Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes October 2, 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 9:31 a.m. at the Iowa State Capitol, Room 116, in Des Moines. The minutes from the August 7, 2013 meeting were reviewed. Dr. Wilbur motioned to accept them, and Larry Ambroson seconded. The vote was unanimous.

IME Updates

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. A separate quality improvement project aims 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 four major work groups focusing on tasks associated with this model, with results to be presented soon. IME is working to get the Iowa Health and Wellness Initiative implemented. CMS approved the State Plan Amendment to increase the dispensing fee from $10.02 to $10.12 retroactively effective to July 1, 2013. An informational letter announcing this decision is in process. The new POS system went live on September 23, 2013, and things are going well, with no major issues thus far.

Prevalence Report Summary

Statistics from July though August 2013 were discussed, including: cost per user ($264.32), number of total prescriptions dispensed (an increase of 1.0% compared to the previous reporting period), average cost per prescription ($59.48), and generic utilization (83.5%). The total paid amount increased by 4.7% from the previous reporting period. There were 140,317 unique users, which is 2.6% less than the total for May and June. 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, Adderall XR, Cymbalta, Advate, 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 $17,059.91 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	*Eliquis*
Luciano Kolodny	Merck	*Januvia*, DPP-4 Inhibitors
Lisa Willshaw	MedImmune	*Synagis*
Todd Houldsworth	Johnson & Johnson	*Xarelto*

Injectable Medications Reimbursed through Pharmacy POS

With the expansion of home health care, more medications are being provided in the home. With the increase in home health care services, the Preferred Drug List (PDL) was expanded to allow for administration of injectable medications in the patient's home. A report detailing injectable drugs from the August 2013 paid claims report was reviewed. Pam Smith will run a report to identify how many injectable drugs are for Plan 300 members, and look into the possibility of auto-allowing these claims to pay since the pharmacies would deliver the medications to the nursing homes or care facilities for those members. When members pick up and transport their own medications, there have been issues with them getting lost along the way to being administered. Contacting providers to ask what medications they keep in stock and to educate them on correct billing of injectables is another possibility. A search will be done on medical claims to identify any providers billing for medications that were already paid through POS. Pam Smith will look into how other states are handling this issue.

Prior Authorization

Annual Review of PA Criteria: The Commission members would like to discuss changes to the following categories: Antifungals, Antithrombotics, Incretin Mimetics (recommend to combine with DPP-4 Inhibitors), Proton Pump Inhibitors, ARBs, and Anti-Acne.

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.

Pam Smith will change the wording for the fifth bullet point to include something about patient counseling, history of prior abuse, and the PMP, and bring the revised criteria back to the next meeting.

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, and*
2. *Patient is 18 years of age or older, and*
3. *Administered in combination with peg-interferon 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™). 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 44 weeks of therapy with boceprevir (Victrelis™) based on response.

Brett Faine motioned to accept the criteria, and Larry Ambroson seconded. All members were in favor with none abstaining.

Apixiban (Eliquis): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for apixaban (Eliquis®). 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 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 provider will also need to provide the member's weight and recent serum creatinine on the PA form. Dr. Wilbur motioned to accept the criteria, and Brett Faine seconded. All members were in favor with none abstaining.

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.

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

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).*

<u>Atrial Fibrillation</u>

- *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.*

<u>Treatment and Prevention of DVT or PE</u>

- *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.*

<u>Prophylaxis of DVT following Hip or Knee Replacement</u>

- *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.

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

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.

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

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.*

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

Dr. Tim Starner from the University of Iowa spoke about Tobi Podhaler.

Focus Studies

Stimulant Use in Adults: This was a follow-up discussion. One-hundred and sixty-three (163) of the 456 members identified changed therapy, for an annualized cost savings of $200,412.75 (state and federal, pre-rebate) as a result of the 1,948 surveys sent out to prescribers and pharmacies. Six-hundred and ninety-two (692) (35.52%) of those surveys were returned.

Second Generation Antipsychotic Use without Mental Health Diagnosis: This was a follow-up discussion. Forty-four (44) of the 208 members identified changed therapy, for an annualized cost savings of $54,408.72 (state and federal, pre-rebate) as a result of the 451 surveys sent out to prescribers and pharmacies. There were 189 (41.91%) surveys returned.

Concurrent Second Generation Antipsychotics: This was a follow-up discussion. Four-hundred and seventy (470) of the 735 members identified changed therapy, for an annualized cost savings of $1,587,793.42 (state and federal, pre-rebate) as a result of the 1,714 surveys sent out to prescribers and pharmacies. There were 733 (42.77%) surveys returned.

Ketoconazole Oral Tablets: The Commission would like to make a recommendation to the P&T Committee to change the status of ketoconazole tablets to non-preferred on the PDL. Letters will be sent to the providers of the 68 members taking ketoconazole tablets outlining the details from the recent FDA Drug Safety Communication and asking if the patient would be a candidate to switch to a different oral antifungal medication. There will also be a DUR Digest article.

Overutilization of Opiates and/or Tramadol: Letters will be sent to the providers of the 38 members potentially exhibiting drug seeking behavior, suggesting they reference the PMP. These members will also be referred to the lock-in department, and an article about the PMP will appear in a future DUR Digest. Additionally, letters will be sent to the providers of the 245 members without cancer that appear to be overutilizing opioids and/or tramadol to ask if the patient could be better controlled with one opioid.

Valproate Sodium & Related Products in Women of Childbearing Age: Letters will

be sent to the providers of the female members with a seizure and/or bipolar diagnosis taking a valproate product that are not using an effective form of birth control to ask if the patient is a candidate for use of an effective form of birth control. Letters will also be sent to the providers of the female members without a seizure and/or bipolar diagnosis taking a valproate product that are not using an effective form of birth control to suggest use of a different medication or the addition of an effective form of birth control. The Commission thought both topics could be merged into one letter.

Miscellaneous

DUR Digest: The Commission member reviewed the final draft for DUR Digest Volume 26, Number 1. There were no recommended changes. The DUR Digest will be posted to the DUR website.

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

A unanimous vote was made at 11:44 a.m. to adjourn the meeting and move to closed session (motion by Brett Faine, second by Dr. Wilbur).

The next meeting will be held at 9:30 a.m. on Wednesday, December 4, 2013, at the Learning Resource Center in West Des Moines.