Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 4, 2009

Attendees:

Commission Members
Rick Rinehart, M.D.; Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Casey Clor, M.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
Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, PA-C, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Mark Graber called the meeting to order at 9:31 a.m. at the Learning Resource Center in West Des Moines. Commission members, guests, and observers were welcomed and introduced.

The minutes from the September 2, 2009 meeting were approved following a spelling correction from Bruce Alexander. (Motion by Bruce Alexander, second by Dr. Sara Schutte-Schenck, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

The re-procurement process is currently underway, with almost all of the IME contracts up for bid. The Department of Human Services is still in the process of finalizing the required budget cuts. Susan Parker reported some of the proposed changes are as follows: The 30-day override for non-preferred drugs on the PDL will be eliminated. The dispensing fee will be lowered to $4.34, which is a temporary rate cut effective December 1, 2009 through June 30, 2010. There will also be some changes to SMAC, and the way that reimbursement is set; the multiplier for that formula will be decreased form 1.4 to 1.2, and the average acquisition cost based solely on generic pricing now. Additionally, a specialty drug list has been created. AWP Reimbursement for drugs on this list will be AWP minus at a rate > AWP minus 12%. AWP reimbursement methodology will no longer be an option within less than two years, because of the lawsuit regarding First Data Bank. Member coverage has thus far not been affected. However, as the Iowa Medicaid population continues to grow, it will become increasingly difficult to provide benefits with a decreased budget. Lastly, Sandy Pranger reported that the next P&T Committee Meeting will be held November 12th, for the annual PDL review to determine next the PDL for 2010 will occur.

Quarterly Management Report

The average amount paid per claim was down to $62.52, compared to $63.59 last quarter; 1,005,342 claims resulted in a total amount paid of $62,854,354.45. The number of eligible members continues to increase; it was 366,476 in the first quarter of State Fiscal Year 2010. Iowa's unemployment rate was 6.7% in September 2009, which is much lower than the national average of 9.8%. ProAir HFA remains the top drug by number of prescriptions per NDC. The top drugs by dollars spent were all mental health drugs. The therapeutic class by total prescriptions report remained the same as last quarter, with SSRIs in the top spot. The therapeutic class by dollars spent also kept the same line-up, with Atypical Antipsychotics costing $10,899,841.64. Lastly, generic utilization was up to 70.85% last quarter.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in an annualized total savings of $2,157.89 pre-rebate (state and federal).

Annual Smoking Cessation Report

The Commission was presented with a copy of the current year's draft report, as well as the finalized report that had been sent to the legislature in 2008. Jeremy Whitaker from the Iowa Department of Public Health was on hand for questions. Quitline received 5,473 fax referrals for Iowa Medicaid members between October 1, 2008 and September 30, 2009, of which 3,339 were enrolled in the program. A total of 9,207 prior authorization requests were received in that same time span for smoking cessation products, of which 6,852 were approved. There were 5,682 prescriptions dispensed, costing just over $512,000. Of that, Chantix costs alone came to $402,000. Administration costs totaled $102,000. The Commission members requested that a report be run to identify any members taking Chantix and antidepressants concurrently. Bruce Alexander recommended searching for any related hospitalizations. A revised report will be brought to the next meeting in December.

Public Comment

Jennifer Stoeffel from Ortho-McNeil Janssen spoke about Nucynta.

PA Criteria

Bupropion SR for Smoking Cessation: The Commission reviewed the prior authorization criteria as follows:

> *Prior Authorization is required for varenicline (Chantix™) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:*
> *1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.*
> *2) Confirmation of enrollment and ongoing participation in the Quitline Iowa counseling program is required for approval and continued coverage.*
> *3) Approvals will only be granted for patients eighteen years of age and older.*

4) The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve month period.
5) Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.
6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.

Bruce Alexander motioned to accept these criteria, and Dr. Casey Clor seconded. The motion passed unanimously.

Short-Acting Narcotics: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting narcotics. Payment will be considered for cases in which there is documentation of previous trial(s) and therapy failures with three (3) chemically distinct preferred short acting narcotics (based on narcotic ingredient only) at therapeutic doses, unless evidence is provided that the use of these products would be medically contraindicated.

Dr. Casey Clor motioned to accept these criteria, and Bruce Alexander seconded. The motion passed unanimously.

Proton Pump Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is not required for the preferred proton pump inhibitors (PPI) for a cumulative 60 days of therapy per 12-month period. Prior authorization will be required for all non-preferred proton pump inhibitors as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products. Prior authorization is required for any PPI usage longer than 60 days or more frequently than one 60-day course per 12-month period. The 12-month period is patient specific and begins 12 months before the requested date of prior authorization. Payment for usage beyond these limits will be authorized for cases in which there is a diagnosis of:

1.Specific Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).
2.Barrett's esophagus.
3.Erosive esophagitis
4.Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses.

5.Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of Helicobacter pylori treatment or a negative Helicobacter pylori test result.

Prior authorization is NOT required for Prevacid SoluTabs for children age 8 years old or younger for the first 60 days of therapy. Prior authorization is required for Prevacid SoluTabs for patients over 8 years of age beginning day one of therapy. Authorization for Prevacid SoluTabs will be considered for those patients who cannot tolerate a solid oral dosage form.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Dr. Casey Clor motioned to accept these criteria, and Dr. Sara Schutte-Schenck seconded. The motion passed unanimously.

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis.

Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum doses unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, and intramuscular gold.

Prior authorization is required for all non-preferred biologicals for ankylosing spondylitis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

Following a discussion of the "International ASAS Consensus Statement for the use of Anti-Tumor Necrosis Factor Agents in Patients with Ankylosing Spondylitis", Dr. Casey Clor motioned to accept these criteria, and Craig Logemann seconded. The motion passed unanimously.

Biologicals for Arthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for arthritis.

Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline.

Prior authorization is required for all non-preferred biologicals for arthritis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

The Commission members asked that a rheumatologist be contacted for input prior to any changes in prior authorization criteria.

Ketorolac: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ketorolac tromethamine, a nonsteroidal anti-inflammatory drug indicated for short term (up to five days) management of moderately severe, acute pain. It is NOT indicated for minor or chronic conditions.
This product carries a Black Box Warning. Initiate therapy with IV/IM and use oral ketorolac tromethamine only as a continuation therapy to ketorolac tromethamine IV/IM. The combined duration of use of IV/IM and oral is not to exceed five (5) days. Payment will be approved under the following conditions:
1. For oral therapy, documentation of recent IM/IV ketorolac tromethamine injection including administration date and time, and the total number of injections given.
2. Request falls within the manufacturer's dosing guidelines. Maximum oral dose is 40mg/day. Maximum IV/IM dose is 120mg/day. Maximum duration of therapy is 5 days per month.
3. Diagnosis indicating moderately severe, acute pain.
Requests for IV/IM ketorolac must document previous trials and therapy failures with at least two preferred nonsteroidal anti-inflammatory drugs at adequate doses.

As this was the second review of this topic, no motion was necessary. The Commission members had no further comments.

Muscle Relaxants: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-preferred muscle relaxants. Payment for non-preferred muscle relaxants will be authorized only for cases in which there is documentation of previous trials and therapy failures with at least three preferred muscle relaxants. Requests for carisoprodol will be approved for a maximum of

120 tablets per 180 days at a maximum dose of 4 tablets per day when the criteria for coverage are met.

Although a vote was taken, (Dr. Rick Rinehart motioned to accept these criteria, and Larry Ambroson seconded. The motion passed unanimously.) it was not required as this was the second review and there were no recommended changes.

Antihistamines: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred antihistamines and preferred second generation prescription antihistamines.

Patients 21 years of age and older must have three unsuccessful trials with antihistamines that do not require prior authorization, prior to the approval of a preferred first generation or preferred second generation prescription antihistamine. Two of the trials must be with cetirizine and loratadine. Prior to approval of a non-preferred second generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred second generation prescription antihistamine.

Patients 20 years of age and younger must have unsuccessful trials with cetirizine and loratadine prior to the approval of a non-preferred first generation or preferred second generation prescription antihistamine. Prior to approval of a non-preferred second generation antihistamine, in addition to the above criteria, there must be an unsuccessful trial with a preferred second generation prescription antihistamine.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Although a vote was taken (Craig Logemann motioned to accept these criteria, and Dr. Sara Schutte-Schenck seconded. The motion passed unanimously.) it was not required as this was the second review and there were no recommended changes.

Fentanyl – Short Acting Oral Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for short acting oral fentanyl products. Payment will be considered only if the diagnosis is for breakthrough cancer pain in opioid tolerant patients. These products carry a Black Box Warning.
Actiq®, Fentora®, & Onsolis™:

- *Are indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain.*
- *Are contraindicated in the management of acute or postoperative pain. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, do not use in opioid non-tolerant patients.*

Although a vote was taken, (Bruce Alexander motioned to accept these criteria, and Dr. Mark Graber seconded. The motion passed unanimously.), it was not required as this was the second review and there were no recommended changes.

Public Comment

There were no speakers in this public comment section.

Focus Studies

TZD plus Congestive Heart Failure: The purpose of this study was to follow-up on the 72 unique members identified as having a diagnosis of CHF while on a TZD during the time frame of 7/1/2008 through 12/31/2008. Letters were sent to providers in March 2009. Fourteen members discontinued a TZD after the DUR intervention. This resulted in a total cost savings of $136,555.61 (state and federal pre-rebate).

Benzodiazepines without SSRI/SNRI: The purpose of this study was to determine how many Iowa Medicaid members are using alternative mental health drugs instead of selective serotonin reuptake inhibitors (SSRI) or serotonin-norepinephrine reuptake inhibitors (SNRI) in members with panic disorder with agoraphobia, panic disorder without agoraphobia, obsessive-compulsive disorder, and/or dysthymic disorder. At the August 2009 DUR Meeting, a report was generated which looked at members with a diagnosis of panic disorder with agoraphobia, panic disorder without agoraphobia, obsessive-compulsive disorder, and/or dysthymic disorder at anytime in their medical claims history, and what drug therapies (SSRI, SNRI, and/or benzodiazepine) were being prescribed. Due to the high number of members who met these criteria, but showed no current treatment with antidepressants or benzodiazepines (7,225), the Commission was interested in seeing if other mental health drugs and/or anticonvulsants were being used as treatment. Further analysis was done to remove members with a diagnosis code for epilepsy or seizure disorder from the members who fit the diagnostic criteria listed above, who were not being treated with an SSRI, an SNRI, or a benzodiazepine. The pharmacy claims histories for the remaining members were searched over a one year time frame (6/1/08 through 6/30/09) for Antipsychotics - Atypicals, Anticonvulsants (minus clonazepam and *Equetro),* Antidepressants - Tri-Cyclics, Antidepressants - MAOI Inhibitors, Antipsychotics - Typical, and *Buspar/*buspirone. Each member who had two or more fills of one or more drugs from these classes who

then continued therapy into July 2009 were accounted for. One-hundred-sixty-nine unique members were identified as fitting the above criteria. Bruce Alexander pointed out there are a total of 113 members using an antipsychotic and the focus should be on these members for current treatment and additional diagnoses. These findings will be brought to a future meeting.

Lithium Drug-Drug Interactions: The purpose of this study was to identify instances where Iowa Medicaid members are combining lithium with drugs that can potentially interact and cause lithium toxicity. Drug-drug interactions between lithium and ACE Inhibitors, diuretics, NSAIDs, and/or COX-2 Inhibitors are frequently identified on the member-specific profile reviews done for each meeting. Lithium and sodium compete for reabsorption in the kidneys. When sodium is depleted, lithium is reabsorbed at a greater rate and serum lithium levels rise, possibly leading to toxicity. While it is not an absolute contraindication, when lithium is combined with ACE Inhibitors and/or certain diuretics, the depletion of sodium can lead to an increase in serum lithium levels. Similarly, NSAIDs and COX-2 Inhibitors can affect the renal proximal tubular resorption of lithium, thus increasing serum lithium levels. Symptoms of lithium toxicity include ataxia, confusion, and tremor. It is recommended that patients be closely monitored anytime a new drug from the above mentioned classes are added to a lithium regimen for signs and symptoms of lithium toxicity. Close monitoring is also recommended anytime there is a dose change of these products. An analysis was performed looking at paid, non-reversed pharmacy claims over a six month time period (1/1/09 through 6/30/09). Members who had two or more fills for lithium during this time frame were identified. Once those members were identified, a second analysis was done to see how many of these patients were combining lithium with an ACE Inhibitor, a diuretic (loop or thaizide), a blood pressure product combined with a diuretic (i.e. lisinopril HCTZ), an NSAID, or a COX-2 Inhibitor. Those who continued the combination of lithium and a potential interacting drug into the month of July 2009 were selected for review. These findings will be narrowed down to target the prescribers of the 34 members who are receiving their prescriptions from different prescribers, adding in members who are also taking ARBs.

Miscellaneous

DUR Digest: The Commission members were given a completed copy of 2009 Volume 22, Number 1.

FUL Update: The Commission members were given a copy of the CMS FUL changes that were implemented September 25, 2009, as well as SMAC changes that went into effect in October.

MedWatch: The commission members received FDA announcements concerning new Black Box Warnings.

A unanimous vote was made at 11:20 to adjourn the meeting and move to closed session (1st by Bruce Alexander, 2nd by Dr. Mark Graber).

The next meeting will be held at 9:30 a.m. on Wednesday, December 2, 2009

at the Learning Resource Center in West Des Moines, IA.