Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes June 5, 2013

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Jason Wilbur, M.D.; Gregory Barclay, M.D.; Kellen Ludvigson, 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., IME; Erin Halverson, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Graber called the meeting to order at 9:36 a.m. at the Iowa State Capitol, Room 116, in Des Moines. The minutes from the April 3, 2013 meeting were reviewed. Dr. Wilbur motioned to accept them, and Brett Faine seconded. The vote was unanimous.

IME Updates

There are now 24 health home entities, with more than 530 providers, enrolled in the health homes for people with chronic diseases program, which began July 1, 2012. Just over 3,000 members are in health homes so far. The IME has recently submitted a State Plan Amendment in coordination with Magellan for the next phase of the health home project, health homes for people with serious and persistent mental illness and serious emotional disturbances. The tentative start date for this project is July 1, 2013; it will begin initially in 5 counties and be phased out state-wide over the next 12 to 18 months. The IME successfully applied for a grant to assist in implementing the core adult quality measures, and is working on two quality improvement projects associated with that, the first targeting a reduction in admissions for short-term complications of diabetes, and the second aiming to improve birth outcomes through decreases in tobacco use in pregnant mothers. IME has applied for a CMS innovation model design grant to develop a multi-payer ACO model based on existing private payer and Medicare efforts already forming in the state. There are currently five major work groups focusing on tasks associated with this model. As has already been reported in the newspapers, the Iowa Legislature passed the Iowa Health and Wellness Plan. The legislature also passed the appropriations bill, which resulted in a 1% increase in reimbursement for several provider types, along with an increase to the dispensing fee from $10.02 to $10.12 effective July 1, 2013. This requires a State Plan Amendment for CMS approval. Additionally, the bill requires the cost of dispensing survey to be done every two years, beginning with state fiscal year 2014-2015, but the exact date is still to be determined. IME is in the middle of determining the semi-annual rebase for the Actual Acquisition Costs of brand and generic drugs, which is based on invoices

obtained from pharmacies in April, and hopes to implement the rate changes within the next week or two. These will be posted to the website, and also sent to the listserv, and hopefully included in an informational letter as well. Dr. Brian Couse from Red Oak will be filling the open physician position on the DUR Commission, effective July 1, 2013.

Prevalence Report Summary

Statistics from March though April 2013 were discussed, including: cost per user ($243.41), number of total prescriptions dispensed (a decrease of 2.2% compared to the previous reporting period), average cost per prescription ($57.10), and generic utilization (84.2%). The total paid amount decreased by 4.2% from the previous reporting period. There were 152,103 unique users, which is 5.9% less than the total for January and February. Lists of the top 20 therapeutic classes were provided. Atypical Antipsychotics were the most expensive (though the percentage of the budget is decreasing due to release of multiple generics), 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. The ten most expensive medications were: Abilify, Vyvanse, methylphenidate hcl er, Focalin XR, Synagis, Adderall XR, Cymbalta, Advate, Advair Diskus, and Strattera.

Case Studies

Pam Smith presented 4 case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of $1612.60 pre-rebate (state and federal).

Public Comment

Nancy Bell from Pfizer spoke about Janus Kinase Inhibitors. Rachel Anhorn from Boehringer-Ingelheim spoke about *Pradaxa*. Jerry Clewell from Abbvie spoke about *Humira*.

Prior Authorization

Oral Constipation Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral constipation agents. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient must have documentation of adequate trials and therapy failures with three (3) different laxatives from each of the following:*
    a. *Saline laxative (milk of magnesia); and*
    b. *Osmotic laxative (polyethylene glycol or lactulose); and*
    c. *Stimulant laxative (senna); and*
3. *Patient does not have a known or suspected mechanical gastrointestinal obstruction; and*
4. *Patient has one of the following diagnoses:*
    a. *A diagnosis of* ***chronic idiopathic constipation*** *(Amitiza or Linzess)*

i. *Patient has less than 3 spontaneous bowel movements (SBMs) per week; and*
ii. *Patient has two or more of the following symptoms within the last 3 months:*
    1. *Straining during at least 25% of the bowel movements;*
    2. *Lumpy or hard stools for at least 25% of bowel movements; and/or*
    3. *Sensation of incomplete evacuation for at least 25% of bowel movements; and*
iii. *Documentation the patient is not currently taking constipation-causing therapies*

b. *A diagnosis of* ***irritable bowel syndrome with constipation*** *(Amitiza or Linzess)*
    i. *Patient is female (Amitiza only); and*
    ii. *Patient has abdominal pain or discomfort at least 3 days per month in last 3 months associated with two (2) or more of the following:*
        1. *Improvement with defecation;*
        2. *Onset associated with a change in stool frequency; and/or*
        3. *Onset associated with a change in stool form*

c. *A diagnosis of* ***opioid-induced constipation*** *with chronic, non-cancer pain (Amitiza)*
    i. *Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and*
    ii. *Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:*
        1. *Hard to very hard stool consistency;*
        2. *Moderate to very severe straining; and/or*
        3. *Having a sensation of incomplete evacuation*

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Kellen Ludvigson motioned to accept the above criteria, and Dr. Wilbur seconded. The decision was unanimous.

Long-Acting Narcotics: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred long-acting narcotics. 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 extended-release morphine sulfate, Opana ER and methadone) at therapeutic doses, and*
2. *A trial and therapy failure with fentanyl patch at a maximum tolerated dose, and*
3. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization, and*

4. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ prior to requesting prior authorization.*
5. *Requests for long-acting narcotics will only be considered for FDA approved dosing.*

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

Brett Faine motioned to accept the above criteria, and Larry Ambroson seconded. The decision was unanimous.

Oral Multiple Sclerosis Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for fingolimod (Gilenya™) or teriflunomide (Aubagio®). Payment will be considered for patients 18 years of age and older 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.

For patients initiating therapy with fingolimod (Gilenya™), documentation of the following must be provided:

- *Patient does not have a recent (within the past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure.*
- *Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.*
- *Patient does not have a baseline QTc interval ≥ 500 ms.*
- *Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.*

For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:

- *Patient does not have severe hepatic impairment.*
- *A negative pregnancy test for females of childbearing age.*
- *Use of a reliable form of contraception for females of childbearing age.*
- *Patient is not taking leflunomide.*

For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:

- *Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.*
- *Upon renewal, documentation of an updated CBC.*

Larry Ambroson motioned to accept the above criteria, and Dr. Wilbur seconded. The decision was unanimous.

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) including documentation of an insufficient response to a corticosteroid, an immunoglobulin, or the patient has undergone a splenectomy.

Payment for eltrombopag (Promacta) for the treatment of chronic hepatitis C-associated thrombocytopenia will only be considered to allow for initiation and/or maintenance of interferon-based therapy with ribavirin when the patient has a baseline platelet count less than 75 x 10^9/L. Requests will not be considered under the following conditions:

1. *Patients taking direct acting antiviral agents for the treatment of chronic hepatitis C genotype 1 infection in addition to interferon-based therapy with ribavirin.*
2. *Patients with decompensated liver disease with a Child-Pugh score > 6 (Class B & C).*
3. *Patients with a history of ascities.*
4. *Patients with hepatic encephalopathy.*

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.

Dr. Graber suggested contacting a hepatologist for input. However, the Commission decided to accept the criteria as written. Dr. Wilbur motioned to accept the criteria, and Kellen Ludvigson seconded. The decision was unanimous.

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

Prior authorization is required for topical testosterone products. Payment for non-preferred topical testosterone products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Payment will be considered under the following conditions:

1. *Patient is male and 18 years of age or older; and*
2. *Patient has a diagnosis of hypogonadism; and*
3. *Patient has two (2) morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (Please attach lab results); and*
4. *Patient has at least one of the signs and symptoms specific to androgen deficiency*
    a. *Incomplete or delayed sexual development*
    b. *Breast discomfort, gynecomastia*
    c. *Loss of body hair, reduction in shaving frequency*
    d. *Very small (<5mL) or shrinking testes*
    e. *Hot flushes, sweats*
    f. *Height loss, low trauma fracture, low bone mineral density; and*

5. *Patient does not have:*
    a. *Breast or prostate cancer*
    b. *Palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL*
    c. *Hematocrit > 50%*
    d. *Untreated severe obstructive sleep apnea*
    e. *Severe lower urinary tract symptoms*
    f. *Uncontrolled or poorly controlled heart failure*

If criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy will require the following:

1. *An updated testosterone level (Please attach lab result); and*
2. *Documentation of how the patient's specific symptoms have responded to therapy; and*
3. *Documentation the patient has not experienced a hematocrit > 54% or an increase in PSA > 1.4ng/mL in the past 12 months.*

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

A note will be added to the PA form stating that Iowa Medicaid does not cover sexual dysfunction or low sperm count diagnoses. Brett Faine motioned to accept the criteria as amended, and Dr. Wilbur seconded. The decision was unanimous.

Repository Corticotropin Injection (H.P. Acthar Gel): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for repository corticotropin injection. Payment will be considered under the following conditions:

1. *Patient is under two years of age and*
2. *Patient has a diagnosis of infantile spasms.*

Treatment of compendia indicated steroid-response conditions will only be considered upon documented contraindications or intolerance to corticosteroids not expected to occur with the use of repository corticotropin injection.

If criteria for coverage are met, authorization will be provided for up to 30 days of treatment for all indications.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Janus Kinase (JAK) Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. *The patient is 18 years of age or older; and*
2. *Has a diagnosis of moderate to severe rheumatoid arthritis; and*

3. *Has a documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, leflunomide, or minocycline) ; and*
4. *Has a documented trial and inadequate response to preferred biological DMARD; and*
5. *The patient is not using or planning to use tofacitinib in combination with biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and*
6. *Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and*
7. *Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to manufacturer labeling; and*
8. *Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and*
9. *Patient is not at an increased risk of gastrointestinal perforation.*

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

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Dabigatran (Pradaxa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for dabigatran (Pradaxa®). Payment will be considered for patients under the following conditions:

1. *Patient has a diagnosis of non-valvular atrial fibrillation; and*
2. *Documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and*
3. *Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1; and*
4. *Patient does not have a mechanical prosthetic heart valve; and*
5. *Patient does not have active pathological bleeding; and*
6. *Patient does not have severe renal impairment (CrCl < 15mL/min) or is not on dialysis.*

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

The DUR Commission also recommends a quantity limit of 60 capsules per 30 days and to include the $CHADS_2$ scoring table on the PA form. Brett Faine motioned to accept the criteria as amended, and Dr. Wilbur seconded. The motion passed with all in favor. The recommendation will be sent to the Department for consideration.

Public Comment

Dr. Robert Calder from Merck spoke about Zetia.

Focus Studies

Low Dose Quetiapine: This was a follow-up discussion. Twenty-two (22) of the 52 members identified changed therapy, for an annualized cost savings of $70,142.34 (state and federal, pre-rebate) as a result of the 125 surveys sent out to prescribers and pharmacies. Fifty-six (56) or 44.8% of those surveys were returned.

Ezetimibe Utilization: The Commission would like to develop prior authorization criteria. Existing users will be grandfathered, but new starts will require a statin trial. Pam Smith will bring a draft of the suggested prior authorization criteria to the August meeting.

Emergency Contraception (Levonorgestrel) Utilization: Letters will be sent to the prescribers of the members with 2 or more fills of an emergency contraceptive, except for those that started an oral contraceptive after use of the emergency contraceptive.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 25, Number 3 a second time. No corrections were suggested. The DUR Digest will be posted to the iadur.org website.

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

A unanimous vote was made at 11:17 a.m. to adjourn the meeting and move to closed session (motion by Kellen Ludvigson, second by Larry Ambroson). A roll call vote was conducted.

The next meeting will be held at 9:30 a.m. on Wednesday, August 7, 2013, at the Iowa State Capitol, Room 116, in Des Moines.