Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 5, 2008

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.; Mark Graber, M.D.; Laurie Pestel, Pharm.D.; and Susan Parker, Pharm.D.

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

Guests
Erin Miusich, University of Iowa Pharm.D. Candidate; Colleen Kacher, IME; Sandy Pranger, IME; Chuck Wadle, D.O., Magellan; Nick Ford, IME; Kelly Espeland, IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Thomas Kline called the meeting to order at 9:29 a.m. in Capitol Room 116. Commission members, guests, and observers were welcomed and introduced.

The minutes from the September 3, 2008 meeting were approved, after a spelling correction on page 3. (Motion by Dan Murphy, second by Dr. Sara Schutte-Schenck, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

Dr. Thomas Kline said that the Clinical Advisory Committee (CAC) had discussed Synagis protocol at their last meeting. He commented that the RSV season had begun, with very few issues thus far. Some of the large providers with large groups of members needing the immunization had logistical problems with timing, but IME staff worked with those providers to meet their needs. The CAC also discussed "Never Events", and decided to support the Department's decision to follow the Medicare guidelines implemented October 1st. There will be an informational letter regarding this topic going out to all providers. Also, the IME is working to improve the Iowa Medicaid Electronic Records System (IMERS) website to make it more useful to providers. The CAC also adapted guidelines for computerized coronary tomography and angiography, based on the American Cardiology guidelines. An informational letter will be sent to providers notifying them of this change in benefits. The IME is working on a new program called Medicaid Value Management, designed to try to determine what value the Medicaid programs are getting for the money spent, with the intent of improving quality and controlling costs. Care Management and Disease Management projects, such as the congestive heart failure program, have been rolled over into the new year. They are currently in the process of enrolling

people in the Diabetes Disease Management program, and there is an asthma project in the works as well. IFMC has purchased a predictive modeling system in the hopes of enhancing all of IME's Medical Services programs. Dr. Thomas Kline announced his resignation as Medical Director, effective probably within the next 6 months. Chad Bissell mentioned that the Commission members had received an updated DHS flowchart with their packets, given the recent personnel changes within the Department. He also talked about the Mental Health Workgroup's last meeting, in particular their discussion of possible quantity limits on Seroquel® (quetiapine). This Work Group had not wanted to offer recommendations yet, instead asking that more detailed data be brought to their December 12th meeting. They will also be discussing multiple second-generation antipsychotic utilization at that time.

Case Reviews

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $1,426.10 pre-rebate (state and federal). Chad Bissell also pointed out that tablet splitting for Lexapro would be required effective January 1, 2009, so the IME is beginning to contact providers.

Management Reports

Chad Bissell summarized reports from the first quarter of State Fiscal Year 2009. The average amount paid per claim for the first quarter of the new fiscal year was $63.06, while the number of claims has decreased slightly. The percentage of controlled substance use has increased. With the PDL status change of Xopenex HFA (levalbuterol) to non-preferred, it has fallen off the top 5 drugs list for the first quarter of State Fiscal Year 2009, after being the #1 drug of the fourth quarter of 2008 as well as the last fiscal year overall. Four of the top five drugs by dollars spent for the first quarter were mental health drugs. Generic utilization is up to 67.3% in the first quarter. Average cost per claim increased anyway, because of the dispensing fee increase to $4.57.

Smoking Cessation Report for Legislature

The Commission was asked to review the proposed draft of the letter outlining the progress of the smoking cessation program due to the legislature January 15, 2009. Chad Bissell highlighted the changes to this document since the last meeting, including the Commission's suggested changes and corrections. Bruce Alexander asked that a statement explaining that the literature that had been given did not include patients with multiple chronic conditions be added to the fifth paragraph of page 2, to further support the Commission's decision not to support coverage of Chantix™ (varenicline). Susan Parker also requested a wording change to the sentence stating the department's decision to cover Chantix. Dr. Laura Griffith asked that the program results from the University of Northern Iowa be broken down by treatment. Dr. Thomas Kline offered to ask a representative from the University of Northern Iowa (UNI) to attend a DUR meeting to explain their process. More details need to be added to the report as

recommended by the Commission members. The finalized report will be brought to the December meeting.

ProDUR

Effective April 30, 2008, Glucagen became preferred and Glucagon non-preferred. There was a recommendation to limit Glucagen to a quantity of 5 per 30 days to mirror the current edit for the Glucagon Emergency Kit. Dr. Laura Griffith motioned to accept this recommendation, and Dan Murphy seconded. The roll call vote passed unanimously.

Focus Studies

Underutilization of Inhaled Corticosteroids: Chad Bissell updated the Commission on a study that had been discussed at the last meeting. Emergency room and office visit claims coded for asthma diagnoses were re-evaluated, removing reversals and identifying claims in which Medicaid was the secondary payer. Between 2/1/06 and 7/31/06, there was only one such claim. It was also confirmed that the reported dollar amounts were solely for the treatment of asthma, and did not include other services. There seemed to be a wide disparity between the billed amounts and the paid amounts on the reviewed claims.

Quarterly Narcotic Utilization Report to Prescribers: Chad Bissell provided the Commission with an example of what this report would look like, designed around real Iowa claims data for the fourth quarter of Iowa fiscal year 2008. The private health information had been removed for the meeting. If the reporting algorithm had been set at 3 or more physicians and/or pharmacies, approximately 5300 letters would have been generated for this quarter alone. With the algorithm set at 5 or more physicians and/or pharmacies, there would have been approximately 1100 letters. Bruce Alexander suggested that quantity and days supply needed to be evaluated as well to identify chronic misuse. He also thought it would be wise to add a consecutive month restriction. Dr. Laura Griffith suggested that anything greater than one month would better target the intended population. Dr. Thomas Kline mentioned that this information would also be located on the IMERS website, updated weekly. The Commission agreed to set the limits at 3 or more pharmacies and/or physicians. There were no additional recommended changes to the report from the Commission. It is hoped mailings can begin going out after the end of the first quarter of 2009, since an educational letter informing physicians will need to be sent beforehand. Dr. Chuck Wadle suggested mentioning IMERS in the letters.

Chronic Singulair Use without Asthma or Allergic Rhinitis Diagnosis: Chad Bissell updated the Commission on a study that had been discussed at the last meeting, in which pharmacy claims data for the drug, Singulair (montelukast), from 8/1/07 through 7/31/08 was reviewed and compared for medical claims data. Singulair is FDA approved for the treatment of asthma, allergic rhinitis, and exercised-induced bronchoconstrictions. There is insufficient data available to

suggest Singulair would be effective for other disease states. During this time frame, 13,983 unique members received a total of 57,961 prescriptions for Singulair. For the members who had prescriptions for a documented non-FDA approved diagnosis, an additional review of the pharmacy claims history uncovered that 4,237 of those members also did not have any paid claims for beta-adrenergics. These findings were broken down into 2 groups: members with no accepted diagnosis and no antiasthmatic-beta adrenergic, and members with no accepted diagnosis and no antiasthmatic-beta adrenergic that did have claims for antiasthmatic steroid inhalants. These groups were further broken down by age range. It was agreed that incorporating the secondary diagnosis codes could make a big impact on these counts. Dan Murphy recommended that letters at least be mailed to the 15+ age group (with no inhalers). Chad Bissell suggested narrowing the field by adding in the secondary diagnosis codes first. Dr. Laura Griffith and Dr. Sara Schutte-Schenck advocated overlooking this anomaly, as they were unaware of any possible off-label uses, and this information most likely resulted from clerical error. The Commission agreed that there were other more worthy projects than this one.

Long Term Gastric Acid Suppressive Drug Use and Risks of Pneumonia and Clostridium difficile: Craig Logemann and Dr. Mark Graber mentioned this topic at the last meeting. With the pneumonia diagnosis, the analysts looked at members who were on gastric acid suppressive drugs for 12 consecutive months and excluded members who had claims for Amoxicillin and Clarithromycin or Prevpak or Tetracycline and Metronidazole in the same month as a GI - Proton Pump Inhibitor fill. Patients that had a past medical claim for pneumonia prior to starting a GI - Proton Pump Inhibitor were also excluded. Even with these exclusions, there were 1,168 members identified (though some may appear in more than one category), of which only 36 (all on H2-Antagonists) had a new pneumonia diagnosis. These findings conflict with current literature. The Commission asked if this data will be re-run, looking for people that have a new diagnosis of pneumonia within 2 months of initiating an acid suppressant. With the *Clostridium difficile* diagnosis, 2 years of data was reviewed. If a diagnosis was found, claim data 2 years from that diagnosis date was searched for gastric acid suppressive drugs. Members with a hospital stay within a year before diagnosis of *Clostridium difficile* were excluded. There was just one member with the combination of a PPI and H2, two members with a PPI, and seven members with a H2. Eighteen members had none of these. This also disagrees with literature, as it states that PPI's have an increased tendency of causing *Clostridium difficile*.

Public Comment

There were no speakers in this public comment session.

Prior Authorization

Vusion Ointment: The Commission voted to recommend the new PA criteria as

follows:

Prior Authorizaiton is requried for Vusion™ ointment. Payment will only be considered for cases in which there is documentation of previous trials and therapy failures with 1) over-the-counter miconazole 2% cream (payable with a prescription) AND 2) nystatin cream or ointment, unless evidence is provided that use of these agents would be medically contraindicated.

The Commission reviewed comments provided by select members of the Iowa Pharmacy Association and one physician. The motion to accept this final recommendation was made by Dan Murphy, and seconded by Craig Logemann. The roll call vote passed unanimously.

Growth Hormone: The Commission voted to revise the PA criteria as follows:

Prior authorization is required for therapy with growth hormones. Payment for nonpreferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones:

1. Standard deviation of 2.0 or more below mean height for chronological age.
2. No intracranial lesion or tumor diagnosed by MRI.
3. Growth rate below five centimeters per year.
4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter.
5. *Annual bone age testing is required for a diagnosis of Growth Hormone* Deficiency. A bone age of 14 to 15 years or less in females and 15 to 16 years or less in males is required.
6. Epiphyses open.

Prior authorization will be granted for 12-month periods per member as needed.

The following FDA approved indication for growth hormone therapy is considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS).

If the request is for **Zorbtive**® [somatropin (rDNA origin) for injection] approval will be granted for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome.

The motion to accept this final recommendation was made by Craig Logemann, and seconded by Dr. Sara Schutte-Schenck. The roll call vote passed unanimously. The Commission was also provided a list of the top 10 growth hormone prescribers as requested at the last September meeting.

Linezolid (Zyvox): The Commission voted to revise the PA criteria as follows:

Prior authorization is required for Zyvox®. Payment for Zyvox® will be considered when there is documentation that:

1. Prescriber is an infectious disease (ID) physician or has consulted ID physician (Telephone consultation is acceptable).
2. Patient *has an active infection and meets one of the following diagnostic criteria*:

• Vancomycin-resistant Enterococcus (VRE) and no alternative regimens with documented efficacy are available and VRE is not in lower urinary tract**.
• Methicillin-resistant Staph aureus (MRSA) and patient is intolerant to vancomycin*
• Methicillin-resistant Staph epidermis (MRSE) and patient is intolerant to vancomycin*
*Severe intolerance to vancomycin is defined as:
− Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration
− Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine)

**VRE in lower urinary tract, considered to be pathogenic, may be treated with linezolid if severe renal insufficiency exists and/or patient is receiving hemodialysis or has known hypersensitivity to nitrofurantoin.

The motion to accept this final recommendation was made by Dan Murphy, and seconded by Bruce Alexander. The roll call vote passed unanimously.

Serotonin 5-HT1-receptor Agonists: The Commission voted to revise the PA criteria as follows:

Prior authorization is required for preferred serotonin 5-HT1-receptor agonists for quantities exceeding *12* unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT1-receptor agonists beyond this limit will be considered on an individual basis after review of submitted documentation. For consideration, the following information must be supplied:
1. The diagnosis requiring therapy.
2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.
Prior authorization will be required for all non-preferred serotonin 5-HT1-receptor agonists as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred serotonin 5-HT1-receptor agonists will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred agents.

The motion to accept this final recommendation was made by Bruce Alexander, and seconded by Dr. Sara Schutte-Schenck. The roll call vote passed unanimously.

Extended Release Formulation: The Commission voted to revise the PA criteria as follows:

Payment for the extended release formulation will be considered only for cases in which there is documentation of previous trial and therapy failure with the immediate release product of the same chemical entity, unless evidence is provided that use of the immediate release product would be medically contraindicated.
Prior authorization is required for the following extended release formulation(s):
1. Seroquel® XR
2. Luvox® CR

The motion to accept this final recommendation was made by Bruce Alexander, seconded by Dr. Rick Rinehart, and was approved by all the members by roll call vote.

Public Comment

There were no speakers in this public comment session.

Miscellaneous

DUR Digest – 2008 Vol. 21 No. 1: These are currently being mailed.

MedWatch: Bruce Alexander commented that a varenicline update just came out.

A unanimous vote was made by role call vote at 11:11 to adjourn the meeting and move to closed session (1st by Dr. Mark Graber, 2nd by Dr. Rick Rinehart).

The next meeting will be held at 9:30 a.m. on Wednesday, December 3, 2008 in Room 116 at the State Capitol in Des Moines.