

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes March 4, 2009

Attendees:

Commission Members

Bruce Alexander, R.Ph., Pharm.D., BCPP; Dan Murphy, R.Ph., Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Rick Rinehart, M.D.; Laura Griffith, D.O.; Laurie Pestel, Pharm.D.; Mark Graber, M.D., FACEP; and Susan Parker, Pharm.D.

Staff

Thomas Kline, D.O.; Chad Bissell, Pharm.D.; and Pam Smith, R.Ph.

Guests

Sandy Pranger, R.Ph., IME; Chuck Wadle, D.O., Magellan; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Thomas Kline called the meeting to order at 9:30 a.m. at the West Des Moines Learning Resource Center. Commission members, guests, and observers were welcomed and introduced.

The minutes from the February 4, 2009 meeting were approved, with a few wording corrections and additions as requested by Bruce Alexander. (Motion by Dan Murphy; second by Dr. Mark Graber; unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

To address old business from the February meeting, Dr. Kline said that substance abuse centers would have access to I-MERS, except that certain designated parties would need to be assigned permission. He also reviewed the topics brought up at the February 20th Clinical Advisory Committee meeting. That committee is still searching for one more primary care member. Also, a SURS coding project will bring savings; they also plan on researching emergency room coding. He also mentioned LTC waiver assessment forms had been discussed, and there will be ICFMR reviews to check quality of care. Dr. Wadle mentioned that it might be helpful to have Iowa Medicaid members evaluate the clarity and wording of questions on the LTC waiver assessment forms, and Susan Parker suggested there were some on the MAC committee who might help with that. IFMC is currently conducting interviews for a new Medical Director; they hope to have a replacement for Dr. Kline chosen by the end of March. Chad Bissell addressed the query from the February meeting regarding profiles, saying that the 300 profiles reviewed each meeting were whittled down from over 62,000 possibilities after the initial algorithms were applied. After being chosen for review and intervention, each member ID number is sequestered for nine months, so that profile will not be revisited at each meeting. A newsletter has been posted on the website www.iowamedicaidpdl.com saying that OTC

cetirizine is now available without a prior authorization; it also has an OTC MAC price on it. The P&T Committee will meet on March 12th, and a subsequent informational letter and PDL updates will go out sometime in April.

P&T Recommendations on Select Mental Health Drugs

The Commission reviewed the P&T Committee's recommendations to move 38 mental health drugs from the Recommended Drug List to the Preferred Drug List. Only 10 of these drugs would become non-preferred, however. These changes would only affect new users as existing users would be grandfathered. The Mental Health Advisory Group has voted unanimously in favor of making these proposed PDL status changes during their meetings in December and February. The Commission also reviewed the letter sent from the Iowa Psychiatric Society (IPS) in response to these recommended changes, and the corresponding response from the Department of Human Services. Sandy Pranger and Susan Parker have been invited to attend the spring IPS meeting, and DHS has also composed a frequently asked questions sheet to help ease the transition for mental health providers unaccustomed to the PA process. As the DUR Commission had no concerns with the recommendations, this topic will return to the P&T Committee for finalization. These changes should be implemented within 60 days.

PA Criteria

Extended Release Formulations: The Commission voted to change the prior authorization criteria as follows:

Payment for a non-preferred extended release formulation will be considered only for cases in which there is documentation of a previous trial and therapy failure with the immediate release product and/or a preferred extended release formulation of the same chemical entity, unless evidence is provided that use of the immediate release product would be medically contraindicated.

The drugs that would be affected are: Adoxa, Amrix, Allegra D 24 hr, Brovex CT, Cardura XL, Cipro XR, Coreg CR, diclofenac ER, Doryx, etodolac ER/CR, Extendryl SR, Flagyl ER, glipizide ER, Glucotrol XL, indomethacin ER, InnoPran XL, Luvox CR, **Metadate CD**, Opana ER, Prozac Weekly, Quibron-T/SR, Requip XL, **Ritalin LA**, Seroquel XR, Sinemet CR, Solodyn ER, Ultram ER, and Xanax XR.

A motion was made by Dan Murphy to approve the proposed criteria, and Bruce Alexander seconded that motion. It passed the roll call vote unanimously.

Modified Formulations: The Commission voted to add the prior authorization criteria as follows:

Payment for a non-preferred isomer, pro-drug, metabolite, and/or alternative delivery system will only be considered for cases in which there is documentation

of a recent trial and therapy failure with the original parent drug product of the same chemical entity, unless evidence is provided that use of the original product would be medically contraindicated.

Prior Authorization is required for the following modified formulations:

- 1) Invega®*
- 2) Pristiq®*
- 3) Risperdal-M® Tabs*
- 4) Zyprexa Zydis®*
- 5) Abilify Discmelt®*

The individual drugs will be listed on the PA form, at least for a while, but the form might be condensed and generalized in the future. A motion was made by Dr. Rick Rinehart to approve the proposed criteria, and Bruce Alexander seconded that motion. It passed the roll call vote unanimously.

Public Comment

Jen Stoffel from Ortho McNeill Janssen spoke about Invega, and Mark Tacelosky from Wyeth spoke about Pristiq.

ProDUR

The Commission reviewed the proposed quantity limits for acetaminophen-containing analgesics. It was reported that there are more deaths associated with acetaminophen toxicity than with any other pharmaceutical agent. Toxicity is likely to occur with a single ingestion greater than 12 grams in a 24-hour period. The suggested quantity limits are based on the maximum daily dose of acetaminophen (4000mg per 24 hours). Dan Murphy asked if the refill-too-soon repeat offenders could be identified and referred to the lock-in program. Dr. Griffith motioned to accept the recommended limits, after 3 quantity corrections from Dan Murphy, and he himself seconded. However, the Commission later voted to withdraw the motion after discussing the topic and deciding to run some test scenarios through the pharmacy point of sale system before instigating quantity limits. This topic will be carried over to the next meeting.

Focus Studies

New Clozapine Users and Frequency of Monitoring: The purpose of this study was to identify new starters of clozapine and follow monitoring for White Blood Count (WBC), Absolute Neutrophil Count (ANC), and clozapine blood levels from May 1, 2008 and October 31, 2008. A secondary purpose was to determine the effect, if any, of clozapine use on doses of atypical antipsychotics. Testing is supposed to be done every week for the first 6 months of therapy, then every 2 weeks until a year of usage, and finally every 4 weeks. For the members identified, only 20% of the required testing is getting done. Out of the 35 members listed on the report, there were 28 that had no lab work done. There were 9 members using clozapine in combination with some other second-generation anti-psychotic, and there were no checks for blood levels in their

claims history. These numbers had been re-run after the January meeting, as the Commission believed there might have been some data capture errors. Additional investigation into capture procedures determined that the lab monitoring data on this report was 90% inclusive; there is a potential that some monitoring may have been done on an inpatient basis that would not have showed up in this report. Additional claims data were added to include November and December claims. The number of members who did not receive lab monitoring did not change. An additional search was performed to identify members who may have developed agranulocytosis. There were no members identified with ICD-9 codes commonly associated with clozapine adverse drug reactions. The Commission decided that the pharmacies and prescribers should be contacted directly by phone to hasten a solution to this problem. Dr. Wadle volunteered to call the doctors, and Pam Smith and Chad Bissell will be calling the pharmacists.

Use of Metered Dose Inhalers vs. Nebulizers: The purpose of this study was to identify unique members, 40 years of age and older, with three or more fills of albuterol nebulizer solution and/or Duoneb who also have one or more fills of a metered dose inhaler between the dates 7/1/2008 to 12/31/2008. According to the evidence-based guidelines published by the American College of Chest Physicians and the American College of Asthma, Allergy, and Immunology, efficacy should not be the basis for selecting one inhalation delivery device over another, as inhalation delivery devices have been found to be equally effective. There is a significant difference in cost between the nebulized solutions of albuterol and Duoneb and the cost of the albuterol and Combivent metered dose inhalers. There were 533 unique members identified using the parameters above. These parameters were then used to refine the data and looked only for those members who combined the nebulizer delivery system with a metered dose inhaler delivery system. There were 327 unique members (61.4% of those identified) who were combining inhalation delivery devices. However, in reviewing the claim level detail, not all of these 327 members were combining delivery devices concurrently. There were some who switched from one to the other, and there were other instances where there was only one fill of a particular delivery system. Only 223 members (68.2% of those combining devices) were using both delivery devices concurrently. Dr. Griffith commented that the portability factor would warrant use of both devices. This topic will be included as an educational piece in the next DUR Digest newsletter.

Concurrent Inhaled Anticholinergics: The purpose of this study was to identify unique members using duplicate inhaled anticholinergics. Inhaled anticholinergics are primarily used in the treatment of chronic obstructive pulmonary disease (COPD). Currently, there are two inhaled anticholinergics available: ipratropium and tiotropium. The current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend regular use of a short- or long-acting inhaled anticholinergic to improve symptoms; it does not support the use of combining the two inhaled anticholinergics. Furthermore, the *Spiriva* (tiotropium) package insert states that “the co-administration of *Spiriva*

HandiHaler with other anticholinergic containing drugs (e.g., ipratropium) has not been studied and is therefore not recommended.” A report was run looking for duplicate therapy with inhaled anticholinergics (ipratropium inhalation solution, *Duoneb*, ipratropium/albuterol inhalation solution, *Combivent*, *Atrovent HFA*, *Atrovent*, and *Spiriva*) between the time period of 9/1/2008 and 11/30/2008. Those members who continued the duplicative therapy in December are also reported. There were 215 distinct members found with duplicate inhaled anticholinergics in their claim histories. Ninety-nine (or 46%) of those members were combining tiotropium and ipratropium. Seventy-five members continued duplicate therapy with inhaled anticholinergics in December. Thirty-six (or 48%) of those 75 members continued using tiotropium in combination with ipratropium in December. Letters will be sent to the prescribers of these 36 members inquiring about the duplicative therapy and asking if one of the inhaled anticholinergics could be discontinued.

Protease Inhibitors with HMG CoA Inhibitors: The purpose of this study was to identify Iowa Medicaid members who are using protease inhibitors in combination with HMG CoA reductase inhibitors. Since the introduction of antiretroviral drugs in 1987, and the introduction of combination therapy referred to as highly active antiretroviral therapy (HAART), AIDS mortality has decreased dramatically. As people who are HIV positive are living longer, it is becoming more and more common for these patients to also develop hypertension, high cholesterol, diabetes, etc. There have been anecdotal reports from infectious disease specialist physicians that there has been an increase in the inadvertent combination of HMG CoA reductase inhibitors (statins) and protease inhibitors. When protease inhibitors are combined with statins, the serum concentration of the statin is increased and there is a higher risk of developing rhabdomyolysis. Lovastatin and simvastatin are contraindicated with any protease inhibitor. With the exception of fluvastatin, which does not appear to interact with protease inhibitors, other statins may be used at low doses and when closely monitored. There are also limited data to suggest that use of pravastatin decreases the serum concentrations of protease inhibitors. Due to the potential severity of this interaction, data were pulled on Iowa Medicaid members using both a protease inhibitor and a statin to see if this was a potential problem within the Iowa Medicaid population. Five distinct members were identified. None of them were using lovastatin or simvastatin, and there was only one instance where different prescribers were involved. Since this does not appear to be a problem within the Iowa Medicaid population, it is recommended that awareness of this interaction be communicated in the next DUR Digest newsletter.

Thiazolidinediones in Congestive Heart Failure: The purpose of this study was to identify unique members with a diagnosis of congestive heart failure who are also taking a thiazolidinedione (TZD). The American Heart Association and the American Diabetes Association first issued a consensus statement in 2003 regarding the use of thiazolidinediones and the increased risk of worsening congestive heart failure due to fluid retention. Since the publication of the 2007 *New England Journal of Medicine* article, “Effect of rosiglitazone on the risk of

myocardial infarction and death from cardiovascular causes”, the safety of thiazolidinediones has come under further scrutiny. This study concluded that rosiglitazone utilization was associated with a significant increase in the risk of myocardial infarction and increase risk of death from other cardiovascular events. While the *New England Journal of Medicine* article had its limitations, the Food and Drug Administration has since required the manufacturers of thiazolidinediones to add language to their labels including the statement that these drugs may worsen heart failure. A report was run showing TZD utilization in Iowa Medicaid members with a diagnosis code for congestive heart failure. All Iowa Medicaid members who received a paid pharmacy claim for a product containing a thiazolidinedione (*Actos, Avandia, Duetact, Avandaryl, Avandamet, Actosplus Met*) between the time period of 7/1/08 and 12/31/08 who also had a diagnosis of congestive heart failure (ICD-9 codes 428.00 – 428.90) in their medical claims history between 1-1-05 and 12-31-08 were included. There were 1,242 distinct members using thiazolidinediones. Eighty-one (or 6.5%) of those members were on a TZD with a diagnosis of congestive heart failure. Educational letters will be sent to the prescribers of these 81 members reminding them of the potential risks and inquire if the risk versus benefits of using TZDs in patients with CHF has been evaluated recently. In addition, this member list will be compared to one maintained by the nurse care managers at the IME who assist in the care of CHF patients.

Public Comment

There were no speakers in this public comment session.

Miscellaneous

DUR Digest 2009 Volume 21, Number 2: The Commission members offered suggested changes to the updated draft.

MedWatch: The Commission members received 2 FDA announcements concerning a serious adverse event with the psoriasis drug Raptiva, as well as a required boxed warning and risk mitigation strategy for metoclopramine-containing drugs.

A unanimous vote was made at 12:10 to adjourn the meeting and move to closed session (1st by Bruce Alexander 2nd by Craig Logemann).

The next meeting will be held at 9:30 a.m. on Wednesday, May 6, 2009 at the Hoover Building (Level A, Conference Room 5) in Des Moines, Iowa.