Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 6, 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; Laura Griffith, D.O.; Laurie Pestel, Pharm.D.; and Susan Parker, Pharm.D.

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

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

Welcome & Introductions

Thomas Kline called the meeting to order at 9:36 a.m. at the Hoover Building (Level A Conference Room 5) in the Capitol Complex. Commission members, guests, and observers were welcomed and introduced.

The minutes from the March 4, 2009 meeting were approved. (Motion by Bruce Alexander, second by Dan Murphy, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

There is a new Department of Human Services Director, Charlie Krogmeier, as Gene Gessow was not confirmed by the legislature for that position. Mr. Krogmeier was previously Governor Culver's Chief of Staff. He will be up for confirmation at the next legislative session. The last Clinical Advisory Committee meeting was cancelled due to Easter, so no updates on that. Dr. Kline explained a new Medical Home Certification program and meetings being held for that. The lock-in program just received their first physician referral from the pharmacy-sponsored physician/pharmacy surveillance program for controlled substances. There are approximately 150 diabetics enrolled in the Disease Management program. The *Synagis* season is almost finished; utilization data will be presented at the next DUR meeting.

Management Reports

Pamela Smith reviewed the quarterly reports from State Quarter 3 (1/1/09-3/31/09). The average amount paid per claim as $65.71, with a total amount paid of $66,620,729.87. There were 1,013,911 paid claims last quarter. The average number of claims per member was down to 5.29, which was considerably less than the 13.36 average for the fiscal year. The percentage of controlled substances was 18.47%. The top 5 drugs per NDC by number of prescriptions were the same as the prior quarter, only in a slightly different order. *Synagis* topped the top drugs by dollars spent report, and the rest of the top 5 was comprised of mental health drugs. There was a large increase in utilization

of Beta-Lactams/Clavulanate Combinations, and this category moved to second place on the therapeutic class by total prescriptions report. The generic utilization rate is continuing to increase, and was up to 69.29% last quarter.

Case Reviews

Pam Smith presented four intervention case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of $5,512.22 pre-rebate (state and federal).

PA Criteria

Modified Formulations: No feedback was received from the letters that were sent out after the last meeting. The Commission agreed to move forward with 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. These criteria will be re-reviewed in June to determine if additional drugs need to be added to the form.

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 previous trial and therapy failure with the preferred 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):*
>
> *Adoxa, Amrix, Cardura XL, Cipro XR, Coreg CR, Doryx, Flagyl ER, glipizide ER, Glucotrol XL, InnoPran XL, Luvox CR, Prozac Weekly, Requip XL, Seroquel XR, Solodyn ER, Ultram ER.*

A motion was made by Dan Murphy to approve the new proposed criteria, after any extended release product that has a preferred generic is removed from the list and a caveat allowing the Department discretion to add or remove new products and make changes to the drug list is added. Craig Logemann seconded that motion. It passed the roll call vote unanimously. The list of affected drugs will be re-reviewed at the June meeting.

ADD/ADHD/Narcolepsy Agents: The Commission voted to change the prior authorization criteria as follows:

> *Prior Authorization (PA) is required for ADD/ADHD/Narcolepsy Agents for members 21 years of age or older. PA is also required for all non-preferred agents, regardless of age, the first day of therapy. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. *If a non-preferred long-acting medication is requested, a trial of the preferred immediate release and extended release product of the same chemical entity is required, unless evidence is provided that use of these products would be medically contraindicated.*

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

Nonsteroidal Anti-Inflammatory Drugs: The Commission voted to change the prior authorization criteria as follows:

> *Prior authorization is required for all non-preferred nonsteroidal anti-inflammatory drugs and all non-preferred COX-2 inhibitors. Prior authorization is not required for preferred nonsteroidal anti-inflammatory drugs.*
> *1. Requests for a non-preferred nonsteroidal anti-inflammatory drug must document previous trials and therapy failures with at least two preferred nonsteroidal anti-inflammatory drugs.*
> *2. Requests for a non-preferred COX-2 inhibitor must document previous trials and therapy failures with two preferred COX-2 preferentially selective nonsteroidal anti-inflammatory drugs.*
> ** If a non-preferred long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested product, unless evidence is provided that use of the immediate release product would be medically contraindicated.*

A motion was made by Craig Logemann to approve the proposed criteria, and Dr. Laura Griffith seconded that motion. It passed the roll call vote unanimously.

Thrombopoeitin Receptor Agonists: The Commission reviewed the proposed 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 there being 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 asked for input from hematologists before proceeding with PA criteria for this new drug class. Craig Logemann suggested keeping the PA wording as close to the package insert as possible. The DUR staff will contact hematologists prior to the June meeting and the criteria will be re-reviewed.

Polyethylene Glycol 3350: Effective April 23rd CMS changed the DESI status of PEG such that the prescription-only version is no longer payable through Medicaid programs. Only the over-the-counter formulation will be payable by the Iowa Medicaid Enterprise. Notification will be sent out to pharmacies to let them know that as of Friday May 8, 2009, the OTC PEG will be covered without a prior authorization for kids up to 12 years of age. A PA will be required for ages 13-18. This drug will not be covered for anyone 19 or older. In February, Warren Bishop, M.D., a pediatric GI specialist at the University of Iowa sent an email to DHS expressing concerns over not having palatable effective bowel prep for children undergoing colonoscopy. He stated they have been using PEG without electrolytes and have been having a high degree of success. Children cannot typically drink the *GoLytely* or the equivalents in quantities sufficient to cleanse the bowel because of the salty musty taste and the discipline needed to drink large quantities over a short period of time. Instead, they have been using a gentle and efficient bowel prep of PEG without electrolytes, which is given over 4 days. This has been widely adopted across the nation by pediatric gastroenterologists. This same doctor also published a paper which has now become the standard of practice in most regions. There is a considerable cost difference between *GoLytely* or one of the equivalents and *Miralax*. There is a 45% cost differential when comparing the 255 gram bottle of *GoLytely* to one bottle of *Miralax*. However, the *Miralax* bottle is about twice as large. There will be an OTC MAC rate on OTC *Miralax*, but it will still cost $11 more. Commission members were provided with utilization data for the last 2 years, and asked if a change needed to be made to the criteria for ages 13 to 18. Dr. Bishop was asked to provide his public comments at this time by the members of the Commission. There was a lengthy discussion debating cost and efficacy, but in the end the Commission members decided to wait 6-9 months to re-evaluate changing the PA criteria and possibly negotiate better pricing. In the meantime, the Commission made a motion to allow payment of OTC *Miralax* for children less than 19 years of age without a preferred drug trial when used as a bowel prep over 4 days (motion by Bruce Alexander, second by Dr. Sara Schutte-Schenck.) The motion carried by unanimous role call vote by those present. At the June meeting, an update will be provided as to how this can be done through the pharmacy POS system.

Public Comment

Warren Bishop, M.D. from the University of Iowa spoke about polyethylene glycol 3350 without electrolytes.

ProDUR

Test scenarios were ran through the pharmacy point of sale system for daily quantity limits, and found there are issues with claims due to the days supply entered, such as pharmacies rounding the days supply down or arbitrarily putting in a days supply. There was concern that this would generate a large number of phone calls to the help desk that are not due to over utilization. The Commission suggested more education be provided to prescribers and pharmacies and to look at other states that may have quantity limits on acetaminophen containing products. This will be a future topic in the DUR Digest.

Focus Studies

New Clozapine Users and Frequency of Monitoring: Pam Smith reported that she contacted 16 pharmacies of those members that were identified as using clozapine but had no lab work in their medical claims history. She found that all members were receiving the appropriate lab work. Most members were receiving their lab work through the hospital lab which is the most likely reason it was not found in medical claims. There was only one pharmacy that was not verifying the WBC and ANC prior to dispensing clozapine which affected two members. The members were in a nursing home that was monitoring the lab work. The remaining pharmacies reported they do not dispense clozapine until the lab work was obtained.

Chronic Triptan Use without Prophylaxis: The purpose of this study was to follow up on the 195 unique members who were identified as having two or more fills for a migraine treatment (triptans) within a three month time frame without trying a prophylactic medication (propranolol, Inderal LA, timolol, amitriptyline, Depakote, Topamax, or verapamil) between 4/1/2008 and 7/1/2008. Imitrex, which had the highest member count in the original study, dropped from 104 members to 52 after the DUR intervention. Relpax also experienced a significant drop from 35 to 19 members. There were 343 surveys sent out, of which 134 were returned. Twenty-six members were started on a prophylactic following intervention. Also impacting these data were the change in the clinical prior authorization criteria for triptans; beginning January 1, 2009, a PA was required for 12 or more triptan tablets per 30 days as opposed to 18. In total, these changes resulted in a savings of $41,357.07 (state and federal), with $16,146.19 for the State.

Multiple Antipsychotic Use in Children: This review was tabled due to time constraints. It will be reviewed at the June meeting.

Safety of Statins Plus Tricor: The P&T Committee reviewed *Trilipix* (delayed-release fenofibric acid) at their March 12th meeting. Prior to making a recommendation to the Department regarding the PDL status of *Trilipix* (delayed-release fenofibric acid), the P&T Committee was interested in the DUR Commission reviewing utilization data to determine if the safety concerns of combining *Tricor* with a statin was significant enough that *Trilipix* (delayed-release fenofibric acid) should be recommended to have a preferred status. *Trilipix* (delayed-release fenofibric acid) is the active metabolite of *Tricor* (fenofibrate) which was approved by the FDA in December, 2008. It is indicated for use in the treatment of reducing triglyceride levels and increasing HDL levels in patients with mixed dyslipidemia and CHD (or a CHD risk equivalent) in combination with a statin. *Trilipix* (delayed-release fenofibric acid) is the only fibrate approved for use in combination with a statin. Other fibrates, such as *Lopid* (gemfibrozil) and *Tricor* (fenofibrate) can produce myopathy and rhabdomyolysis when combined with statins. Post-marketing data have reports of there being more than a 5-fold increase in the risk of rhabdomyolysis in patients taking a statin in combination with a fibrate compared to monotherapy. Studies looking at statins plus *Tricor* (fenofibrate) show that in addition to greater improvements in lipid levels compared to monotherapy, there were no cases of myopathy, rhabdomyolysis, or other drug-related adverse events reported. In a review published in *The Pharmacist's Letter/Prescriber's Letter* (February 2009), it is stated that, "based on available data, there appears to be no significant difference in the safety and efficacy of combining either fenofibric acid or fenofibrate with a statin." The Commission was asked to review utilization data from 1/1/09-2/28/09 to determine if the data suggests that prescribers are concerned with the safety of combining statins and Tricor, therefore making the case that Trilipix offers a clinical advantage over Tricor and that there should be a recommendation to the P&T Committee to reconsider the PDL status of Trilipix. The Commission members reviewed the data and asked for clarifications from the studies reported in *The Pharmacist's Letter.* The Commission members also discussed their personal experiences with dealing with the interaction. The DUR Commission did not feel it necessary to recommend a change in PDL status to the P&T Committee.

Duplicate NSAIDs (including topical diclofenac): This topic was tabled until the June meeting due to time constraints.

Public Comment

Dr Mohamed Morsy spoke on behalf of Abbott for the drug, *Trilipix*.

Miscellaneous

DUR Digest 2009 Volume 21, Number 3: The Commission members offered suggested changes to the updated draft.

FUL Updates Effective 4-30-09: The Commission members were given a copy of the CMS FUL changes that had gone into effect April 30th.

MedWatch: The Commission members received FDA announcements concerning OsmoPrep, Visicol, Premarin Vaginal Cream, and Truvada.

A unanimous vote was made at 12:40 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, June 3, 2009 at the West Des Moines Learning Center, 3550 Mills Civic Parkway in West Des Moines, Iowa.