Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 5, 2010

Attendees:

Commission Members
Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Rick Rinehart, M.D; Susan Parker, Pharm.D.; and Mark Graber, M.D., FACEP.

Staff
Thomas Kline, D.O.; 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

Chairperson Dr. Mark Graber called the meeting to order at 9:31 a.m. in Room 116 at the State Capitol in Des Moines. Commission members and guests were welcomed and introduced.

The minutes from the March 3, 2010 meeting were approved. (Motion by Dr. Richard Rinehart, second by Craig Logemann, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

As of July 1, 2010, a new vendor will be overseeing the Disease Management and Care Management programs, so there will be some changes to the daily workload within the Medical Services Unit. The high-tech radiology program is moving forward, however; prior authorizations are now being processed for outpatient CTs, MRIs, and PET scans. Providers are getting accustomed to this PA process, despite the lack of pre-implementation education due to time constraints resulting from the budget crisis. Medical Services is currently going through a URAC accreditation process as well. The Iowa Care Expansion program, effective 10-1-10, will increase the budget for Iowa Care and allow for 2 more primary care location options (in Council Bluffs and Sioux City prospectively) for members in addition to Broadlawns and the University of Iowa, which are their only current options for treatment. In 2014 when Healthcare Reform goes into effect, this Iowa Care program will cease to exist as it will be included into the Medicaid Expansion. Healthcare Reform is going to have some effects on State Medicaid programs, especially the pharmaceutical aspects. The Federal Government has imposed additional minimum rebate requirements to the manufacturers, but all of that will go back to the Federal Government. That will change the perspective on what a drug's real net pricing is; the State and Federal points of view on this will differ substantially. Another aspect of Healthcare Reform is that new formulations will require the same rebate as the existing forms. This will cut into the supplemental rebate revenue significantly, and goes retroactive back to 1-1-10. Also, the Iowa Code previously excluded certain categories of medications from being included on the

Preferred Drug List, including those used for mental illness. However, the Legislature removed that exemption this session so medications used in the treatment of mental illnesses will be subject to preferred and non-preferred status rather than just being on the Recommended Drug List, effective January 1, 2011. Anyone established on a mental health drug up to that point would be grandfathered. Any mental health drug requiring prior authorization will be eligible for a 7-day supply while obtaining prior authorization, as opposed to the 3-day supply currently allowed for all other products.

Quarterly Management Reports

The average amount paid per claim was $59.87 for the last quarter. 1,065,956 claims paid out a total of $63,820,590.81 for the 379,425 eligible members. 74.40% of these claims were for generic medications, and 18.59% were for controlled substances. ProAir HFA continued to have the highest number of prescriptions, while the largest amount of money ($5,119,146.43) was spent on *Synagis*.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of $2,442.59 pre-rebate (state and federal).

Public Comment

Karen Loihl from the Iowa Psychiatric Society voiced concerns regarding the proposed prior authorization criteria for *Intuniv*.

PA Criteria

Extended Release Formulations: At the March DUR meeting, while discussing the proposed PA criteria for extended release guanfacine, it was suggested that the language for the Extended Release Formulations PA criteria be re-evaluated. Specifically, the commission questioned if there needs to be a therapy failure with the immediate release product, or if it would be more appropriate if the patient showed some therapeutic benefit from the immediate release product. The current language reads:

> *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, Luvox CR, metronidazole sr, Prozac Weekly, Requip XL, Ryzolt, Seroquel XR, Solodyn ER, tramadol sr, Ultram ER.*

The Commission members agreed that these criteria needed to be changed. They suggested adding in “the member has shown improvement on the immediate release medication, but does not tolerate due to side effects” and requiring a trial of another

drug in the same category. Pam Smith will revise the wording and bring it to the June meeting.

Cymbalta, Lyrica, Savella: At the March meeting, the Commission reviewed a draft PA form for *Cymbalta, Lyrica, and Savella* and requested the form be split into three different PA forms for each drug. After discussion with the PA Department, it was felt that the PA form should not be split. The Commission reviewed the draft PA form with some modifications.

No motion was necessary as this had been discussed prior to this meeting, and no further changes were made. The Commission members did request, however, that a search function be added to the PDL website, so that forms (especially ones like this used for multiple drugs) could be found more easily. This capability might be added in the future, depending on programming requirements.

Extended Release Guanfacine (Intuniv): The Commission reviewed the prior authorization criteria as follows:

> *Prior authorization is required for Intuniv. Payment will be considered for patients when the following is met:*
> *1) The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
> *2) Previous trial and therapy failure at a therapeutic dose with immediate release guanfacine; and*
> *3) Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant; and*
> *4) Previous trial and therapy failure at a therapeutic dose with Strattera.*
>
> *The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

A quantity limit of 30 tablets per 30 days for all strengths (1mg, 2mg, 3mg, and 4mg) was also recommended. Susan Parker noted that the age restrictions were most likely unalterable (as Dr. Wadle had commented that many prescribers were wanting to use it on children younger than 6), because they needed to match the FDA standards due to Healthcare Reform allowing for more federal scrutiny about use of mental health drugs and PA criteria. Craig Logemann would also like to revise the second bullet point, stating a requirement for "previous trial with inadequate response or intolerance with therapeutic dose of the immediate release guanfacine". This topic was referred to the Mental Health Advisory Group.

Public Comment

James Osborn from GlaxoSmithKline spoke about DHS' educational efforts in regards to Beta Agonists used for Asthma. Lisa Goetz from Medimmune spoke about Synagis.

Focus Studies

Tamoxifen Interactions with Select SSRIs: The purpose of this study was to follow-up on the 16 unique members identified as using tamoxifen in combination with an SSRI that is a strong or mild inhibitor of CYP2D6 during the time frame 05/01/09 to 07/31/09. Letters were sent to providers in October 2009. Medication discontinuations resulted in $257.28 in savings (state and federal pre-rebate). This was just a follow-up discussion, so no further action was taken.

Antipsychotic Utilization in Children & Adolescents 2005 versus 2009: The purpose of this study was to compare mental health drug utilization in children between 2005 and 2009. The "Kids Getting Anti-Psychotics" project is a 15 state collaborative effort jointly sponsored by AHRQ, NASMD, NASMHPD, and the Medicaid Medical Directors Network (NMDN). The project, implemented in late 2008, has as its purpose a review of costs, utilization, and safety issues related to children receiving mental health medications. Data analysis covers four years, 2004 to 2007, for children 0-18 years of age enrolled in Medicaid in each year. The project's primary focus is on atypical antipsychotic (AAP) use in children; however, a broad review of mental health drugs (MHD) is included. The issue, especially for atypical antipsychotic medications, is a concern that for children, most AAP use is off label and that AAP use may lead to long-term health hazards, including the development of obesity and diabetes. Parents and child advocates nationally have voiced concerns that children are receiving too many psychotropic medications at too high a dose too young. Results from this project can be used to help define quality indicators to help assess and promote best practices. While Iowa did not participate in this project, an analysis was performed over a similar time period (2005 - 2009) with similar data parameters to examine this utilization within the Iowa Medicaid population. The number of children on typical antipsychotics did not change much between 2005 and 2009, but the percentages on atypicals did fluctuate. Generally speaking, usage went down in the younger age groups and up in those 15 to 18 years of age. The Commission decided to wait for national data for comparison before doing a focus study.

Duplicate Antihistamines: The purpose of this study was to determine the frequency of which Iowa Medicaid members are using multiple antihistamines. Regular reviews of member-specific charts have revealed a moderately high incidence of combining two or more antihistamines over an extended period of time. Although second generation antihistamines have less CNS depression than first generation antihistamines, the combination can still lead to increased CNS sedation and other anticholinergic side effects. Typically what is observed is a member is started on a first generation antihistamine or over-the-counter second generation antihistamine and uses it for a period of time, then requests use of a preferred or non-preferred second generation antihistamine, which is approved. When the second generation antihistamine that required a prior authorization is initiated, the over-the-counter product is never discontinued. An analysis of pharmacy claims was conducted between 10/1/2009 and 12/31/2009 to identify the number of unique members combining oral antihistamines for greater than or equal to 30 cumulative days. Antihistamines combined with decongestants were also included in this search. Additionally, we looked at members who combined the antihistamine nasal spray, *Astelin/Astepro* (azelastine) with oral antihistamines for greater than or equal to 30 cumulative days. One hundred eighty-

seven members continued their duplicate antihistamine regimen into December, and letters will be sent to the providers associated with these members.

Synagis Utilization in 2009-2010 RSV Season: The Commission was provided trending information over several recent years of palivizumab (*Synagis*) utilization data within the Iowa Medicaid population to determine if changes to the palivizumab (*Synagis*) coverage policy for the 2010-2011 season are necessary. Palivizumab (*Synagis*) has required a clinical prior authorization for all Iowa Medicaid members since the Preferred Drug List was implemented in January of 2005. The prior authorization criteria are based on the manufacturer labeling and the *Redbook* guidelines adopted by the American Academy of Pediatrics (prior to the 2009-2010 RSV season). Prior to the 2009-2010 RSV season, *Redbook* released updated recommendations for the use of palvizumab (*Synagis*) for the upcoming season. These updated recommendations were based primarily on updated pharmacoeconomic studies. In August of 2009, the American Academy of Pediatrics' Committee on Infectious Diseases updated their Policy Statement in support of the new *Redbook* guidelines. Following a thorough review of the new data behind the revised guidelines, the DUR Commission was opposed to adopting the full updated *Redbook* guidelines. The Commission did, however, recommend limiting the season to 5 doses beginning in November and ending in March per the new guidelines, but recommended not adopting the guideline that called for a maximum of 3 doses or dosing only until the infant reaches 90 days of age for those born from 32 weeks, 0 days' gestation through 34 weeks, 6 days' gestation who qualify for prophylaxis. It is important to note that independent of the DUR Commission's deliberations, the University of Iowa Hospitals and Clinics adopted similar guidelines for their physicians who prescribe palvizumab. For the 2009-2010 RSV season in Iowa, RSV was considered to be at epidemic levels (two consecutive weeks with two 10% positive rapid antigen RSV tests) the week ending December 26, 2009. At this point, most members who qualified for palvizumab had received two doses. While the Iowa Medicaid Enterprise adopted a hybrid of the new *Redbook* guidelines last season, of the states that responded to a survey, 21 state Medicaid programs adopted the full complement of guidelines and 6 states did not adopt the new guidelines. Overall, the feedback from those states has been positive in that there was very little push-back from the prescribers or hospitals. The Commission decided to wait for surveillance and epidemiologic data from the most recent RSV season to be made available for review before making any changes to the existing Iowa PA criteria.

Compliance with ACE, ARB, and/or Beta Blocker in CHF: The purpose of this study was to determine the rate of ACE inhibitor, beta-blocker, and/or angiotensin-receptor blocker (ARB) utilization and compliance in chronic heart failure (CHF) patients. Numerous studies have proven the benefit of ACE inhibitors and beta-blockers in patients with CHF. These products are typically initiated after the symptoms of fluid overload are addressed with loop diuretics. Current treatment guidelines from the American College of Cardiology and the American Heart Association recommend treatment with an ACE inhibitor in patients with CHF due to their favorable effect on survival. Additionally, beta-blockers are recommended for all stable patients with current or previous symptoms of heart failure and reduced left ventricular ejection fraction. It is also recommended that beta-blockers and ACE inhibitors be used in all patients with a recent or past medical history of myocardial infarction. Angiotensin II receptor blockers

are also approved for the treatment of CHF, but it is recommended that their use is reserved for those patients who are intolerant to ACE inhibitors. The goals of therapy are to improve symptoms, slow or reverse the reduction of myocardial function, and reduce mortality. An analysis was performed looking at those members with a diagnosis of CHF and their pharmacy claims histories to ensure that current guidelines were being followed with regard to prescription drug use. Members with current Iowa Medicaid eligibility were screened to identify those with ICD-9 codes in their medical claims history that correspond to a diagnosis of CHF. Non-reversed, paid pharmacy claims between 1/1/10 and 2/28/10 were analyzed. Claims for ACE inhibitors, beta-blockers, and angiotensin II receptor blockers were identified. Once these were found, a medication possession ratio was performed. 11,090 unique members were identified as having a CHF diagnosis, but only 1,205 (10.9%) of them are using an ACE inhibitor, beta-blocker, and/or an angiotensin II receptor blocker. These numbers will be rerun to identify people who have had a hospital admission or ER visit, with a primary diagnosis of CHF. Dr. Graber also recommended looking at members who've had echocardiograms. New findings will be brought back to a future meeting for analysis.

Under-Utilization of Statins in Diabetes: The purpose of this study was to determine the extent of statin utilization in patients with diabetes. After reviewing utilization patterns of cholesterol-lowering medications in patients following a new diagnosis of myocardial infarction, unstable angina, or acute coronary syndrome, there was an interest to review statin utilization in another vulnerable population. The American Diabetes Association 2010 Standards of Medical Care in Diabetes recommends statin therapy be added to lifestyle modifications for diabetic patients regardless of baseline lipid levels for those with overt cardiovascular disease (CVD), for those without CVD who are over 40 years of age and have at least one risk factor for CVD, and for those with LDL greater than 100. For those with multiple CVD risk factors, the goal LDL level is less than 100mg/dL. For patients with overt CVD, the recommended goal LDL level is less than 70mg/dL. Medicaid members with current eligibility and a new diagnosis for diabetes in 2009, who also had at least one diagnosis code for cardiovascular disease in their medical claims history that have never filled a statin, were identified. Three thousand, three hundred-six unique members with a new diagnosis of diabetes in 2009 with at least one diagnosis for CVD were identified. Twenty-seven of them were under 18 years of age, of which none have ever filled a statin. Three hundred-ninety two were between 18 and 39 years of age, of which 337 (86%) have never filled a statin; and 2,887 were 40 years of age or older, of which 2,409 (83.4%) have never filled a statin. It is extremely difficult, if not impossible, with this large of a population size to determine how many potential CVD risk factors members have. Additionally, lipid levels are not collected in data, so there is no way to determine if a diabetic patient has an LDL greater than 100 mg/dL without pharmacotherapy. Thus, this will appear as an article in an upcoming DUR Digest.

Long-Acting Beta Agonists in Asthma: The purpose of this study was to identify members using long-acting beta-agonist inhalers for the treatment of asthma, and to make prescribers aware of new warnings from the FDA. In February of 2010, the FDA released new recommendations to help improve the safe use of long-acting beta-agonist (LABA) inhalers for the treatment of asthma. This alert was in response to an analysis of studies that showed an increased risk of hospitalizations and death in adults

and children with asthma using LABA inhalers due to an increased risk of severe exacerbation of asthma symptoms. The drugs that were included in this recommendation were salmeterol (*Serevent*), formoterol (*Foradil*), fluticasone/salmeterol (*Advair*), and budesonide/formoterol (*Symbicort*). While manufacturers of LABAs are updating their package inserts and implementing strategies to reduce the overall use of these medications, we performed an analysis to determine how these products were being used in the Iowa Medicaid population. Medicaid members with current eligibility and a diagnosis of asthma in their medical claims were identified. Of these members, we reviewed non-reversed, paid pharmacy claims between 12/1/09 and 2/28/10 to identify how many members had claims for salmeterol (*Serevent*), formoterol (*Foradil*), fluticasone/salmeterol (*Advair*), and/or budesonide/formoterol (*Symbicort*). For those identified as using one of these products, we looked at how many were combining this regimen with an asthma-controller medication (corticosteroid, leukotriene, anti-inflammatory, and/or xanthine). We also looked at those under 18 years of age who were using the single ingredient products compared to the combination products. Of these 27,184 members, 1,834 (6.75%) were identified as having claims for a long-acting beta agonist between 12/1/09 and 2/28/10, of which 575 members were under the age of 18 years old; 17 of these members were found to be using duplicate LABAs. Of the 1,834 members identified as having recent claims for a long-acting beta agonist between 12/1/09 and 2/28/10, 824 (44.9%) were identified as combining the long-acting beta agonist with a "controller" medication. 1,010 (55.1%) members were identified as using a long-acting beta agonist without a "controller" medication. For those under 18 years of age, the ratio of single ingredient products to combination products was 0.08. This will appear as a DUR Digest article.

Valproate Use as Mood Stabilizer in Women of Childbearing Age: The purpose of this study was to determine the frequency of which women of childbearing age in the Iowa Medicaid population are using valproate for non-seizure diagnoses. The FDA recently published a reminder to health care professionals about the increased risk of major birth defects in infants exposed to valproate sodium and related products in utero. These birth defects can include neural tube defects, craniofacial defects, and cardiovascular malformations. Infants exposed to valproate during the first 12 weeks of a pregnancy have an increased risk of neural tube effect in 1 in 20 infants. When used to treat epilepsy, the North American Antiepileptic Drug Pregnancy Registry reports that the rate of major malformations in infants born to women with epilepsy taking valproate is nearly 4 times higher than the rate of major malformations in infants born to women taking other agents. The communication from the FDA goes on to encourage health care providers to counsel women of childbearing age about the increased risk of birth defects when valproate is taken during pregnancy, and that effective contraception should be used in women not planning a pregnancy. An analysis of pharmacy claims was conducted between 12/1/2009 and 2/28/2010 to identify the number of female members of childbearing age (aged 16 years and older) who received two or more prescriptions for any valproate product. Of those identified, we removed any member who also had claims during the same time for hormonal contraceptive products, physician administered contraceptive products, and those who had undergone surgical sterilization. We also removed any member with a seizure diagnosis. The remaining members were determined to be using valproate for a mental health or other compendia-listed indication. A sub-analysis was performed to determine how many

members also had a pregnancy diagnosis during the time valproate was used. Seven hundred-four unique female members, aged 16 years or older, received two or more prescriptions for valproate between 12/1/09 and 2/28/10. The remaining female members, aged 16 years of age or older, who are using valproate for a diagnosis other than seizure disorder who may have a higher risk of pregnancy totaled 177. Dr. Graber recommended that the data be rerun, limiting the ages to between 16 and 45, to allow for use in post-menopausal women. Letters will be sent to the prescribers of the members within this age bracket. Craig Logemann also noted that the ones using valproate for seizures should still be included in the study. Dr. Graber thought it would also be interesting to see how many women taking anti-seizure medication were also on folic acid.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 22, Number 3.

SMAC Updates: The Commission members were given a copy of the SMAC changes that had gone into effect in March and April.

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

A unanimous vote was made at 11:26 to adjourn the meeting and move to closed session (first by Rick Rinehart, second by Sara Schutte-Schenck).

The next meeting will be held at 9:30 a.m. on Wednesday, June 2, 2010 at the Learning Resource Center in West Des Moines.