

Idaho Drug Utilization Review Program

DUR BOARD MEETING MINUTES

January 20, 2005 9:00 am

Department of H&W, 3232 Elder Street
Boise, Idaho

Board Members Attending: N. Mann, J. Steiner, S. Cooper, W. Baures, and M. Olson-Fisher

DUR Staff: H. Brandt, P. Cady, V. Culbertson, N. Murdock, and T. Pettinger

Medicaid Representatives: T. Eide

Excused:

Guests:

	Subject	Discussion	Action/Follow up
1.	Approval of meeting minutes (Sep 2004)		No action taken
2.	Quarterly report - V. Culbertson		No action taken
3.	Follow-up Studies	<p><u>Carisoprodol (Soma®) Safety</u> –N. Murdock</p> <p>Introduced in the late 1950s, carisoprodol (Soma®) is a widely prescribed skeletal muscle relaxant (SMR) with similar efficacy to other members of its class. It is relatively inexpensive and until recently, has been considered safe. However, beginning in the late 1980s, concern regarding its abuse has been growing. Anecdotal descriptions of a “buzz” or euphoria have been documented with carisoprodol, particularly when combined with opioids. Additionally, documented cases of withdrawal symptoms, drug-seeking behavior, and fatalities related to carisoprodol have been reported.</p> <p>This intervention characterized SMR use in the Idaho Medicaid population, with a focus on carisoprodol utilization, especially chronic use (≥3 consecutive months) and/or concomitant hydrocodone use. In addition, its aim was to provide educational information to Medicaid providers regarding the abuse potential of carisoprodol and the appropriate use of SMRs in general. A review of pertinent literature was also provided, as well as a questionnaire to assess prescribing habits and experience with SMRs.</p> <p>To follow up, a Summer newsletter article was included in the ‘DUR</p>	<p>Intervention presented</p> <p>The board would like this reviewed in 6 months for completion of data set. Current data should be passed on to the Idaho Board of Pharmacy for support of legislation to schedule carisoprodol as a controlled substance.</p>

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		<p>Discovery’ to ensure that all Medicaid providers and pharmacies receive information on the potential for carisoprodol abuse.</p> <p>In the six months following intervention and newsletter mailings, some changes in SMR utilization have been noted. Of greatest significance, carisoprodol is no longer the most prescribed SMR in the Idaho medicaid population. Another encouraging finding relates to a decrease in chronic carisoprodol use (>3 months duration) and a decrease in chronic concomitant hydrocodone use. A further analysis of utilization should be undertaken in another six months to one year to determine if educational materials discouraging the use of carisoprodol have had a long-lasting effect on SMR prescribing.</p> <p><u>Stimulants and Strattera®</u> –T. Pettinger</p> <p>Several well-controlled trials in children with uncomplicated ADHD have established the efficacy of stimulants with response rates reaching 60 to 75% in stimulant naive patients with placebo response rates ranging from zero to 30%. Furthermore, it has been demonstrated that a trial of an alternative stimulant after initial failure may push response rates up to 80 to 90%. The common stimulants used in ADHD include methylphenidate, dextroamphetamine, and mixed amphetamine salts. Pemoline (Cylert®) is considered a second-line agent due to its propensity to induce hepatotoxicity. Other second-line agents include tricyclic antidepressants, bupropion, clonidine, and Strattera®. Evidence of efficacy in ADHD for most of these agents is inferior to that of the stimulants. Strattera® has received much attention since its release into the U.S. market. It is a non-cyclic, non-stimulant, norepinephrine reuptake inhibitor that has demonstrated clinical efficacy for controlling the core symptoms of ADHD in four well-controlled trials with good tolerability. One open-label trial has suggested that the efficacy of Strattera® may approach that of stimulants, although no large head-to-head trials have been conducted to date. Also of note, Strattera® has not yet been studied in combination with stimulants for ADHD refractory to stimulants alone.</p> <p>The purpose of this intervention was to characterize ADHD drug utilization in the Idaho Medicaid population, with a focus on Strattera® use and inappropriate prescribing of long-acting stimulants. In addition, to identify concomitant drug use including CNS depressants (opioids, benzodiazepines, and sleep aids). Finally, to provide educational information to Medicaid providers regarding the appropriate use of drugs</p>	<p>Intervention presented. Board Members thought the following information would be helpful in a follow-up report:</p> <ul style="list-style-type: none"> --Total number of prescriptions with the graphs --The number of providers that are using Strattera first line for their patients --Number of prescriptions of Strattera in adults vs. children --How many patients are given a prescription for another medication such as an antidepressant or sedative along with the stimulant <p>Overall the Board Members were impressed by the intervention. They were also concerned over the use of multiple doses of long-acting stimulants and recommended continued monitoring.</p>

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		<p>for the treatment of ADHD.</p> <p>Upon follow up it was determined that ADHD drug therapy utilization and costs continue to increase. Methylphenidate remains the most commonly used agent, however, Strattera® utilization is increasing. The inappropriate use of long-acting stimulants (Concerta®, Ritalin LA®) is associated with clinical and economic concerns and appears to be on the decline following the recent intervention.</p>	
4.	Current Intervention responses	<p><u>SSRI's in Pediatric Patients</u> – N. Murdock & T. Pettinger</p> <p>With the advent of fluoxetine (Prozac®) in 1988, a new era in the treatment of depression began. Since fluoxetine, several therapeutically similar agents have been approved constituting a group of drugs commonly referred to as 'newer generation' antidepressants. These drugs, including selective serotonin reuptake inhibitors (SSRIs) and some chemically unrelated agents (bupropion, venlafaxine, and mirtazapine) have largely replaced older pharmacologic treatment modalities in the management of major depressive disorder in both adults and children due to equivalent or superior efficacy to older agents and an improved side effect profile.</p> <p>The objective of this intervention was To identify pediatric patients (≤ 18 years) receiving antidepressant medications, specifically newer agents, and to provide information to prescribers and pharmacists regarding recent FDA warnings and emerging clinical data concerning the potential for increased suicide risk in this population.</p> <p>Results: See Intervention report</p> <p>Conclusions: Antidepressant medications continue to represent a significant proportion of the Idaho Medicaid drug budget with costs</p>	<p>Intervention discussed. T. Eide questioned the Board as to the role of Medicaid in this situation. Does Medicaid serve only as a payer or act in the best interest of the pt? Many thought that providers need to be responsible for their judgment and that Medicaid could not be a “ruler”. Patients need an evaluation by a psychiatrist.</p> <p>The idea of an “informed consent” to the provider from Medicaid to act as a reminder for proper follow-up and evaluation was offered. This document may educate patients/parents about such warnings. May serve as another reminder that this is important and shouldn't be taken lightly.</p> <p>The board did ask if it was possible to look at multiple antidepressants for</p>

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		<p>continuing to rise. This is partially reflective of increases in the overall population, but more importantly related to increasing costs of these medications. Although TCAs and trazodone make up a portion of antidepressant utilization, it is not surprising that over 95% is related to so-called “newer” agents, including SSRIs. Among the newer agents, nearly three-quarters of claims in 2003 were for paroxetine, sertraline, venlafaxine, bupropion, and fluoxetine. This utilization trend may be of benefit for future P&T discussions involving the selection of representative agents for the class.</p> <p>Pediatric patients make up the largest single group of antidepressant users in the Idaho medicaid population, although chronic use (indicating either compliance and/or routine follow up) is less than 50%. This lack of continued use is likely sub-therapeutic and represents an area for increased awareness and education to improve both clinical outcomes and contribute to more cost-effective therapy.</p> <p><u>Drugs in Pregnancy</u>—T. Pettinger</p> <p>Although most physicians are extremely cautious with medication use in their pregnant patients, it is estimated that at least 10% of birth defects can be attributed to maternal drug exposures. In order to provide guidance to health care professionals, the FDA has developed a categorization system for medications based on their potential for fetal risk.</p> <p>Medications with recognized harmful effects to a developing fetus are in the categories “D” and “X”. Category “D” medications may provide benefit to the mother in certain medical conditions; however, the benefit must outweigh the risk to the fetus in order for such drugs to be used. Examples of category “D” drugs include ACE inhibitors, lithium, and certain anticonvulsants such as phenytoin and carbamazepine. Category “X” medications are absolutely contraindicated in pregnancy as they are associated with more harm to the fetus than any possible benefit that could be obtained. Examples of category “X” medications are HMG Co-A reductase inhibitors (statins), warfarin, vitamin A derivatives, and many benzodiazepines.</p> <p>The objective of this intervention was To describe and characterize the prevalence of prescription drug use among pregnant women on Idaho</p>	<p>chronic use. Do we have many children on >1 antidepressant</p> <p>Intervention discussed. The Board Members were surprised at the number of inappropriate medications being prescribed.</p> <p>Since this is a required intervention the Board Members were asked for ideas for future interventions regarding drugs in pregnancy. Ideas suggested included a drug-specific intervention such as statins and pregnancy. Questionnaires should also be sent to pharmacists, family practitioners, and OB/GYNs. It was also suggested that prenatal vitamin use be looked at during the same time period.</p>

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		<p>Medicaid. In addition, to provide educational materials to physicians to promote the safe and appropriate use of medications in this population For results, see Intervention report</p> <p>Conclusion: Category “X” medications pose a significant risk to a developing fetus. Despite over 20,000 births, 153 pregnant women received one of these medications over the past two years. Better patient education and physician screening techniques are warranted to further decrease the incidence of inappropriate prescribing this population.</p> <p><u>COX-2 Inhibitors Outcomes Study</u> –H. Brandt</p> <p>Selective cyclooxygenase-2 (COX-2) inhibitors were first released into the US market in December 1998 with the introduction of Celebrex® (celecoxib). Since that time, two additional COX-2 inhibitors have been approved, Vioxx® (rofecoxib) and Bextra® (valdecoxib), although rofecoxib was voluntarily withdrawn by its manufacturer in September 2004 due to reports of increased cardiovascular events. These medications are indicated for use in the treatment of osteo- and rheumatoid arthritis, dysmenorrhea, acute pain, migraine headache, and familial adenomatous polyposis (celecoxib only).</p> <p>Although the exact mechanism of action for any non-steroidal anti-inflammatory drug (NSAID) is not completely understood, it is clear that one or both known isoforms of the COX enzyme are affected. While traditional NSAIDs mainly inhibit the COX-1 isoform, COX-2 inhibitors are considered more selective in their inhibition of COX-2. This selectivity is thought to contribute to the lower risk of gastrointestinal (GI) adverse effects with COX-2 inhibitors. The selectivity with which these medications inhibit COX-2 varies greatly; according to some assay studies, rofecoxib is nearly 10 times more selective for COX-2 than celecoxib.</p> <p>COX-2 inhibitors have shown some advantage over previously available NSAIDs in randomized, controlled clinical trials, including decreased GI irritation and ulceration while demonstrating similar analgesic efficacy to traditional agents. Long-term safety of these medications, however, has not been established and recent findings indicate that cardiovascular risks, including myocardial infarction and stroke, may be significant and potentially limiting adverse effects, especially in at-risk patients taking</p>	<p>Study discussed. It was received well received by the Board.</p>

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		<p>long-term normal to high doses of these agents.</p> <p>The objective of this study was to evaluate outcomes related to the enhanced prior authorization program (EPAP) regarding the selection of rofecoxib as Idaho Medicaid's preferred COX-2 agent.</p> <p>For results, see COX-2 Outcomes Study report.</p> <p>Conclusions: The total cost of COX-2 inhibitors decreased substantially by six months after the implementation of the PA in March 2004. Analyses of claims data showed that selecting rofecoxib as the preferred COX-2 selective agent did not increase new office visits or emergency room visits, suggesting that additional adverse gastrointestinal or cardiovascular events did not occur. Similar switch rates between all COX-2 inhibitors help confirm the similarity of clinical efficacy and tolerability of all of these agents. Overall, this outcomes review did not identify any adverse outcomes, clinical or financial, from the selection of rofecoxib as the agent of choice in this population. It is important to note, however, that further clinical implications of selectively inhibiting the COX-2 enzyme are now becoming available. As additional long-term trials are conducted and further data is collected and analyzed, the safety of these medications will become more established. In the future, further utilization review of this class of medications will be necessary.</p>	
5.	Future interventions for next quarter	<p><u>Idaho Health Initiatives Proposal</u> –N. Murdock</p> <p>Preventative research studies have demonstrated great benefit from engaging in health promoting behaviors including the following:</p> <ul style="list-style-type: none"> ❖ Cardiovascular Health ❖ Appropriate asthma treatment ❖ Fluoride use in children ❖ Vaccinations in elderly and/or children²⁵. <p>Although well-established guidelines exist for all of the above interventions, it has been demonstrated that many of these recommendations are not being fully carried out by the US health care system today. Healthy People 2010 is an initiative designed to increase both the lifespan and quality of healthy life in a nationwide effort. This study has outlined 467 specific objectives consistent with these goals,</p>	<p>Initiative was presented. Much discussion followed. Ideas were shared as to how some of the interventions may be carried out. The additional idea of possible prenatal care was brought up. This could only be retrospectively as we would only be able to identify these patients by a delivery date. The fluoride in children intervention was discussed concerning the difficulties of determining which counties had fluoride in the water supply. Suggestions to call the department of water, and possible discuss with</p>

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		<p>baseline data were identified when available, and specific targets were set for the year 2010. Similar efforts can be made in the Idaho Medicaid population to reinforce these guidelines ultimately providing longer, healthy lives for our patients.</p> <p>This is designed as a series of interventions to take place over the next 12-24 months. Several guidelines which have been mentioned above will be considered when designing the future interventions. Idaho Medicaid claims will be screened to identify patients at risk or in need of such interventions. These interventions will be designed to identify both areas of weakness which can be improved upon and uncovering areas of strength for which the Idaho Medicaid providers should be commended. The bottom line in this series of interventions is to ensure that Idaho Medicaid patients receive the best healthcare possible, as determined by evidence-based medicine.</p> <p><u>Untreated Hypertension</u>—N. Murdock</p> <p>It has been determined that hypertension prevalence is increasing in the United States. Hypertension is an established cardiovascular risk which has been shown to be directly related to the risk of stroke, coronary heart disease, and mortality. The risk of cardiovascular disease increases by twofold with each increment of 20/10 mmHg for levels as low as 115/75 mmHg. The 1999-2000 NHANES data shows a 28.7% prevalence of hypertension of individuals >18 yrs of age. Hypertension prevalence increases with age reaching 65.4% among those age ≥60 years. A large percentage of the Idaho Medicaid patient population consists of patients which fit into this age range. Only about 58.4 % of patients with hypertension are treated nationwide. From previous interventions, it was noted that the Idaho Medicaid patient population has a similar status of untreated hypertension. This is no surprise as it meets the average for the nation, yet it leaves much room for improvement. There are many factors that can result in a patient being untreated for hypertension. These include, but are not limited to: patient noncompliance, lifestyle modifications being utilized, and the indifferent treatment of a “silent” disease state. Many of these factors may be improved upon with proper education of the patient and reminders to the providers on the benefits of aggressive treatment to reach goal blood pressures.</p> <p>Idaho Medicaid claims will be screened for the incidence and prevalence of hypertension over the most recent 24 month time period. We will then</p>	<p>dental residents involved with Pocatello Family Medicine. Another limitation to the study was brought up. Some areas run a “swish and spit” program through the school district (which all children at that school are given fluoride treatments).</p> <p>The overall intervention was taken very well by the board</p> <p>The intervention was presented. It was surprising to the board that Idaho providers are only treating approximately half of those patients with hypertension. The intervention was taken well and they liked the idea of patient education component as well.</p>

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		<p>determine the percentage of patients being treated for hypertension during this time frame. An educational leaflet concerning the risks of untreated hypertension and the importance of controlling blood pressures to goal will be distributed to the providers. An educational leaflet regarding the importance of treating hypertension and compliance with medications will be made available for distribution to patients who have been identified at risk.</p> <p><u>Appropriate Asthma Therapy</u> –N. Murdock</p> <p>Asthma is a condition characterized by chronic inflammation of the airways. Recent evidence indicates that this inflammatory condition may result in irreversible airway injury in some patients. It is postulated that appropriate use of inhaled anti-inflammatory agents may help attenuate these chronic changes.</p> <p>The NAEPP guidelines recommend that patients who are regular users of inhaled short-acting beta-2-agonists are candidates for inhaled anti-inflammatory (corticosteroid) therapy. When patients begin using greater than one beta-2-agonist canister monthly for quick relief or rescue, re-evaluation of pharmacologic therapy may be indicated. In addition, it is recommended that inhaled corticosteroid therapy be optimized before the addition of long-acting beta-2 agonists (salmeterol) and that long-acting agents not be used in the absence of anti-inflammatory treatment.</p> <p>Idaho Medicaid paid claims files will be screened for patients who received >1 unit of a short-acting beta-2-agonist inhaler monthly over a three-month period and/or long-acting beta-2-agonist treatment without inhaled corticosteroid therapy.</p> <p>Physicians and pharmacists responsible for treatment of these patients will be identified and sent a packet of information including an education leaflet, questionnaire, and a copy of the patient's</p> <p><u>Proton-Pump Inhibitors Outcomes Study</u> –H. Brandt</p> <p>Proton-pump inhibitors are agents commonly used in the treatment of peptic ulcer disease (PUD), moderate-to-severe gastroesophageal reflux disease (GERD) and in the management of hypersecretory states such as Zollinger-Ellison syndrome. Omeprazole (Prilosec®) was the first PPI approved in 1988. Since then, four additional drugs in the class have</p>	<p>The intervention was presented. It was also taken very well by the board. T. Eddie suggested including the leukotriene inhibitors in this intervention. It was discussed that the role of the leukotriene inhibitors in asthma is not as clear cut as the inhaled steroids and short acting beta agonists.</p> <p>Both approved as intervention/outcomes studies for next quarter.</p>

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		<p>become available: lansoprazole (Prevacid[®]), rabeprazole (Aciphex[®]), pantoprazole (Protonix[®]), and most recently, esomeprazole (Nexium[®]).</p> <p>These agents are potent inhibitors of gastric acid secretion and have been heavily marketed to both consumers and physicians. While possessing many benefits over older acid-suppressants, the long-term use of PPIs may be unnecessary and is associated with significant economic concerns. PPIs are expensive agents, with average wholesale prices (AWPs) ranging from \$100 to \$150 per month. The newly available Prilosec OTC costs about \$30 per month. In 2003, Idaho Medicaid spent nearly \$3.7 million on PPIs. Because of the high cost of these agents, PPIs were included in the enhanced prior authorization program (EPAP) for Idaho Medicaid on April 1, 2004.</p> <p>Outcome studies will be conducted as part of the Idaho Drug Utilization Review (DUR) program and will include the following components:</p> <p>I. <u>Market Share Analysis</u> – Including the number of scripts filled for each product as a percent of total market share for the drug class.</p> <p>IIa <u>General Screening Tests</u> – comparison of the relative incidence of new office visits, hospitalizations, and/or ER visits in preferred versus non-preferred agents. Additionally, the switch rate from preferred agents to non-preferred agents will be used as a surrogate marker of potential adverse outcomes.</p> <p>An abnormally high incidence will prompt a more thorough investigation in an attempt to identify any drug-induced causes for these events.</p> <p>IIb <u>Prescriber Intervention</u> – Frequent prescribers of non-preferred agents will be identified for mail or personal intervention</p> <p>III. <u>Specific Adverse Outcome (AO) Surveillance</u> – comparison of adverse outcomes will be made between preferred and non-preferred agents and will include incidence of GI bleed and ulceration.</p> <p><u>Triptans Outcomes Study</u>–H. Brandt</p>	

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		<p>Triptan drugs are classified as ‘abortive agents’ in that they provide relief during acute migraine attacks, but lack the ability to prevent future headaches. Currently there are seven triptans available in the US: almotriptan (Axert®), eletriptan (Relpax®), frovatriptan (Frova®), naratriptan (Amerge®), rizatriptan (Maxalt®), sumatriptan (Imitrex®), and zolmitriptan (Zomig®). Although the benefit of these agents in periodic acute settings is undisputed, excessive use of these drugs has been associated with significant problems including rebound or medication overuse headache, the potential for misuse, and important economic concerns. In 2002, Idaho Medicaid spent nearly \$1 million on triptan drugs, with a substantial number of patients on triptan therapy (25%) receiving maximum recommended doses for six or more months. Because of the high cost of these agents, triptans were included in the enhanced prior authorization program (EPAP) for Idaho Medicaid on May 1, 2004.</p> <p>Outcome studies will be conducted as part of the Idaho Drug Utilization Review (DUR) program and will include the following components:</p> <p>I. <u>Market Share Analysis</u> – Including the number of scripts filled for each product as a percent of total market share for the drug class.</p> <p>IIa <u>General Screening Tests</u> – comparison of the relative incidence of new office visits, hospitalizations, and/or ER visits in preferred versus non-preferred agents. Additionally, the switch rate from preferred agents to non-preferred agents will be used as a surrogate marker of potential adverse outcomes.</p> <p>An abnormally high incidence will prompt a more thorough investigation in an attempt to identify any drug-induced causes for these events.</p> <p>IIb <u>Prescriber Intervention</u> – Frequent prescribers of non-preferred agents will be identified for mail or personal intervention</p> <p>III. <u>Specific Adverse Outcome (AO) Surveillance</u> – comparison of adverse outcomes will be made between preferred and non-preferred agents.</p>	
6.	Annual Report		No Discussion

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7.	Medicaid Update -T. Eide		<p>The switch of federal funds for those patients dually eligible for Medicare and Medicaid was explained. The federal government will receive the rebates for those patients. The potential effects on the DUR were also briefly discussed.</p> <p>The P&T Committee will be discussing anti-epileptics for mood disorders and neuropathic pain at the meeting the following day.</p> <p>Mental Health Initiative will look for opportunities for educational interventions and increase the effectiveness and safety of these medications. Cost is not the main focus of this initiative.</p>
8.	Other business	<p>WINTER NEWSLETTER SSRIs and suicidality Drugs in the Elderly Tablet Splitting: Pros and Cons</p> <p>TOP 50</p> <p>Baseline Information for P&T on following drugs classes: ACEI, ARBs, Beta-blockers, Calcium channel Blockers</p> <p>Conflict of interest statement.</p> <p>Pergolide-induced valvular heart disease</p>	<p>Articles reevaluated for inclusion in DUR Newsletter. The Board was very positive as to the content of the upcoming newsletter.</p> <p>Review and briefly discussed.</p> <p>The Board found this information useful for determining future interventions and for possible patient specific interventions to ensure appropriate and cost-effective use of medications.</p> <p>Conflict of interest statement signed by available Board Members.</p> <p>V. Culbertson's request to send out a "Dear Doctor" letter regarding</p>

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			pergolide's potentially dangerous adverse affect was granted. The Board was very positive toward this letter.
9.	Meeting Dates	April 21, July 14, October 20, and January 19, 2006	No changes were discussed at this time.
10.	Adjournment	Meeting adjourned at 2:00 PM	