triptan class of medication in 2012. There were more than 7,200 claims paid for in 2012. • The question the Idaho DUR Board is beginning to investigate is "Are these medications being used appropriately and are recipients getting the appropriate treatment for the prevention of migraines?" Dr. England briefly reviewed the epidemiology of migraines. Idaho Medicaid Statistics • participants with a paid Triptan claim between 1/1/2012 and 12/31/2012 • Overall Average Age: 35 years (range 4 – 78) • Average Age Females: 35 (range 6 – 68) • Average Age Males: 31 (range 4 – 78) Unique Recipients • Male – 418 (18%) • Female – 1949 (82%) Claims • Male – 1108 (15%) • Female – 6143 (85%) Amount Paid at POS • Male - $105,894 (14%) • Female - $667,532 (86%) Dr. England discussed both abortive (e.g. triptans) and preventative treatment

		Preventative Therapy Background • Should be taken in absence of headache with the goal of reducing the frequency and severity of the migraine, making acute attacks respond better to abortive therapy, and ultimately improving the patient's quality of life. • Three primary classes of medications that have Level A quality of evidence showing that they are effective: antiepileptics, antidepressants, and antihypertensives. • Botulinumtoxin A was discussed in greater detail in a subsequent presentation. • An evidenced- based guideline update document was reviewed (attached below). Idaho Medicaid Statistics • In 2012 there were 5,022 unique recipients with a migraine diagnosis in their electronic medical record. • Of these 5,022 recipients, 1,258 had a Triptan claim in their profile. • Side note: In 2012 there were 2,367 unique recipients with a Triptan claim • Of these 1,258 recipients, 281 (22%) had a claim for one of the Level A Medications as described in the Evidence-based guideline update.  Evidence based guidline update_episc

○ Botulinumtoxin Products	Jane Gennrich, Pharm.D.	Botulinumtoxin products are excluded from coverage by the outpatient pharmacy prescription drug program – these medications are only administered by health care professionals and are not safe for patients to pick up and "brown bag" to the doctor's office. Botulinumtoxin products are currently payable on the medical side using J-codes. There are four commercially available products at this time (Botox, Dysport, Myobloc, and Xeomin).They are not therapeutically equivalent and they have different dosages and different FDA approved indications. While Idaho Medicaid does not cover medications for cosmetic uses (e.g. wrinkles), at this time there is no diagnosis verification or medical review for J0585 (Botox), J0586 (Dysport), or J0587 (Myobloc) to assure that the botulinumtoxin is being prescribed for a medical diagnosis rather than for a cosmetic indication. Prior authorization has been required for J0588 (Xeomin) since August 2012 but to date there have been no requests for this medication. Therefore, the Pharmacy Unit at Idaho Medicaid has completed a DUR (Drug Utilization Review) project evaluating diagnoses of patients who have paid claims for botulinumtoxin in the past 3 months. The FDA approved indications for each botulinum-toxin product were reviewed. There were 98 patients with paid claims for botulinumtoxin between 10/01/2012-12/31/2012. The electronic profiles for these 98 patients were reviewed to determine the diagnosis applicable to the botulinumtoxin product. • Cerebral Palsy: 49 • 42 children, 7 adults • Cervical dystonia, torsion dystonia, or upper limb spasticity: 28 • Traumatic brain injury/intracranial

		hemorrhage with muscle spasms: 12
		• Migraines: 5
		• Misc: 4
		  • dysphasia
		  • spina bifida
		  • closed fracture of vertebral column, muscle spasm
		  • blepharospasm
		
		Dr. Gennrich reviewed the references used for establishing appropriate use:
		• Botulinum Toxin A Treatment for Chronic Headache and Chronic Migraine. Center for Evidence-based Policy: Medicaid Evidence-based Decisions Project. Oregon Health & Science University. February 2012.
		• Botox Prescribing Information. Allergan, Inc. Revised 01/2013.
		
		She discussed the general conclusions from the Medicaid Evidence-based Decisions Project. Overall, the evidence for the effectiveness of BTX-A on chronic migraine is inconsistent, with the studies that do show a benefit finding that the improvement is small and potentially clinically insignificant.
		
		The five (5) participants currently receiving botulinumtoxin products were reviewed and discussed.
		
		Additional notes
		• IDHW has been receiving prior authorization requests for Botox for migraines as it has been assumed by some physicians that prior authorization is required.
		  • In general, insufficient documentation is being sent especially quantifying the number of migraines per month and the duration of each headache/migraine.

		• Inadequate description of success/failure of both prophylactic and abortive medications to treat migraines is being provided by the prescribers. **Recommendations for Botox used for chronic headaches/migraines** • Require prior authorization for botulinumtoxin for treatment of chronic headaches and migraines. A new prior authorization form has been created (see copy in your packet). Proposed implementation date is July 1, 2013. • Therapeutic criteria: 1. Quantification of headaches/migraines prior to botulinumtoxin therapy. Botox is FDA approved for the treatment of 15 or more chronic headaches per month with each headache lasting at least 4 hours. Per package insert: Safety and efficacy has not been established for prophylaxis of episodic migraine (14 headache days or fewer per month). 2. What has been tried prior to botulinumtoxin – including prophylactic therapy and treatment of migraines. • The DUR board recommended that prophylactic trials of at least two agents be required prior to approving Botox for migraines. • The DUR board recommended that there should be documentation of fills of abortive medications at least monthly for the previous three months. If approved, initial patient approval will be for two injections (given 3 months apart). This duration was used in the clinical studies that the FDA reviewed to

		approve Botox for chronic headaches. Idaho Medicaid will then require additional documentation including quantification of migraines after botulinumtoxin therapy as well as utilization of migraine treatment medications (e.g. Triptans), ER utilization, office visits for migraines, and any adverse reactions to Botox. Sample Prior Authorization form for Botox for Migraines/Chronic Headaches document provided (attached below). **Botulinumtoxin – Recommendations for other indications besides chronic headaches/migraines** • Cerebral Palsy • Overactive bladder • Urinary incontinence • Upper limb spasticity • Cervical dystonia • Severe axillary hyperhidrosis • Blepharospasm • Strabismus **Committee Recommendations**: 1. Require prior authorization for all botulinumtoxin products. 2. Require prior authorization including chart notes documenting effectiveness and safety of current therapy in current patients for all indications. " i.e. do not grandfather 3. Proposed implementation date: July 1, 2013  Botulinumtoxin_Migraine.pdf  Botulinumtoxin_Other.pdf

○ Injectable Testosterone Products	Chris Johnson, Pharm.D	The topical formulation of testosterone currently requires prior authorization with the following criteria: • Diagnosis of hypogonadism • At least one non-sexual symptom of hypogonadism as Idaho Medicaid does not authorize payment of medications for sexual dysfunction • Documented low testosterone level Initial requests are approved for 3 months with follow-up lab results required for continuation of therapy Injectable testosterone does not currently require prior authorization and appropriate use for diagnosis is not evaluated. Injectable testosterone is a controlled substance with potential for abuse. **Goals of Current DUR** • Evaluate whether testosterone injections are being prescribed appropriately • Determine if there are duplicative payments for treatments between outpatient pharmacy benefit and medical benefit (e.g. double billing) This DUR evaluated injectable testosterone (testosterone cypionate and testosterone enanthate) utilization in 2012, comparing prescriptions and medical procedure codes with common diagnosis for use including 257.2 testicular hypofunction and 257.9 testicular dysfunction, unspecified.

		Results
		
		• Age: 0- 75 years Average of 41 years
		• Average days supply: 28 days (range: 14-34 days
		• Average dispensed quantity: 4 mls (range: 1-10 mls)
		• The most prescribed: Testosterone cypionate 200 mg vial
		• Pharmacy (POS) Claims Data:
		  ○ Total 152 participants with 532 claims
		  ○ 4 female
		• Medical Claims(Provider Administered) Data:
		  ○ Total 104 participants with 533 claims
		  ○ 6 female
		• Duplicative Data:
		• Total of 15 participants with both Pharmacy and Medical claims
		  ○ 5 participants had pharmacy/medical claims on the same dates
		• Diagnosis
		  ○ Pharmacy Claims
		  ▪ 15.7% of participants without a documented diagnosis or unapproved diagnosis
		  ○ Medical Claims
		  ▪ 7.6% of participants without a documented diagnosis or unapproved diagnosis
		  ○ 33% of participants with duplicative claims noted between medical and pharmacy claims for the same billing dates.
		
		Prior Authorization of injectable testosterone for therapeutic diagnosis may be required to evaluate

		appropriate use and maintain consistency of therapeutic criteria between topical and injectable testosterone.
○ Psychotropic Medications in Foster Children ○ Two (2) or more concomitant stimulant medications ○ Long acting plus short acting	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 (January 2013) • Two (2) or more concomitant stimulant medications (current April focus) • long-acting plus short-acting 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 ADHD Drug Therapy Focus** • Children in Foster Care ages 0-17 • Claims review of any foster child receiving an ADHD Drug between 11/1/2012 and 1/31/2013 • Reviewed both Stimulant and Non Stimulants ○ Stimulants Included the following; • amphetamine salt combo • Adderall XR (amphetamine salt combo extended release) • dexmethylphenidate • Focalin XR (dexmethylphenidate extended release)

		• dextroamphetamine IR/ER • Procentra (dextroamphetamine) • Vyvanse (lisdexamfetamine) • Metadate CD (methylphenidate) • Methylin Chew tabs (methylphenidate) • methylphenidate ER (Concerta generic) • Methylin solution (methylphenidate) • methylphenidate IR • methylphenidate ER (Ritalin SR generic) • methylphenidate ER (Ritalin LA generic) • Daytrana (methylphenidate) • Quillivant XR (methylphenidate) ○ Non-Stimulants included the following: • Strattera (atomoxetine) • clonidine • Kapvay (clonidine extended release) • guanfacine • Intuniv (guanfacine extended release) <u>Methodology</u> Limitations in evaluation • "Snap-Shot" in time – did not include drug and dose changes before or after except as noted below • Excluded from analysis any child that did not have 2 continuous months of stable (same) drug therapy • Exception: if less than two months

		because of new start between 12/24/2012 and 1/31/2013 then following month was looked at in electronic record for evaluation of continuation • No medical history or profile review completed Final Evaluation Numbers • 759 children in original data pull • 187 with less than 2 months of any drug • 572 evaluated <u>Results</u> The following aspects were discussed: • Treatment patterns • One drug/one dose • Mixture of ER and IR dosage forms • Same chemical entity with more than one strength, • Two different chemical entities, • Three different chemical entities, • Patient with four different chemical entities, • Duplicate Therapy analysis The DUR Board recommended that no further evaluation was necessary.
➢ **Study Proposals for Next Quarter** o P&T Committee Narcotic Analgesic Studies – next steps	Tami Eide, Pharm.D.	The next step will be implementation to limit to one long- acting and one short- acting opioid. Additionally, the DUR board recommended providing prescribers with a "roadmap" of future narcotic opioid changes to be implemented in future.

○ Use of Psychotropic Medications in Foster Children – next steps ○ Three(3) or more concomitant mood stabilizer medications	Mark England, Pharm.D.	Next steps include an evaluation on foster children receiving three (3) or more concomitant mood stabilizer medications, with report findings to be presented at the next DUR meeting.
○ Hepatitis C Agents	Jane Gennrich, Pharm.D.	Review past 6 months of data for usage of Incivek and Victrelis. Review to include: • Therapy continuation after initial start • Chart notes evaluation to determine reasons patients discontinued therapy (e.g. intolerable side effects vs. non-responders to therapy based on viral counts vs. non-compliance) • Trend evaluation of patients that discontinued therapy (e.g. does rate vary between practices or geographically) • Validation that patients are actually receiving TRIPLE therapy with ribavirin and interferon as well as a protease inhibitor. • Audit that viral counts are evaluated at appropriate time intervals Will look at quarterly trends in usage since Incivek/Victrelis were approved by the FDA in May 2011 as patients were not started on double therapy (ribavirin/interferon) as the specialists were waiting for triple therapy to be available. In the future an all oral regimen is going to be available for treatment of Hepatitis C so there may be patient “warehousing” again.
○ Antipsychotic Indications evaluation – hold for future ○ AAP and DVT’s – hold for future		

➢ **ProDUR Quarterly Report**	Mark England, Pharm.D.	Dr. England reviewed the quarterly report. ProDUR trends remain the same. No specific actions taken.
➢ **DUR Newsletter**	Mark England, Pharm.D.	Current Newsletter was provided via hard copy which included a review of Idaho Medicaid spending, calculation of pharmacy specific spending with 50% rebate collection of pharmacy expenditure. Trends seen included generic drug use is up and cost of drugs going down as well as demand for specialty drugs is increased. For the next newsletter, the DUR Board suggested including an article stating what specialty drugs require prior authorization. Newsletter available on IDHW website. Goal to improve distribution of newsletter was mentioned.  022013newsletter.pdf
➢ **Medicaid Update**	Tami Eide, Pharm.D.	Update on Expansion: A task force was assigned to evaluate the cost of expansion. The Legislature did not hear recommendations until the last days of session and they did not have time to take action. There may be a possible future special session to only discuss Medicaid expansion. IDHW is moving

		forward as if expansion will happen and is leaning toward a managed care model for the new population. ACA rule is to be implemented in Idaho which requires all prescribers be enrolled and approved as an Idaho Medicaid provider. Currently working towards streamlining enrollment and how to handle emergency situations.
➢ ***Adjourn, 2pm***	Mark Turner, M.D.	
Next Meeting: **July 18, 2013 – 9:00 AM**	Mark England, Pharm.D.	