

*Idaho Drug Utilization Review Program*

**DUR BOARD MEETING MINUTES**

September 16, 2004 9:00 am

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

**Board Members Attending:** K. Clifford, K. Jensen, and J. Steiner

**DUR Staff:** P. Cady, V. Culbertson, N. Murdock, T. Pettinger, and C. Owens

**Medicaid Representatives:** T. Eide and S. Kittridge

**Excused:** N. Mann, M. Olson-Fisher, R. Ting, and G. Wilburn

**Guests:**

|    | <b>Subject</b>                                 | <b>Discussion</b>   | <b>Action/Follow up</b>   |
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| 1. | <b>Approval of meeting minutes (June 2004)</b> |   | No action taken   |
| 2. | <b>Quarterly report</b><br>- V. Culbertson     |   | No action taken   |
| 3. | <b>Follow-up Studies</b>                       | <p><b><u>Carisoprodol (Soma®) Safety</u></b> –V. Culbertson</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 (<math>\geq 3</math> 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>Results indicated that carisoprodol was the second most prescribed SMR</p> | <p>The Idaho Pharmacists Association voted down an initiative to implement a pharmacist-driven intervention to curb Soma® prescribing citing excessive workload issues on the part of pharmacists already. Although disappointing, it was agreed that further educational programs should be undertaken. It was suggested that an MD directed intervention might be helpful. Dr. Clifford “applauded” this effort and agreed to write a cover letter to accompany the faxable form. Form will also be made available for download on DUR, Medicaid, and State Board websites. If educational efforts ultimately prove unsuccessful, it was indicated that a discussion by the P&amp;T committee may result in removing Soma® from the preferred list.</p> |

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|  |                | <p>in 2003 with approximately 2,000 patients and 10,000 claims that year. In terms of cost, carisoprodol was ranked third among the SMRs in 2003, with a total expenditure of \$280,709. The majority of carisoprodol users in 2003 were prescribed the agent for longer than 2 weeks of therapy and a significant number also received concomitant opioids.</p> <p>For further results, see results in ‘Carisoprodol Safety’ packet</p> <p>To follow up, a Summer newsletter article was included in the ‘DUR Discovery’ to ensure that all Medicaid providers and pharmacies receive information on the potential for carisoprodol abuse. V. Culbertson suggested at last meeting that a pharmacist driven patient-specific intervention program to discourage the use of Soma in favor of equivalent, safer options be undertaken on a state-wide basis. A one page educational document outlining Soma® concerns and alternatives was prepared and presented to the Idaho Pharmacists Association. A poster highlighting this intervention is also to be presented at the Idaho Society of Health-Systems Pharmacists meeting in Sun Valley in October, 2004.</p> <p><b><u>Appropriate Use of Synagis® in RSV</u></b> –P. Cady</p> <p>At the direction of Medicaid Administration, the Medicaid Pharmacy Program requested that the DUR Board undertake a study of the outcomes associated with the department’s prior authorization (PA) of palivizumab (Synagis®). The PA of palivizumab went into effect for the 2003-2004 RSV season and restricted use of the agent to high risk infants as defined by a policy statement established by the American Academy of Pediatrics in 1998. This study has begun to characterize RSV trends in the state of Idaho as well as the use of palivizumab. This interim report sums up some important early findings and outlined results that will be presented at the September meeting.</p> <p>For part one of the report, Idaho Medicaid claims were queried to identify cases of RSV infection per season (season was defined as July to June, starting in 1998). Diagnosis codes used to identify patients were 079.6 (RSV) and 466.11 (acute bronchiolitis due to RSV). Drug costs per patient and overall costs per season were also tabulated.</p> <p>In the April board meeting, the coding for RSV was discussed. It was suggested that restricting a definition of RSV diagnosis to only the ICD-9 codes mentioned (079.6 and 466.11) may inadequately reflect all cases of</p> | <p>Results presented. Medicaid department expressed appreciation for outcome study and data presentation. The DUR was asked to present this study at next P&amp;T committee meeting in November 2004.</p> |

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|    |                                       | <p>RSV diagnosed in Idaho. It was further suggested that many physicians will use ICD-9 codes indicative of bronchiolitis (466, 466.1, and 466.19) to identify RSV patients as well. For this report we included a comparison of these two methods of identifying RSV as well cost data up through the end of the 2003-2004 RSV season. Results: Cost of Synagis® decreased by \$1.3 million since the implementation of the PA program. Among patients denied Synagis® therapy, there was no increase in hospitalization or healthcare utilization. Actually, there were more hospitalizations in the Synagis® treated group, reflecting their less healthy baseline status.</p> <p>For complete results, see “Synagis® Utilization in Idaho Medicaid Population 2003-2004.”</p>  |   |
| 4. | <b>Current Intervention responses</b> | <p><b><u>Appropriate Medication Use in the Elderly</u></b> – C.Owens</p> <p>Inappropriate medication use in the elderly (≥65 years) has been associated with a substantial number of adverse drug reactions, worsening physical function, and excessive healthcare utilization. For these reasons, vigilant monitoring in this population is important to improve patient safety and relieve unnecessary economic burden on healthcare resources.</p> <p>Criteria identifying inappropriate drug use in the elderly population have been developed and reviewed by a number of expert panels in geriatric medicine and pharmacology, the most well-known being led by Mark Beers, M.D. The Beers Criteria, as they have come to be known, were first established in 1991, but have since been revised and updated.</p> <p>A total of 48 individual medications or classes of medications to avoid in older adults were originally identified by the Beers group. Further categorization by Zhan and colleagues classified these medications as</p> | <p>Intervention discussed. It was recommended that this intervention to be repeated periodically. Additional ideas for future study include the undertreatment of depression among the elderly (nursing home, etc) and an outcomes study of Beers List medications (recurrent UTIs, etc.)</p> |

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|  |                | <p>drugs that should always be avoided (AA), those that are rarely appropriate (RA), and those that have some indications for use in the elderly but are often misused (SI).</p> <p>The objective of this intervention was to identify elderly patients who may be at risk for adverse events due to inappropriate medication use and provide information to physicians and pharmacists regarding the Beers Criteria.</p> <p>Results: Approximately 29% of elderly patients in the Idaho medicaid population filled at least one prescription for a potentially inappropriate drug in the past year, according to Beers criteria.</p> <p>For further results, see results in ‘Drugs in Elderly’ packet</p> <p><b><u>Hormone Replacement Therapy</u></b>—N. Murdock</p> <p>Long-term use of hormone replacement therapy (HRT) has come under increased scrutiny in recent years due to the well-publicized findings from the Women’s Health Initiative (WHI). For decades, peri- and postmenopausal patients have enjoyed significant benefits from HRT including vasomotor and genitourinary symptom control and osteoporosis prevention. In addition, purported cardiovascular benefits were also thought to be derived from HRT. However, results from the Heart and Estrogen/Progestin Replacement Study (HERS) in 1998 suggested that combined estrogen/progestin therapy did not in fact confer the long-believed cardiovascular benefits. HERS looked at postmenopausal women with established heart disease using conjugated equine estrogen (CEE) and medroxyprogesterone (MPA) and found that after one-year of treatment these women were at increased risk of coronary heart disease (CHD) events. This analysis was carried out an additional 2.7 years in the HERS II trial to examine the long-term CHD effects of combined CEE+MPA. Investigators found with additional HRT treatment, women with established CHD still did not have a reduced rate of CHD events. The WHI study published in 2002 addressed the use of CEE alone and in combination with MPA in healthy postmenopausal women in terms of cardiovascular and cancer risks.</p> <p>The objective of this intervention was to evaluate the use of estrogen preparations among Idaho Medicaid patients and provide educational</p> | <p>Intervention discussed. Board appreciated information presented. The information provided by this intervention will act as a baseline and reference for P&amp;T on estrogen products.</p> |

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|  |                | <p>materials to physicians, pharmacists, and patients regarding the appropriate use of hormone replacement therapy in light of recent clinical study findings. The information from this intervention will also serve as a baseline for the P &amp; T committee, who recently reviewed estrogen preparations. This intervention was done two years ago when the WHI had released its initial results and was repeated to assess differences in prescribing since that time.</p> <p>For results, see ‘Hormone Replacement Therapy’ packet</p> <p><b><u>Appropriate Use of Methadone</u></b> –C.Owens</p> <p>Chronic nonmalignant pain is a common cause of disability and is estimated to affect one in five adult Americans. The American Pain Society and the American Academy of Pain Medicine have endorsed the use of opioids for refractory chronic non-cancer pain when used according to published guidelines. Long-acting opioids are especially useful in the treatment of this type of pain due to an extended duration of action, dosing convenience, and a tolerable adverse effect profile for most patients. At the Idaho Medicaid P&amp;T Meeting held in March 2004, long-acting opioids were discussed and comparative evidence was presented. While all agents are available to Medicaid patients, three preferred drugs were selected to be used first-line: two long-acting morphine sulfate preparations, Avinza® and Kadian®, and methadone.</p> <p>Morphine sulfate enjoys regular clinical use with readily available dosing and equipotent dose conversion guidelines. Methadone, on the other hand, is less commonly used and possesses pharmacodynamic and pharmacokinetic properties that can make it difficult to use safely. In addition, significant interpatient variability is more marked with methadone and the lack of published guidelines adds to the complexity of appropriately using this drug.</p> <p>Clinicians should not be deterred from using methadone in their patients with chronic pain, as it is an extremely effective agent in this regard; however, a good understanding of its pharmacodynamic and kinetic intricacies is essential.</p> <p>The objective of this intervention was to evaluate the use of long-acting opioids among Idaho Medicaid patients and provide educational materials to prescribers and pharmacists regarding preferred agents with a focus on</p> | <p>Intervention discussed. The board appreciated the educational information provided on the appropriate use of methadone. It was recommended that further information on the subject be made available in other DUR newsletters and on the website to assist providers in appropriately using methadone. These results will also be presented at the P&amp;T meeting tomorrow. MMWR report from S. Carolina and the use of methadone.</p> |

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|    |  | <p>the appropriate use of methadone. The information will also serve as a baseline for the P&amp;T committee for future outcome studies with the long-acting opioid class.</p> <p>For results, see ‘Opioids in Chronic Non-malignant Pain’ packet.</p>  |   |
| 5. | <b>Future interventions for next quarter</b> | <p><b><u>SSRI’s in Pediatric Patients</u></b> –T. Pettinger</p> <p>Although fluoxetine (Prozac®) is the only SSRI approved for the treatment of pediatric major depressive disorder and fluoxetine, sertraline (Zoloft®), and fluvoxamine (Luvox®) are approved for pediatric obsessive compulsive disorder, many other antidepressants including paroxetine (Paxil®), citalopram (Celexa®) and venlafaxine (Effexor®) are used off-label for the treatment of depression in children. Debate regarding the place in therapy of these agents and their appropriate use in pediatric patients has recently been the subject of both public broadcast programs and drug regulatory agency recommendations in both the United Kingdom and the United States.</p> <p>Paxil® has been at the center of this controversy and within the past two months, its manufacturer, GlaxoSmithKline, agreed to make public all of data it has on paroxetine, including significant findings associated with pediatric patients. This information will be added to existing clinical trial data that the FDA is reviewing in an effort to determine whether there is sufficient evidence to establish that some or all antidepressants increase the risk of suicidality.</p> <p>For now, the FDA has asked manufacturers to include a warning statement in the labeling of ten antidepressant drugs that recommends close observation of adult and pediatric patients for worsening depression or the emergence of suicidality. The drugs that are the focus of this warning are: fluoxetine, sertraline, paroxetine, fluvoxamine, citalopram, escitalopram, bupropion, venlafaxine, nefazodone, and mirtazapine.</p> <p>Idaho Medicaid claims will be queried to identify trends in antidepressant prescribing over the past 10 years. Pediatric patients taking an above-mentioned antidepressant on a chronic basis (10 fills in the most recent 12 months) will be identified. Physicians who prescribed these agents and dispensing pharmacies will receive intervention information highlighting the need for careful monitoring of these patients.</p> | Approved as intervention for 4 <sup>th</sup> quarter. Board thought this intervention is very timely. |

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|  |         | <p>For more information, see ‘SSRIs in Pediatric Patients’ proposal</p> <p><b><u>Drugs in Pregnancy</u></b>—T. Pettinger</p> <p>Several classes of medications are contraindicated in pregnancy due to adverse effects on the fetus. The FDA has provided five pregnancy categories to help in identifying the potential of a medication for causing birth defects. The categories rely on information from studies and observations for each drug. The drug classes of D and X provide the most risk to the fetus and should be avoided in pregnancy unless the risk:benefit ratio dictates otherwise. Several common classes of drugs are considered class D or X, including non-steroidal anti-inflammatory drugs (NSAIDs), ACE inhibitors, benzodiazepines, and fluroquinolones.</p> <p>Idaho Medicaid claims will be queried to identify patients receiving category D or X medications within the eight months prior to delivery. Patients prescribed a contraindicated medication will be identified. Physicians who prescribed these agents and dispensing pharmacies will receive intervention information highlighting the need for re-evaluation of the each medication in these patients.</p> <p><b><u>COX-2 Inhibitor Outcome Study</u></b> –C. Owens</p> <p>Non-steroidal anti-inflammatory (NSAID) agents that are selective for cyclooxygenase 2 (COX-2) are relatively new agents possessing both important benefits and the potential for adverse outcomes. Although benefits in terms of GI protection have been demonstrated, the analgesic efficacy of COX-2 inhibitors appears similar to that of nonselective NSAIDs. Recently, the cardiovascular safety of these agents has been called into question. Currently, there are three agents in the COX-2 class, celecoxib (Celebrex®), rofecoxib (Vioxx®), and valdecoxib (Bextra®). These agents carry FDA-labeled indications for the treatment of osteoarthritis, rheumatoid arthritis, dysmenorrhea, acute pain, and migraine headache. In 2003, Idaho medicaid spent \$1.3 million on COX-2 inhibitor therapy.</p> <p>Because of the high cost of these agents and their apparent analgesic equivalence to less-expensive nonselective NSAIDs, COX-2 inhibitors were included in the enhanced prior authorization program (EPAP) for</p> | <p>Approved as intervention for 3<sup>rd</sup> quarter. It was suggested that we separate category D and X drug users for this intervention. Although this intervention has been done previously, it is important to update drug codes, etc.</p> <p>Approved to take the place of an intervention for 4<sup>th</sup> quarter.</p> |

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|    |                                    | <p>Idaho medicaid since March 1, 2004. The use of these agents is restricted to patients meeting specific criteria indicating a moderate to high risk for serious GI complications. Furthermore, rofecoxib (Vioxx®) was chosen as the preferred agent from this class.</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. <b><u>Market Share Analysis</u></b> – Including the number of scripts filled for each product as a percent of total market share for the drug class.</p> <p>IIa <b><u>General Screening Tests</u></b> – 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 <b><u>Prescriber Intervention</u></b> – Frequent prescribers of non-preferred agents will be identified for mail or personal intervention</p> <p>III. <b><u>Specific Adverse Outcome (AO) Surveillance</u></b> – comparison of adverse outcomes will be made between preferred and non-preferred agents and will include incidence of GI bleed, ulceration, and increased incidence of cardiovascular adverse events.</p> |   |
| 6. | <b>Annual Report</b>               |  | No Discussion   |
| 7. | <b>Medicaid Update</b><br>-T. Eide | <p>Administration is pleased with DUR activities as they relate to P&amp;T. The P&amp;T committee continues to meet every other month to discuss drug classes for preferred drug lists and enhanced PA program. At the next meeting tomorrow, ARBs and beta-blockers will be discussed. All agents currently discussed are open for re-bid and discussion every year.</p> <p>Shawna Kittridge will be resigning her position at Medicaid effective Oct 1, 2004.</p>  | C. Owens will continue to attend P&T meetings. Next meeting Nov 19. |

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|            |                       | Idaho Medicaid web address: <a href="http://www.idahohealth.org">www.idahohealth.org</a>   |   |
| <b>8.</b>  | <b>Other business</b> | <p>SUMMER NEWSLETTER</p> <ol style="list-style-type: none"> <li>1. Purpose of DUR</li> <li>2. Soma Safety</li> <li>3. Opioids in the treatment of chronic non-malignant pain</li> <li>4. Cost Corner: Opioids, NSAIDs</li> <li>5. Web address and information regarding intervention educational leaflets available online.</li> </ol> <p>Future Ideas:<br/> Idaho DUR mentioned in JAPhA article as conducting beneficial activities.<br/> Review of EPAP process for selecting preferred agents<br/> Chart clearly outlining switch to methadone<br/> Tablet splitting</p> <p>TOP 50<br/> Highest cost patients, Most popular drugs (number of claims), and highest cost drugs for first quarter presented. In addition, top users of Soma® and long-acting stimulants.</p> <p>Conflict of interest statement.</p> | <p>Articles reevaluated for inclusion in DUR Newsletter. The newsletter was sent out in August. Several positive responses regarding last newsletter.</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 tabled until next meeting.</p> |
| <b>9.</b>  | <b>Meeting Dates</b>  | January 20, 2005   |   |
| <b>10.</b> | <b>Adjournment</b>    | Meeting adjourned at 2:00 PM   |   |