Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 3, 2011

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Casey Clor, M.D. ; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brett Faine, Pharm.D.; Gregory Barclay, M.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Chuck Wadle, D.O., Magellan; Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; Laureen Biczak, D.O. (via phone); and Melissa Biddle, IME.

Welcome & Introductions

Dr. Graber called the meeting to order at 9:40 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 6, 2011 meeting were reviewed. Craig Logemann motioned to accept them, and Brett Faine seconded. The vote was unanimous. The Commission members also completed their annual conflict of interest and confidentiality forms. Dr. Schutte-Schenck nominated Dr. Graber to remain as Chairperson, and Dr. Clor seconded this motion. The vote was unanimous. Craig Logemann nominated Laurie Pestel to remain as Vice-Chair, and Dr. Schutte-Schenck seconded this motion. This decision was also unanimous.

IME Updates

The IowaCare expansion has continued as of July 1st, with 3 new FQHCs in Fort Dodge, Dubuque, and Marshalltown to act as medical home centers for members in specific counties on IowaCare. Another FQHC in Council Bluffs will be added in October, and more counties will be added to the existing medical homes. Magellan has initiated a demonstration of integrated health homes, integrating mental health care with physical health care. The legislature has finalized the budget, and it is signed by the Governor. Susan Parker acknowledged departing Commission member Rick Rinehart's service to the Commission, as well as Sandy Pranger's resignation from Iowa Medicaid. She then noted some changes that had been brought about by the Legislature. The pharmacy dispensing fee will be increasing to $6.20, retroactively effective to August 1, 2011, pending approval from CMS. Effective September 1, 2011, a 15 day supply will be implemented on the initial fill of select drugs with high discontinuation rates. Additionally effective September 1st, the Cough and Cold PDL categories (excluding OTC payable pseudoephedrine products and dextromethorphan-guaifenesin syrup) and the Weight Loss PDL category will be removed from Medicaid coverage.

Prevalence Report Summary

Statistics for the Pharmacy Program from May and June 2011 were discussed, including: cost per user ($251.76), number of total prescriptions dispensed (a decrease

of 8.5% compared to the previous reported period), average cost per prescription ($59.79), and generic utilization (76.8%). The total paid amount decreased by 7.9% from the previous period. There were 152,515 unique users, which is 9.7% less than the total for March and April. Lists of the top 20 therapeutics classes were provided. Atypical Antipsychotics were the most expensive, and Stimulants-Amphetamines-Long-Acting came in second. SSRIs had the highest prescription count, and Anticonvulsants came in second. The top 100 drugs were also reviewed. Eight of the ten most expensive medications were mental health drugs, including 3 different strengths of Abilify.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $3,845.30 pre-rebate (state and federal).

Public Comment

Speaker	***Topic***
Harvey Schuck from Merck	HCV (*Victrelis*)
Rupa Shah from Purdue	BuTrans
Tammy Reeder from Taro	Ivermectin (*Ovide*)
Susan Harrell M.D. (no manufacturer affiliation)	Synagis
Lisa Willshaw from MedImmune	Synagis
Lisa Borland from Vertex	HCV (*Incivek*)

Ivermectin (*Stromectol*) Utilization

The Commission reviewed 5 years of utilization data on ivermectin and decided no criteria change was needed at this time. Pam Smith will get more information on claims for October's meeting and this will be revisited in a year. It will also appear as a DUR Digest article.

Prior Authorization

Palivizumab (Synagis): The Commission reviewed the following prior authorization criteria, which incorporated the full 2009 AAP RSV Guidelines:

> *Prior authorization is required for therapy with palivizumab. Prior authorizations will be approved for a maximum of five doses per patient. No allowances will be made for a sixth dose. Payment for palivizumab will be considered for patients who meet one of the following criteria:*
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> *Chronic Lung Disease (CLD)*
>
> - *Patient is less than 24 months of age at start of therapy and has chronic lung disease of prematurity (i.e. bronchopulmonary dysplasia) requiring medication (bronchodilator, corticosteroid, or diuretic therapy) or oxygen within six months before the anticipated start of RSV season.*
>
> *Prematurity*

- *Patient is less than 12 months of age at start of therapy with a gestational age 29 weeks.*
- *Patient is 12 months of age or younger at the start of therapy with a gestational age less than 35 weeks and has either severe neuromuscular disease or congenital abnormalities of the airway that compromises handling of respiratory secretions.*
- *Patient is less than 6 months of age at start of therapy with a gestational age of 29 weeks through 31 weeks.*
- *Patient is less than 3 months of age at start of therapy or born during the RSV season with a gestational age of 32 weeks through 34 weeks and has one of two risk factors. Risk factors include: day care attendance or siblings less than 5 years of age in household. Doses will be limited to a maximum of 3 doses or until patient reaches 90 days of age, which ever comes first).*

Congenital Heart Disease (CHD)

- *Patient is less than 24 months of age at start of therapy and has hemodynamically significant congenital heart disease further defined by any of the following: receiving medication to control congestive heart failure, moderate to severe pulmonary hypertension, or cyanotic congenital heart disease.*

Severe Immunodeficiency

- *Patient is less than 24 months of age at start of therapy and has severe immunodeficiencies (e.g., severe combined immunodeficiency or advanced acquired immunodeficiency syndrome).*

Dr. Laureen Biczak, an Infectious Disease Specialist with GHS, presented a slide show regarding this topic. Afterward, the Commission had a lengthy discussion, but ultimately decided to accept the full 2009 AAP RSV Treatment Guidelines for the treatment of RSV. Dr. Clor made the motion, and Craig Logemann seconded. Dr. Schutte-Schenck abstained. All others were in favor, so the motion passed. The start date for the upcoming season will be November 28th, unless the RSV season begins early, at which point that could be adjusted. Epidemiology levels above 10% for two consecutive weeks (of a statistically significant sample) will signal the start of the season.

Oxycodone ER/CR (OxyContin): The Commission reviewed the prior authorization criteria as follows:

Extended release oxycodone/OxyContin® is non-preferred except for patients being treated for cancer related pain. Prior authorization at any dose twice daily for cancer related pain will be approved. For all other diagnoses, payment will be considered under the following conditions:

1. *There is documentation of previous trials and therapy failures with two (2) chemically distinct preferred long-acting narcotics (such as morphine sulfate ER and methadone) at therapeutic doses, and*
2. *A trial and therapy failure with fentanyl patch at maximum tolerated dose, and*
3. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization.*
4. *Requests will only be considered for 12 hour dosing.*

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

Providers will also have to check a box on the PA form to confirm that they've checked the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ before prescribing OxyContin. Dr. Clor motioned to accept the revised criteria as listed above, and Brett Faine seconded. The motion passed with all in favor.

Anti-Acne: This topic was tabled until a future meeting due to time constraints.

Topical Retinoids: This topic was tabled until a future meeting due to time constraints.

Dextromethorphan/Quinidine (Nuedexta): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Nuedexta™. Payment will be considered under the following conditions:

1. *Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS).*
2. *A trial and therapy failure at a therapeutic dose with amitriptyline and an SSRI.*
3. *Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire.*
4. *Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.*

Dr. Graber mentioned that OTC *Delsym* is a prolonged release dextromethorphan and suggested adding it as a trial to the criteria. Pam Smith responded that *Delsym* is not currently covered. Susan Parker said it could be looked into, but the rebate status must be confirmed first. This will be brought back to the next meeting. No motion was made.

Hepatitis C Protease Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all oral hepatitis C protease inhibitors. Payment will be considered under the following conditions:

1. *A diagnosis of hepatitis C genotype 1.*
2. *Patient is 18 years of age or older.*
3. *Administered in combination with peginterferon alfa and ribavirin.*
4. *HCV-RNA results are required at treatment week 4 for telaprevir (Incivek™). Additional prior authorization will be considered with documentation of response to treatment, measured by HCV-RNA levels. A maximum 12 weeks of therapy will be allowed for telaprevir (Incivek™).*

HCV-RNA results are required at treatment week 8, 12, and 24 (including lead in period) for boceprevir (Victrelis™) and patient must not be a prior null responder to standard treatment. Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels. Prior authorizations will be approved for a maximum of 24, 32, or 40 weeks of therapy with boceprevir (Victrelis™) based on response.

Brett Faine motioned to accept the recommended criteria, and Dr. Schutte-Schenck seconded. The vote was unanimous.

Colchicine (Colcrys): The Commission reviewed the prior authorization criteria as follows:

> *Prior authorization is not required for colchicine (Colcrys®) for the treatment of acute gout for three (3) tablets per 60-day period. Prior authorization is required for colchicine (Colcrys®) for the treatment of chronic hyperuricemia/gout prophylaxis or Familial Mediterranean fever. Payment will be considered under the following conditions:*
> 1) *Chronic hyperuricemia/gout prophylaxis following a trial and therapy failure at a therapeutic dose with allopurinol or probenecid. A quantity limit of sixty (60) tablets per thirty (30) days will be applied, when criteria for coverage for chronic hyperuricemia or gout prophylaxis are met.*
> 2) *Familial Mediterranean fever. A maximum quantity limit of 120 tablets per thirty (30) days will be applied for this diagnosis.*
>
> *The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary.

Fingolimod (Gilenya): The Commission reviewed the prior authorization criteria as follows:

> *A prior authorization is required for Gilenya™. Payment will be considered under the following conditions:*
> 1. *A diagnosis of relapsing forms of multiple sclerosis, AND*
> 2. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*
>
> *The required trial may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary.

Public Comment

There were no public comments provided.

Focus Studies

Duplicate Antihistamines: This topic was tabled until a future meeting due to time constraints.

Valproate Use in Females of Childbearing Age: This topic was tabled until a future meeting due to time constraints.

Treatment of Bipolar Depression: As requested at the April Commission meeting, a search was run in the members' claims histories for any hospitalizations for members not on a mood stabilizer or antipsychotic over a two year time span. After reviewing the results, the members decided to contact the prescribers of the members who are being treated with an antidepressant and not a mood stabilizer or antipsychotic for bipolar depression.

PPI Use in Patients with Liver Dysfunction: This topic will be addressed in a future DUR Digest article.

Topiramate Use in Females of Childbearing Age: The prescribers of the 290 members who are using topiramate without effective contraception (for all diagnoses) will be contacted, to ensure that the provider has counseled the member on the increased risk of oral clefts in infants who are exposed to topiramate during the first trimester of pregnancy, and request that a safer alternative be selected or that an oral contraceptive or other contraceptive method be added if the member is to continue on topiramate.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 24, Number 1.

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

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

A unanimous vote was made at 12:35 to adjourn the meeting and move to closed session (1st by Craig Logemann, 2nd by Larry Ambroson).

The next meeting will be held at 9:30 a.m. on Wednesday, October 5, 2011 at the Learning Resource Center in West Des Moines.