Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes June 4, 2014

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; Erin Halverson, R.Ph., IME; Megan Smith, Pharm.D., IME; and Melissa Biddle, IME.

Welcome & Introductions

Mark Graber, M.D., called the meeting to order at 9:35 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 2, 2014 meeting were reviewed. Kellen Ludvigson, Pharm.D. motioned to accept them, and Jason Wilbur, M.D. seconded. All members were in favor.

IME Updates

The legislature did provide new language to allow the switch from Average Acquisition Cost (AAC) to the National Average Drug Acquisition Cost (NADAC) if the new Federal Upper Limits (FUL) went into place, as DHS was concerned about the FULs not reimbursing adequately. The new FULs were originally scheduled to be put in place in July 2014, but CMS has delayed that. In addition, a cost of dispensing survey was recently completed; once responses are evaluated, any change to the dispensing fee would be effective August 1, 2014. Mark Graber, M.D., has been re-appointed to the P&T Committee, and will attend his first meeting in August.

Prevalence Report Summary

Statistics from March though April 2014 were discussed, including: cost per user ($276.18), number of total prescriptions dispensed (an increase of 11.9% compared to the previous reporting period), average cost per prescription ($58.87), and generic utilization (83.7%). The total paid amount increased by 8.8% from the previous reporting period. There were 184,340 unique users, which is 6.1% more than the total for January and February. Lists of the top 20 therapeutic classes were provided. 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, Lantus, Cymbalta, Advate, Adderall, Synagis, and Advair Diskus.

Case Studies

Pam Smith presented 4 case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of $906.04 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Parris Pope	Jazz Pharmaceuticals	Narcolepsy and Xyrem
Seonyoung Ryu	Genentech	Xolair
Joe Llewellyn	Gilead	Sovaldi
Luke Weedin	Forrest Pharmaceuticals	Fetzima
Mike Asmus	Pfizer	Chronic Pain Syndromes PA criteria and Lyrica

Review of Medical Necessity

Naloxone Rescue: In April 2014, the U.S. Food and Drug Administration approved the first naloxone treatment to be given by family members or caregivers to treat a person known or suspected to have had an opioid overdose. Evzio (naloxone hydrochloride injection) is a hand-held auto-injector that delivers a single dose of naloxone, using voice commands to assist in administration of the drug. As this drug will most likely be rebatable, and thus required to be covered by Iowa Medicaid, it was recommended that the DUR Commission develop prior authorization criteria. Pam Smith will check to see if naloxone prescriptions have been written in the past, and try to find out how many opioid overdoses have resulted in death. The members were worried that providing the rescue medication would enable people to overdose on purpose to experience the high.

Focus Studies

Zolpidem 10mg Dose in Females: This was a follow-up discussion. Three-hundred seventy-two (372) of the 851 members identified changed therapy, for an annualized cost savings of $4,053.27 (state and federal, pre-rebate) as a result of the 2,272 surveys sent out to prescribers and pharmacies. Eight-hundred and eight (808) or 35.56% of those surveys were returned.

Zolpidem 12.5mg Dose in Females: This was a follow-up discussion. Nine of the 25 members identified changed therapy, for an annualized cost savings of $784.64 (state and federal, pre-rebate) as a result of the 67 surveys sent out to prescribers and pharmacies. Sixty (60) or 22.39% of those surveys were returned.

Duplicate SSRIs: This was a follow-up discussion. Twenty-eight (28) of the 57 members identified changed therapy, for an annualized cost savings of $798.25 (state and federal, pre-rebate) as a result of the 151 surveys sent out to prescribers and pharmacies. Sixty-nine (69) or 45.70% of those surveys were returned.

Duplicate TCAs: This was a follow-up discussion. Three of the 13 members identified changed therapy, for an annualized cost savings of $114.85 (state and federal, pre-rebate) as a result of the 31 surveys sent out to prescribers and pharmacies. Twenty-one (21) or 67.74% of those surveys were returned.

Duplicate Antidepressants (Two or More Concurrently): This was a follow-up discussion. Fifty-three (53) of the 135 members identified changed therapy, for an annualized cost savings of $8,662.56 (state and federal, pre-rebate) as a result of the 357 surveys sent out to prescribers and pharmacies. One-hundred fifty-five (155) or 43.42% of those surveys were returned.

Duplicate Antidepressants (MAO Inhibitor plus SSRI or TCA): This was a follow-up discussion. One of the 2 members identified changed therapy, for an increase of $773.88 in annual expenditures (state and federal, pre-rebate) as a result of the 5 surveys sent out to prescribers and pharmacies. Two (40.00%) of those surveys were returned.

Prescriber Trends in Opiate Prescribing: After the February meeting, findings were plotted on provider-type-specific graphs to illustrate opioid units per day, morphine sulfate equivalents per day, and number of prescriptions. At the April meeting, the Commission pointed out statistical outliers and other lines that didn't make sense with common prescribing practices. Pam Smith looked at claim level detail for the outlying prescribers, and brought her findings back to the June meeting. Dentists that appeared to be using long-acting opiates had been a concern, but Pam Smith discovered that tramadol had been included in the report parameters.

Long Term Use of Short-Acting Opioids: The Commission wants to lower the existing quantity limits, and limit use to one short-acting at a time. At the April meeting, it was suggested that short-acting opioids be limited to a quantity of 120 per 30 days, while long-acting could be allowed 30 to 60 per 30 days. Susan Parker suggested doing this in stages, with soft POS edits notifying providers of the changes prior to implementation of the quantity limits. Erin Halverson also suggested just tackling the short-acting opioids for now, since the hope is to increase use of the long-acting medications. At the June meeting, quantity limits on breakthough medications and cumulative quantity limits on all short-acting opioids were suggested. Erin Halverson would like to know how many members would exceed the proposed limits prior to implementation. Pam Smith will refresh the data, and letters will be sent to the prescribers of members identified as taking 4 or more doses per day of a short-acting opioid, or two or more short-acting opioids concurrently, to inquire if they would be a candidate for use of a long-acting opioid with use of a short-acting opioid for breakthrough pain. Pam Smith will also run the numbers as Erin Halverson requested, and provide morphine sulfate equivalents. Providers will be forewarned via letter before the limits are put into place.

Naltrexone Use in Children: Letters will be sent to inquire about the reasoning for

use.

Adalimumab Use without Methotrexate: Letters will be sent to the prescribers of the 10 members not combining adalimumab with methotrexate or other non-biologic DMARD to ask if the patient would be a candidate for the combined use.

Public Comment

Name	Representing	Drug/Topic
Rachel Anhorn	Boehringer-Ingelheim	Pradaxa

Prior Authorization

Chronic Pain Syndromes: The Commission reviewed the prior authorization criteria as follows:

A prior authorization is required for duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™). For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further consideration. Decreased utilization of opioids must be maintained while taking a drug for the treatment of a chronic pain diagnosis. Payment will be considered under the following conditions:

1. *A diagnosis of **fibromyalgia** (Cymbalta®, Lyrica®, and Savella™)*
   a. *A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, SSRI, or SNRI, **WITH***
   b. *Documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.), **AND***
   c. *Documentation of a previous trial and therapy failure at a therapeutic dose with Savella™ when Cymbalta® and Lyrica® are requested.*
2. *A diagnosis of **post-herpetic neuralgia** (Lyrica®)*

   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, valproate, or carbamazepine.
3. *A diagnosis of **diabetic peripheral neuropathy** (Cymbalta® and Lyrica®)*

   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or topical lidocaine.
4. *A diagnosis of **partial onset seizures**, as adjunct therapy (Lyrica®)*
5. *A diagnosis of **major depressive disorder** or **generalized anxiety disorder** (Cymbalta®)*
6. *A diagnosis of **chronic musculoskeletal pain** (Cymbalta®)*

A trial and therapy failure at a therapeutic dose with at least three drugs from three distinct therapeutic classes from the following: NSAIDs, opioids, tramadol, or tricyclic antidepressants.

Requests for concomitant use of these agents for an indicated chronic pain diagnosis may only be considered once each agent has been tried at maximum tolerated dose separately. Duplicate use of drugs from the same therapeutic category will not be considered. Requests for doses above the manufacturer recommended dose will not be considered.

Pam Smith modified the first paragraph with the changes requested, and will bring the revised criteria back to the August meeting.

Omalizumab (Xolair): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

Moderate to Severe Persistent Asthma

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Patient is 12 years of age or older; and*
3. *Pretreatment IgE level is between 30 IU/mL and 700 IU/mL; and*
4. *Patient's weight is between 30 kg and 150 kg; and*
5. *History of positive skin or RAST test to a perennial aeroallergen; and*
6. *Prescriber is an allergist, immunologist, or pulmonologist; and*
7. *Patient is currently using a high dose inhaled corticosteroid AND long-acting beta-agonist, is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy.*
8. *Patient must have access to an EpiPen to treat allergic reactions that may occur after administration of Xolair®.*

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid and long-acting beta-agonist.

Chronic Idiopathic Urticaria

1. *Patient has a diagnosis of moderate to severe chronic idiopathic urticaria for 6 or more weeks; and*
2. *Patient is 12 years of age or older; and*
3. *Patient has documentation of a trial and therapy failure with at least one second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
4. *Patient has documentation of a trial and therapy failure with at least one first-generation antihistamine; and*
5. *Patient has documentation of a trial and therapy failure with at least one potent H1*

receptor antagonist (hydroxyzine and/or doxepin); and

6. *Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.

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

Jason Wilbur, M.D. motioned to accept the criteria as amended, and Brian Couse, M.D. seconded. All members were in favor.

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

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

1. *Patient does not have a mechanical prosthetic heart valve; and*
2. *Patient does not have active pathological bleeding; and*
3. *Patient has a diagnosis of non-valvular atrial fibrillation; with*
4. *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*
5. *Presence of at least one additional risk factor for stroke, with a CHADS2 score ≥ 1; OR*
6. *For patients requiring deep vein thrombosis (DVT) prophylaxis undergoing hip or knee replacement. Requests will be considered when the patient has contraindications to use of the preferred agent(s). If patient meets criteria for coverage, requests will be approved for the following doses:*
    - *Hip replacement: 2.5 mg twice daily for up to 35 days following hip replacement; or*
    - *Knee replacement: 2.5 mg twice 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.

Brian Couse, M.D. motioned to accept the criteria, and Jason Wilbur, M.D. seconded. All members were in favor.

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 does not have a mechanical prosthetic heart valve; and*
2. *Patient does not have active pathological bleeding; and*
3. *Patient has documentation of a previous trial and therapy failure with*

warfarin (TIA, stroke, recurrence of DVT/PE, or inability to maintain a therapeutic INR with a minimum 6 month trial).

Non-valvular atrial fibrillation (in addition to the above)

- *Patient has the presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1; and*
- *Patient does not have severe renal impairment (CrCl < 15mL/min) or is not on dialysis.*

Treatment and prevention of DVT or PE (in addition to the above)

- *Patient does not have a CrCl < 30mL/min or is not on dialysis.*
- *For patients with current DVT/PE, patient must have documentation of 5 to 10 days of parenteral anticoagulation prior to initiation of dabigatran.*

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

Brett Faine, Pharm.D. motioned to accept the criteria, and Brian Couse, M.D. seconded. All members were in favor.

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

Prior authorization is required for direct-acting oral antiviral agents against the hepatitis C virus. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient's prior treatment history is provided (treatment naïve, prior null responder, partial responder, or relapser); and*
3. *If patient has a history of failed treatment due to non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and*
4. *Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and*
5. *Patient is not a pregnant female or a male with a pregnant female partner; and*
6. *Women of childbearing potential and their male partners must use two forms of effective contraception (non-hormonal contraception for patients taking Incivek™ and Sovaldi™) during treatment and for at least 6 months after treatment has concluded; and*
7. *Documentation that routine monthly pregnancy tests are performed during this time; and*
8. *Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test, and*

9. *Prescriber is an infectious disease specialist, gastroenterologist, hepatologist, or other hepatitis specialist.*
10. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
11. *Lost or stolen medication replacement requests will not be authorized.*
12. *The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.*

Incivek

- *Patient has a documented diagnosis of hepatitis C genotype 1; and*
- *Administered in combination with peg-interferon alfa and ribavirin; and*
- *Patient does not have HIV co-infection; and*
- *Patient is not receiving dialysis or does not have a CrCl < 50 mL/min.*
- *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™).*

Victrelis

- *Patient has a documented diagnosis of hepatitis C genotype 1; and*
- *Administered in combination with peg-interferon alfa and ribavirin; and*
- *Patient does not have HIV co-infection; and*
- *Patient does not have decompensated cirrhosis.*
- *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.*

Olysio

- *Patient has a documented diagnosis of hepatitis C genotype 1; and*
- *Administered in combination with peg-interferon alfa and ribavirin; and*
- *Patient does not have HIV co-infection; and*
- *Patient does not have the NS3 Q80K polymorphism with hepatitis C genotype 1a; and*
- *The patient is not receiving dialysis or does not have a CrCl < 30 mL/min.*
- *HCV-RNA results are required at treatment week 4 for simeprevir (Olysio™).*
- *Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels.*
- *A maximum 12 weeks of therapy will be allowed.*

Sovaldi

- *The patient is not receiving dialysis or does not have a CrCl < 30 mL/min; and*
- *Patient does not have decompensated cirrhosis; and*

- *Documentation the patient has stage 3 or greater fibrosis as confirmed by a liver biopsy.*
- ***Genotype 1:*** *Patient has a documented diagnosis of hepatitis C genotype 1 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks therapy will be allowed.*
- ***Genotype 2:*** *Patient has a documented diagnosis of hepatitis C genotype 2 (mono-infected or HCV/HIV co-infected) and used in combination with ribavirin. A maximum 12 weeks of therapy will be allowed.*
- ***Genotype 3:*** *Patient has a documented diagnosis of hepatitis C genotype 3 (mono-infected or HCV/HIV co-infected) and used in combination with ribavirin. A maximum **24** weeks of therapy will be allowed.*
- ***Genotype 4:*** *Patient has a documented diagnosis of hepatitis C genotype 4 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed.*
- ***Hepatocellular carcinoma:*** *Patient has a documented diagnosis of hepatitis C genotype 1, 2, 3, 4 with a diagnosis of hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and in combination with ribavirin for up to 48 weeks or until liver transplantation, whichever comes first. Milan criteria are defined as:*
  - *One lesion smaller than 5 cm in diameter for subjects with a single lesion;*
  - *Up to 3 lesions smaller than 3 cm in diameter in subjects with multiple lesions;*
  - *No extrahepatic manifestations;*
  - *No vascular invasion.*
- *Requests for peg-interferon alfa free regimens will be considered on a case-by-case basis for patients with hepatitis C genotype 1 or 4 where Peg-interferon alfa is contraindicated. Contraindications include: documented life-threatening side effects; decompensated hepatic disease; autoimmune hepatitis and other autoimmune disorders; a baseline neutrophil count below 1500/µL, a baseline platelet count below 90,000/ µL, or a baseline hemoglobin below 10g/dL; and a history of preexisting unstable cardiac disease.*

Susan Parker, Pharm.D. will bring cost projections to the next meeting, to compare including Stage 2 Fibrosis coverage for Sovaldi and excluding it. Jason Wilbur, M.D. motioned to accept the criteria as amended, and Larry Ambroson, R.Ph. seconded. All members were in favor.

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

Prior authorization is required for non-preferred antidepressants subject to clinical criteria. Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

1. *The patient has a diagnosis of Major Depressive Disorder (MDD) and is 18 years of age or older; and*

2. *Documentation of a previous trial and therapy failure at a therapeutic dose with two preferred generic SSRIs; and*
3. *Documentation of a previous trial and therapy failure at a therapeutic dose with two preferred generic SNRIs; and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with one non-SSRI/SNRI generic antidepressant.*
5. *If the request is for an isomer, prodrug or metabolite of a medication indicated for MDD, one of the trials must be with the preferred parent drug of the same chemical entity that resulted in a partial response with a documented intolerance.*

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.

Ivacaftor (Kalydeco): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met:

1. *Patient is 6 years of age or older; and*
2. *Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, and S549R as detected by a FDA-cleared CF mutation test; and*
3. *Prescriber is a CF specialist or pulmonologist; and*
4. *Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus.*

As this was the second review of these criteria, no motion was necessary.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 26, Number 3. This was the second review of the DUR Digest and will be posted to the DUR website.

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

A unanimous roll call vote was made at 11:57 to adjourn the meeting and move to closed session (motion by Jason Wilbur, M.D., second by Larry Ambroson, R.Ph.).

The next meeting will be held at 9:30 a.m. on Wednesday, August 6, 2014, at the Learning Resource Center in West Des Moines.