Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 7, 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.; Brian Couse, 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; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Graber called the meeting to order at 9:34 a.m. at the Iowa State Capitol, Room 116, in Des Moines. The minutes from the June 5, 2013 meeting were reviewed. Dr. Wilbur motioned to accept them, and Dr. Barclay seconded. The vote was unanimous. Annual conflict of interest disclosures were collected in closed session. Laurie Pestel nominated Dr. Graber to remain Chairperson. Kellen Ludvigson and Dr. Wilbur both seconded simultaneously, and all members were in favor. Dr. Graber then nominated Laurie Pestel to remain Vice-Chairperson, which was seconded by Dr. Wilbur and agreed upon by all members.

Annual Federal DUR Report

Pam Smith reviewed the DUR program report for the last federal fiscal year. Overall, the program produced a net cost savings of $747,654.95 for federal fiscal year ending (FFYE) 2012, versus $615,600.07 saved in FFYE 2011. Patient-focused reviews brought a savings of $328,419.35, while problem-focused studies resulted in $689,235.60 in savings.

IME Updates

The health homes for people with serious and persistent mental illness and serious emotional disturbances project began in five counties on July 1, 2013, and will 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 reduce emergency department use for patients with asthma. 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 four major work groups focusing on tasks associated with this model. The State Plan Amendment to increase the dispensing fee from $10.02 to $10.12 effective July 1, 2013,

was submitted to CMS for approval on July 31st, after which they have 90 days to finalize or comment on it. Additionally, CMS has had the pharmacy portion of the CFR out for pending rule changes since February of 2012, which speaks to specific parts of the Medicaid pharmacy reimbursement for outpatient drugs, including the actual acquisition cost reimbursement, drug rebate changes and other pharmacy issues. DHS has heard that the final rule may be implemented in January of 2014, so the department will be watching for final rules. There are not any real issues, since Iowa Medicaid already reimburses at the actual acquisition cost, as these rules recommend. The Affordable Care Act also implements a change to calculation of the Federal Upper Limits that are now based on Average Manufacturer Price (AMP), which is different than the current calculation. There are some potential issues with some FUL reimbursements being below cost, so a work group has been looking into these and hopes to resolve the issues before the rules become final. The National Drug Acquisition Cost (NADAC) will also be finalized by CMS.

Prevalence Report Summary

Statistics from May though June 2013 were discussed, including: cost per user ($245.86), number of total prescriptions dispensed (a decrease of 4.9% compared to the previous reporting period), average cost per prescription ($57.51), and generic utilization (83.9%). The total paid amount decreased by 4.4% from the previous reporting period. There were 144,343 unique users, which is 4.9% less than the total for March and April. 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, *Advate*, *Focalin XR*, *Adderall XR*, *Cymbalta*, *Advair Diskus*, *Lantus*, and *Strattera*.

Case Studies

Pam Smith presented 4 case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of $4,211.92 pre-rebate (state and federal).

Public Comment

Matthew Stafford from Merck spoke about Zetia, and Ben Skoog from Biogen Idec spoke about Tecfidera.

Prior Authorizations

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 two preferred biological DMARDs; 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.

Kellen Ludvigson motioned to accept the criteria, and Larry Ambroson seconded. The decision was unanimous.

Sodium Oxybate (Xyrem): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 years of age or older under the following conditions:

1. *A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline.*
2. *Patient is enrolled in the Xyrem® Success Program.*
3. *A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.*
4. *Patient has been instructed to not drink alcohol when using Xyrem®.*
5. *Requests for patients with a prior history of substance abuse, concurrent use a sedative hypnotic, or a semialdehyde dehydrogenase deficiency will not be considered.*

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

This was deferred to the next meeting so more information could be obtained in regards to a prior history of substance abuse.

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

Prior authorization is required for testosterone products. Payment for non-preferred testosterone products will be authorized only for cases in which there is documentation of

previous trials and therapy failures with two preferred agents. Requests for symptoms of sexual dysfunction, erectile dysfunction and infertility will not be considered. Payment for a diagnosis of hypogonadism (testosterone deficiency) will be considered under the following conditions:

1. *Patient is male and 18 years of age or older (or 12 years of age and older for testosterone cypionate); and*
2. *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*
3. *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*
4. *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.*

Requests for FDA approved indications other than hypogonadism will not be subject to prior authorization criteria with adequate documentation of diagnosis.

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 criteria as amended, and Dr. Wilbur seconded. The decision was unanimous.

Rivaroxaban (Xarelto): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for rivaroxaban (Xarelto®). Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient does not have a mechanical prosthetic heart valve; and*
3. *Patient does not have active bleeding; and*
4. *Patient is not pregnant; and*
5. *Patient does not have severe renal impairment (CrCl < 15mL/min).*

Atrial Fibrillation

- *Patient has a diagnosis of non-valvular atrial fibrillation; and*
- *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*
- *Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1.*
- *For a CrCl > 50mL/min a dose of 20mg once daily will be considered; or*
- *For a CrCl 15 to 50mL/min a dose of 15mg once daily will be considered.*

Treatment and Prevention of DVT or PE

- *Documentation of a previous trial and therapy failure with warfarin (recurrent DVT, recurrent PE, TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and*
- *Patient does not have a CrCl < 30mL/min; and*
- *Patient does not have significant liver disease (hepatitis or cirrhosis).*
- *For treatment of acute DVT or PE a dose of 15mg twice daily for 21 days followed by 20mg once daily for remaining treatment will be considered; or*
- *For prevention of DVT or PE a dose of 20mg once daily will be considered.*

Prophylaxis of DVT following Hip or Knee Replacement

- *Patient does not have a CrCl < 30mL/min; and*
- *Patient does not have significant liver disease (hepatitis or cirrhosis); and*
- *For patients undergoing hip replacement, patient is not undergoing staged bilateral total hip replacement.*
- *Requests will be approved for the following dosing:*
    - *Hip replacement: 10mg daily for up to 35 days following hip replacement; or*
    - *Knee replacement: 10mg daily for up to 12 days following knee replacement.*

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

Dr, Wilbur motioned to accept the criteria as amended, and Brett Faine seconded. The decision was unanimous.

Ezetimibe (Zetia): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ezetimibe and ezetimibe containing products. Requests for non-preferred ezetimibe combination products may only be considered after documented separate trials and therapy failures with the individual ingredients. Payment will be considered under the following conditions:

1. *Patient is being treated for an elevated total cholesterol level; and/or*
2. *Patient is being treated for an elevated LDL-C level; and*

3. *Patient has not achieved goal with the use of two or more preferred HMG-CoA reductase inhibitors at a maximally tolerated dose for a minimum of three (3) consecutive months.*

Initial authorizations will be approved for six months; additional prior authorizations will be considered on an individual basis after review of medical necessity and documented improvement in total cholesterol and/or LDL-C levels since the beginning of the initial prior authorization period.

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

Dr. Wilbur motioned to accept the criteria as amended, and Brett Faine seconded. The decision was unanimous. There was discussion around programming the POS system to do a look-back for preferred trials to remove the need for prior authorization. Existing users would be grandfathered.

Insulin, Pre-Filled Pens: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for pre-filled insulin pens. Prior authorization for non-preferred insulin pens will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent.
Prior authorization is granted when documentation indicates:

1. *The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin, and*
2. *There is no caregiver available to provide assistance, and*
3. *Patient does not reside in a long-term care facility.*

Dr. Wilbur motioned to accept the criteria as amended, and Brett Faine seconded. The decision was unanimous.

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.

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

Long-Acting Opioids: 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.

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

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.*

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

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.

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

Public Comment

There were no additional public comments.

Focus Studies

Drospirenone Containing Oral Contraceptive and Risk of Blood Clot: This was a follow-up discussion. Nineteen of the 39 members identified changed therapy, for an annualized cost savings of $20,766.24 (state and federal, pre-rebate) as a result of the 101 surveys sent out to prescribers and pharmacies. Forty-six (45.54%) of those surveys were returned.

Overutilization of Albuterol Inhaler: Letters will be sent to providers of members over-utilizing their albuterol MDI pointing out the over-reliance and asking if the patient's asthma is being adequately controlled. Letters will also be sent to providers of members over-utilizing their albuterol MDI that are not using an inhaled corticosteroid. Both versions of the letter will mention that spacers are covered by Iowa Medicaid as DME items.

Valproate for the Treatment of Migraine in Females: Letters will be sent to providers

of female members taking valproate products for migraine, pointing out the recent change to the drug label, and suggesting the use of a different preventative medication now that valproate products are contraindicated for prevention of migraine in women of childbearing age. The Commission also wants to look closer at the members with a diagnosis of seizure or bipolar disorder to identify those members that are using an effective form of birth control while taking a valproate product.

Diabetes Diagnosis without Prescription Treatment: Results will be broken out by provider, and identify patients with claims for the preferred test strips but no diabetic prescriptions in their claim histories, and also patients with claims for diabetes complications with no diabetic medications in their histories.

Miscellaneous

DUR Digest: The Commission member reviewed the draft for DUR Digest Volume 26, Number 1. Dr. Couse's appointment date will be corrected.

MedWatch: There were no MedWatch announcements to review.

A unanimous vote was made at 11:37 to adjourn the meeting and move to closed session (motion by Dr. Wilbur, second by Brett Faine).

The next meeting will be held at 9:30 a.m. on Wednesday, October 2, 2013, at the Iowa State Capitol, Room 116, in Des Moines.