Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes April 6, 2011

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Casey Clor, M.D.; Richard Rinehart, 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.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Chuck Wadle, D.O., Magellan; Jason Kessler, M.D.; Sandy Pranger, R.Ph., IME; Erin Halverson, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Graber called the meeting to order at 9:33 a.m. at the Learning Resource Center in West Des Moines. The minutes from the February 2, 2011 meeting were reviewed. Craig Logemann motioned to accept them, and Dr. Clor seconded. The vote was unanimous.

IME Updates

J-code issues can now be emailed to pcapricinginquiry@dhs.state.ia.us; this address is posted on both the Iowa Medicaid PDL and IME websites. Letters to manufacturers to begin the process for supplemental rebate negotiations for 2012 have been sent. This is also posted on www.iowamedicaidpdl.com on the Manufacturers/Supplemental Rebate Information page. May 10, 2011 is the deadline for initial submission of supplemental rebate offers. Additional contact and 2012 timeline information were provided in the letter as well. IME is continuing to work on a state-wide health care home project, and also applied for a grant as part of the Affordable Care Act. The annual provider training session will be June 6, 2011.

Psychotropics in Children

Dr. Wadle presented a PowerPoint presentation on the use of psychotropics in children. After reviewing the slides, the Commission felt that the findings for those ages 5 and below should be examined more closely. They agreed that 8 weeks would be a reasonable length of time for a drug trial. Pam Smith will inquire if an algorithm could be created to ascertain true multiple providers, and screen out those that are clinic-related. The Commission asked that children with more than 2 providers within 2 months be identified as well. Results will be brought back to a future meeting for possible creation of intervention and/or prior authorization criteria, and this topic will also be presented to the Mental Health Advisory Group.

Prevalence Report Summary

Statistics from January though February 2011 were discussed, including: cost per user ($238.02), number of total prescriptions dispensed (a decrease of 1.8% compared to the previous reporting period), average cost per prescription ($60.11), and generic utilization (77.0%). The total paid amount decreased by 1.7% from the previous period. There were 167,174 unique users, which is 4.5% more than the total for November and December. Lists of the top 20 therapeutic classes were provided. Atypical Antipsychotics were the most expensive, and Long-Acting Amphetamines came in second. SSRIs had the highest prescription count, and Beta-Lactams/Clavulanate Combinations came in second. The top 100 drugs were also reviewed. Nine of the ten most expensive medications were mental health drugs, including 3 different strengths of Abilify. Pam Smith will see if all strengths of each drug could be combined on one line to provide a more accurate picture of overall expenditures. Hydrocodone/apap had the highest prescription count.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $5,360.19 pre-rebate (state and federal).

Public Comment

Aleksandra Sundberg from Novartis spoke about Gilenya. Barbara Felt from GlaxoSmithKline talked about the asthma population and the corresponding focus study recommendations to be discussed later in the meeting. Julie Zatizabal from EMD Serono, spoke about Egrifta. Richard Wurdesen from AstraZeneca spoke about Crestor.

Prior Authorization

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

Dr. Clor motioned to accept the recommended criteria, and Dr. Rinehart seconded. The motion was unanimous.

Tesamorelin (Egrifta): The Commission deemed this medication not medically necessary, so it will not be covered. Craig Logemann motioned to make this a non-covered drug, and Brett Faine seconded. All members were in favor of the motion. Pam Smith will contact some providers as requested to get their opinions on this decision.

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.*

Dr. Clor motioned to accept the recommended criteria, and Larry Ambroson seconded. The vote was unanimous. A quantity limit of 1 capsule per day was also recommended.

Topical Immunomodulators: The Commission reviewed the prior authorization criteria as follows:

> *Prior authorization is required for topical immunomodulators. Payment for pimecrolimus (Elidel®) or tacrolimus (Protopic®) 0.03% will be considered for non-immunocompromised patients two years of age and older and tacrolimus (Protopic®) 0.1% for members 16 years of age and older when there is an adequate trial and therapy failure with two preferred topical corticosteroids. If criteria for coverage are met, requests will be approved for one tube per 90 days to ensure appropriate short-term and intermittent utilization of the medication. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 60 grams or 100 grams for all other areas. The required trials may be overridden when documented evidence is provided that 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.

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. Requests for PPIs exceeding one unit per day will be considered after documentation of a therapeutic trial and therapy failure with concomitant use of once daily PPI dosing and a bed time dose of a histamine H2-receptor antagonist. Upon failure of the combination therapy, subsequent requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a retrial of the recommended once daily dosing will be required. A trial of the recommended once daily dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day.*
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.*

A quantity limit of one unit per day for all PPIs was also recommended. The Commission had no further changes. As this was the second review of these criteria, no motion was necessary.

Selected Brand Name Drugs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for selected brand-name drugs, as determined by the Department, for which there is available an "A" rated bioequivalent generic product as determined by the Federal Food and Drug Administration, unless the brand drug has been designated by the Department as preferred (payable) under the Iowa Medicaid Preferred Drug List (PDL). For prior authorization to be considered, the prescriber must submit a completed Selected Brand Name PA form with:

- *Documentation of trials and therapy failures with two different generic manufacturers of the same chemical entity, if available. If an allergy to an inactive component is suspected, the second trial must be with a generic product that does not contain the allergen, if available.*
- *Documentation of the failure must include the specific adverse reaction as defined by the FDA (See Section B of the Select Brand Name form). Intolerances, such as nausea or vomiting, to the generic drug will not be considered as a basis for approval.*
- *Trials may be overridden when evidence is provided that use of the generic product would be medically contraindicated.*

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

Vitamins, Minerals and Multiple Vitamins: The DUR Commission reviewed the prior authorization criteria as follows:

> *Payment for vitamins, minerals and multiple vitamins for treatment of specific conditions will be approved when there is a diagnosis of specific vitamin or mineral deficiency disease or for patients under 21 years of age if there is a diagnosed disease which inhibits the nutrition absorption process as a secondary effect of the disease. (Prior approval is not required for prescribed multi-vitamins with or without iron or vitamin D supplements for patients under 12 months of age or a prescription product primarily classified as a blood modifier, if that product does not contain more than three vitamins/minerals or for products principally marketed as prenatal vitamin-mineral supplements.)*

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

Cholesterol Lowering Medications Post-MI: This was a follow-up discussion, and the Commission had no further comments.

Serotonin Syndrome Drug Interactions: The Commission wanted to know how many unique prescribers were involved. They also want to develop a focus study and contact the prescribers of those members who have a past medical history of serotonin syndrome and/or past medical history of hyperthermia to alert them of the possible drug-drug interaction. Anyone with 60 or less tramadol will be excluded from the mailing.

Atypical Antipsychotics and Metabolic Screening: The Commission wanted to develop a DUR Digest article to update providers on the progress in this area but encourage continued improvement in monitoring. Additionally, medical societies will be contacted, to inquire if they would publish this article as well.

Utilization of Drugs on Beers List: The Commission wished to develop a focus study and contact the prescribers of those patients using a drug considered to always be avoided (phenobarbital, flurazepam, butabarital, mephobarbital), recommending they switch to an alternative treatment (or discontinue altogether) since these products are considered to always be avoided in the elderly.

Antidepressant Use in Children: The Commission wants to develop a focus study and contact the prescribers of the 314 members using an antidepressant that do not have a mental health diagnosis in their medical claims.

Treatment of Bipolar Depression: A search will be run in the members' claims histories for any hospitalizations for members not on a mood stabilizer or antipsychotic over a two year time span. Results will be brought back to a future meeting.

Inhaled Long Acting Beta Agonists in Asthma: The Commission wished to contact the prescribers of all members 16 years of age or younger who were identified as using an inhaled LABA single-ingredient product to recommend the inhaled LABA be discontinued or changed to a fixed-dose LABA/corticosteroid product for the shortest duration of time necessary. Additionally, the prescribers of all the members identified as using a single-ingredient inhaled LABA without a steroid will be contacted.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 23, Number 3.

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

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

A unanimous vote was made at 12:20 to adjourn the meeting and move to closed session (1st by Dr. Clor, 2nd by Dr. Rinehart).

The next meeting will be held at 9:30 a.m. on Wednesday, June 1, 2011 at the Learning Resource Center in West Des Moines.