Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 5, 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, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Thomas Kline called the meeting to order at 9:33 a.m. at the Hoover Building in Des Moines. Commission members, guests, and observers were welcomed and introduced.

The minutes from the June 3, 2009 meeting were approved following some noted corrections. (Motion by Bruce Alexander, second by Dr. Rick Rinehart, unanimous approval by voice vote.)

The Commission members were reminded they needed to complete their annual Conflict of Interest Disclosure forms, Business Associates' Agreement, and Confidentiality forms. They also elected Dr. Mark Graber as Chairperson (Bruce Alexander nominated him, and Craig Logemann seconded) and Laurie Pestel as Vice-Chairperson (Dr. Rick Rinehart nominated her, and Bruce Alexander seconded).

The Commission developed a new policy for literature cited during public comment. Any data that are to be referenced during the Public Comment period(s) should be limited to published, peer reviewed literature only. "Data on file" and "articles submitted for review" are not considered published, peer reviewed literature and should not be referenced during public testimony. All referenced data that is to be presented should be submitted to the DUR professional staff electronically at info@iadur.org at least one week prior to the meeting date for consideration and distribution to the Commission members. This policy applies to any articles Commission members bring to the meetings themselves, as well. Craig Logemann motioned to accept this new policy, and Bruce Alexander seconded. The motion passed with no objections.

Iowa Medicaid Enterprise Updates

The Medical Services department at the IME is attempting to obtain URAC accreditation. As part of this process, all of Medical Services' policies are up for review at the next Clinical Advisory Committee meeting. There is a current state-wide movement to develop a patient-centered medical home. The University of Iowa is sponsoring this project, and there will be a meeting September 18th to discuss it. The SSDC met in June to discuss supplemental rebate negotiation. The P&T Committee will have its annual review of the PDL in November. Any changes will be effective January 1, 2010. The Department of Human Services has put out a letter stating they will be providing RFP in the fall of this year for 7 of the 9 contracts that are currently being handled at the IME. New contracts will be effective July 1, 2010. Chad Bissell explained how his new position with the company contracted to provide the professional staffing services for the DUR Commission has resulted in a transition of primary duties to Pam Smith.

Management Reports for Quarter 4

Iowa Medicaid member enrollment, as well as number of claims, was down in the 4th Quarter of State Fiscal Year 2009 compared to Quarter 3. The average price per claim was $63.88, which was also less than the $65.71 average for the 3rd quarter. Generic utilization is over 70% now. Behavioral Health drugs continue to dominate the top 5 drugs by dollars spent and top therapeutic classes by total prescriptions reports. However, Synagis was the top drug by dollars spent for the entire fiscal year, and ProAir HFA had the most prescriptions for SFY 2009.

Public Comment

Lisa Goetz, Pharm.D. (MedImmune) and Susan Harrell, M.D. both spoke about *Synagis*. Geoff Wall, Pharm.D., from Iowa Methodist Medical Center spoke about *Uloric*.

PA Criteria

Thrombopoietin Receptor Agonists: The Commission reviewed the prior authorization criteria as follows:

> *Payment for a preferred thrombopoietin receptor agonist will only be considered for cases in which there is a diagnosis of chronic immune thrombocytopenic purpura (ITP) in addition to documentation of a recent trial and therapy failure with a preferred corticosteroid, a preferred immunoglobulin, and/or the member has undergone a splenectomy. Payment for a non-preferred thrombopoietin receptor agonist will be considered following documentation of a recent trial and therapy failure with a preferred thrombopoietin receptor agonist unless such a trial would be medically contraindicated.*

The Commission members had no further comments regarding these criteria. This recommendation will be sent to the Department for consideration.

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

> *Prior authorization is required for febuxostat (Uloric). Payment for febuxostat (Uloric) will only be considered for cases in which symptoms of gout still persist while currently using a therapeutic dose of 300mg per day on a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.*

Bruce Alexander motioned to accept, Dr. Mark Graber seconded, and the motion passed unanimously. Craig Logemann also motioned that a quantity limit be placed on the 40mg Uloric tablet, limiting to 30 for 30 days, since the 40mg and 80mg tablets are the same price. Larry Ambroson seconded this. This also passed with no objections; however, Bruce Alexander abstained, as he was out of the room during the end of the discussion. Additionally, Pam Smith and Susan Parker explained how FUL and SMAC pricing, OBRA, and supplemental rebates work for the new Commission members. These recommendations will be sent to the medical and pharmacy association(s) for comments.

Palivizumab (Synagis): In June, 2009, Red Book modified their guidelines for use of palivizumab *(Synagis)* for RSV prevention in high-risk infants and young children. Using additional data regarding the seasonality of RSV and risk factors for babies born between 32 and 35 weeks gestation, the guidelines for use have been modified to ensure cost/benefit optimization. The updated recommendations include:

1. *Modification of recommendations for initiation and termination of RSV prophylaxis based on current CDC descriptions of seasonality in different areas of the United States.*
2. *Emphasis on need for no more than a maximum of 5 doses in all geographic areas.*
3. *Modification of risk factors for severe disease (congenital abnormalities of the airway or neuromuscular disease) in infants less than 12 months of age and born before 35 weeks of gestation.*
4. *For infants 32 through 35 weeks of gestation who qualify for prophylaxis based on presence of risk factors, prophylaxis is recommended beyond 90 days of age (maximum of 3 doses)*

The Commission decided to leave the Iowa Medicaid criteria for Synagis the same as what was used last year for now due to the lack of published evidence behind the new Red Book guidelines. The start date for PAs will be November 1st (unless virology data shows it should be earlier), with an initial 5 doses approved; additional doses would be contingent upon RSV epidemiology data collected by the Iowa Department of Public Health. However, this decision may be re-evaluated once the data that spawned the new Red Book guidelines is released.

Annual Review of Clinical PA Criteria: The Commission members suggested some changes to existing PA criteria. Pam Smith recommended that since OTC cetirizine is now available (and a much more cost-effective alternative), that the criteria on the Antihistamine PA form be modified to require 3 preferred trials

(among them OTC cetirizine and OTC loratadine) for any member 20 years of age or older, and a trial of both OTC cetirizine and OTC loratadine for anyone younger than 20. In the Biologicals for Ankylosing Spondylitis category, Chad Bissell recommended requiring a trial of 2 NSAIDs for a duration of 3 months, which matches the requirements of the Spartan Guidelines. If a member had only peripheral symptoms, they would also have to have a trial of a preferred DMARD product, such as sulfasalazine or methotrexate. For the Biologicals for Rheumatoid Arthritis, Dr. Graber made a comment about updated guidelines suggesting two DMARDS be tried prior to initiation therapy with a biological. These guidelines will be reviewed more closely and brought to a future meeting. It was suggested that the Ergotamine Derivatives PA form no longer be required as the category is not being utilized. A new product will be added to the Fentanyl PA Form. There will be new wording on the Ketorolac PA Form, as there is no longer a preferred ketorolac agent, as follows: "*prior to the consideration of IM/IV Ketorolac Injection, a recent trial and therapy failure with two preferred COX-2 preferrentially selective NSAIDs".* In the Muscle Relaxants category, Pam Smith said long term use of the non-preferred agents, specifically carisoprodol, had been an issue within the PA Department. Recommended duration of therapy with this drug is two to three weeks, and requests for chronic treatment are not uncommon. Susan Parker asked that Wellbutrin and Zyban be added to the Nicotine Replacement PA Form. Pam Smith said that the Pregabalin PA Form needed to be more specific; "at adequate doses" should be added to all line items so they match. Sandy Pranger suggested that criteria needed to be developed for Lidoderm, as Iowa sported the highest utilization at the SSDC meeting. Also, Januvia was suggested to have criteria developed. These criterion will be brought to future meetings for more specific discussion.

Public Comment

There were no speakers in this public comment section.

Focus Studies

Duplicate SSRIs: The purpose of this study was to follow-up on the 15 unique members identified as having duplicate SSRIs in their claims history for three consecutive months during the time frame 8/1/08 to 10/31/08. Letters were sent to providers at the end of December, 2008. Five unique members were still using duplicate SSRI therapy after DUR intervention. Ten members discontinued duplicate therapy which resulted in a total savings of $8,723.49 (State and Federal, pre-rebate), of which $3,280.03 (pre-rebate) were State funds.

Long Acting Narcotics Plus Methadone: The purpose of this study was to follow-up on the 16 unique members identified as using methadone in combination with other long acting narcotics in their claims history during the time frame 8/1/08 to 11/30/08. Letters were sent to providers at the end of November, 2008. Ten unique members were still using methadone in combination with long acting narcotics after DUR intervention. However, six members' therapy changes resulted in a total savings of $2,081.70 (State and Federal, pre-rebate), of which $782.72 (pre-rebate) were State funds.

Benzodiazepines without SSRI/SNRI: The purpose of this study was to determine how many Iowa Medicaid members are being treated for various anxiety disorders with benzodiazepines but not a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI). At the February 2009 DUR Meeting, a report was generated which looked at duplicate benzodiazepine utilization for members between the time period of 9/1/2008 through 11/30/2008. This report found 300 unique members who were using two or more benzodiazepines concurrently. In the discussion, an interest was expressed to look at members who were being treated for anxiety disorders with benzodiazepines but not an SSRI/SNRI. A second report was reviewed at the June 2009 DUR meeting which looked at benzodiazepine use without an SSRI/SNRI. Following a review of the diagnosis codes used to develop the study population, some changes were recommended. This report was run looking at members with a diagnosis code of panic disorder with agoraphobia, panic disorder without agoraphobia, obsessive-compulsive disorder, and/or dysthymic disorder at anytime in their medical claims history. Members with Medicare Part D eligibility were excluded from this analysis. These members' pharmacy claim histories were reviewed to identify utilization with SSRI/SNRIs and benzodiazepines between the dates of 6/1/2008 and 6/30/2009. Those members who had two or more months of utilization with SSRI/SNRIs and benzodiazepines that continued therapy through the month of June, 2009 are reported. Eight thousand, seven hundred sixty members were identified as fitting these diagnostic criteria. As of June 2009, 45 members were still using BZD but no SSRI/SNRI, 578 members were using both SSRI/SNRI and BZD concurrently, and 912 members were using SSRI/SNRI but no BZD. With such a small number of members, the Commission decided not to send letters. However, they asked that the data be re-run to evaluate if the members fitting the criteria but not taking BZD or SSRI/SNRIs were on Antipsychotics or Tricyclics. These findings will be brought to the November meeting.

Utilization of Products for Influenza: The purpose of this study was to provide trending information over several recent years' influenza treatment and outpatient vaccine utilization within the Iowa Medicaid population. (These data were collected prior to when the 2009 H1N1 influenza strain was identified.) Influenza is a highly contagious upper respiratory tract infection that affects several million Americans each year. Drugs that are commonly used to treat or prevent influenza, oseltamivir (Tamiflu), zanamivir (Relenza), amantadine, rimantadine, and the annual influenza vaccine, all appear on the Preferred Drug List as preferred products. During the 2008-2009 influenza season, the Centers for Disease Control (CDC) and Prevention revised their recommendations for treating seasonal influenza a couple of months into the influenza season after a high percentage of isolated strains showed resistance to oseltamivir (Tamiflu) and zanamivir (Relenza). The utilization data suggests that providers followed the CDC's revised recommendations when treating members with influenza. There is currently a quantity limit in place for oseltamivir (Tamiflu) for quantities greater than 75mL for the liquid and 14 units for the capsules. Compared to other Sovereign State Drug Consortium states, Iowa has extremely high utilization of

oseltamivir (Tamiflu) compared to other states of similar Medicaid size. Additionally, prior to the 2008-2009 season, there were several cases where members were treated twice in the same season with oseltamivir (Tamiflu). Susan Parker suggested contacting Iowa Medicaid Member Services to see if they had any informational letters planned for this topic.

Chronic Use of Metoclopramide: The purpose of this study was to identify instances where Iowa Medicaid members are using metoclopramide on a chronic basis or high doses in light of the new black box warning issued by the FDA. Metoclopramide stimulates the upper gastrointestinal tract to increase motility and increase the rate of stomach emptying. It is FDA approved for short-term management of gastroesophageal reflux disease (GERD), diabetic gastroparesis, and nausea. Short-term management is defined as 4 to12 weeks by the manufacturers of metoclopramide. Recently, the FDA announced that manufacturers of metoclopramide must include a Black Box Warning regarding the risk of developing tardive dyskinesia after receiving reports of this side effect with long term use or use at high doses. The symptoms of tardive dyskinesia are often times irreversible, and may continue to be bothersome for a considerable time following the discontinuation of the causative agent. The FDA reports suggest that metoclopramide is the most common cause of drug-induced tardive dyskinesia. A claims analysis was conducted over a six month time frame (1/1/09 through 6/30/09) to identify: 1) unique members (adult and children) with one or more fills of metoclopramide in their claims history, and 2) the number of unique members using a high dose of metoclopramide (>60mg/day) for more than two months. Due to a higher rate of extrapyramidal side effects, the manufacturer does not recommend the use of metoclopramide in children. However, metoclopramide has been known to be used off-label in children for GERD. A second analysis was done to determine the extent of chronic metoclopramide use at three and four or more consecutive months. There were 23 members taking metoclopramide for four or more consecutive months, and four unique members on a high dose (more than 60mg per day). Dr. Wadle suggested that direct contact would achieve better results with this small population than an article in the DUR Digest. Some further analyses will be done to determine how many providers are involved in prescribing metoclopramide for long term use or at high doses.

Miscellaneous

SMAC Update: The Commission members were given a copy of the SMAC changes effective August 14, 2009.

FUL Update: The Commission members were given a copy of the CMS FUL changes that were implemented July 17, 2009.

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

A unanimous vote was made at 12:26 to adjourn the meeting and move to closed

session (1st by Bruce Alexander 2nd by Dr. Rick Rinehart).

The next meeting will be held at 9:30 a.m. on Wednesday, September 2, 2009 at the Learning Resource Center in West Des Moines, IA.