Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes April 2, 2014

Attendees:

Commission Members
Laurie Pestel, Pharm.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; Megan Smith, Pharm.D., IME; and Melissa Biddle, IME.

Welcome & Introductions

Laurie Pestel, Pharm.D. called the meeting to order at 9:35 a.m. at the Learning Resource Center in West Des Moines. The minutes from the February 5, 2014 meeting were reviewed. Kellen Ludvigson, Pharm.D motioned to accept them, and Brian Couse, M.D. seconded. All members were in favor.

IME Updates

Dr. Kessler provided an update on the chronic condition health home program, along with the current quality improvement projects that aim to: reduce admissions for short-term complications of diabetes; reduce emergency department use for patients with asthma; and improve birth outcomes through decreases in tobacco use in pregnant mothers. The Iowa Health and Wellness Dental Plan will go into effect on May 1, 2014.

Prevalence Report Summary

Statistics from January though February 2014 were discussed, including: cost per user ($269.37), number of total prescriptions dispensed (an increase of 20.6% compared to the previous reporting period due to IHAWP going into effect January 1st), average cost per prescription ($60.67), and generic utilization (83.1%). The total paid amount increased by 20.0% from the previous reporting period. There were 173,253 unique users, which is 16.4% more than the total for November and December. 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, Synagis*, methylphenidate hcl er, *Focalin XR, Advate, Lantus, Cymbalta, Advair Diskus*, and *Strattera*.

Case Studies

Pam Smith, R.Ph. presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $3,271.26 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Donald Hillebrand	Unity Point Center for Liver Disease	Hepatitis C Agents, specifically Sovaldi
Michelle Mattox	Vertex	Kalydeco
Carolyn Savini	Gilead	Sovaldi
Anthony Pudlo	Iowa Pharmacy Association	IPA's efforts targeting substance abuse
Jennifer Stoffel	Janssen	Olysio

Focus Studies

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. The Commission pointed out statistical outliers and other lines that didn't make sense with common prescribing practices. Pam Smith will check to make sure methodone was considered a long-acting agent in the study results. The members feel it would be beneficial to share these findings with the IME Lock-in and Program Integrity units in addition to working with the Medical Board to share the data. Pam Smith, R.Ph. will also look at claim level detail for the outlying prescribers.

Butalbital Utilization: All members were in favor of a quantity limit of 60 units per 30 days being implemented. Members on high doses will be allowed time to taper though the prior authorization process.

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. 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. Arkansas' limits will be used for comparison. Pam Smith, R.Ph. will bring her findings back to the June meeting.

Overutilization of Nitroglycerin for Acute Angina Pectoris: Letters will be sent to the prescribers of members identified as filling nitroglycerin monthly to ask if the patient's therapy has been recently evaluated to decrease the need for regular use of nitroglycerin (optimize dose of beta-blocker, calcium-channel blocker, or ranolazine and/or add an additional agent if needed) and provide information on the proper storage of product and when to replace product.

Chronic Use of Transdermal Scopolamine: A quantity limit of 8 patches per 30 days will be implemented. Additionally, the prescribers of the 34 members identified will be sent letters inquiring what the medical necessity is for continued use of transdermal scopolamine (*Transderm Scōp*), also suggesting other alternative agents and informing

them of the new quantity limit.

Public Comment

Name	Representing	Drug/Topic
Jennifer Pudenz	Herself (ARNP at Trinity in Fort Dodge)	Better access to neuropathic meds
Jim Baumann	Pfizer	Chronic Pain Syndromes PA criteria
Tom Yelle	GlaxoSmithKline	Mekinist – updated FDA indication

Review of Medical Necessity

Mirvaso: Medicaid programs pursuant to Sec. 1927(d)(2) of the Social Security Act, may exclude from coverage agents when used for cosmetic use [441IAC 78.2(4)]. Iowa Medicaid Rules currently exclude drugs used for "cosmetic purposes or hair growth." The Commission members unanimously agreed that *Mirvaso* was not medically necessary, as it was for the treatment of erythema of rosacea only, so it will not be covered by Iowa Medicaid.

Osphena: Medicaid programs pursuant to Sec. 1927(d)(2) of the Social Security Act, may exclude from coverage agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition other than sexual or erectile dysfunction, for which the agents have been approved by the FDA. Iowa Medicaid Rules currently exclude coverage of drugs used for sexual or erectile dysfunction. The Commission members unanimously agreed that *Osphena* was not medically necessary, as treatment of dyspareunia due to menopause fell into the sexual dysfunction category, so it will not be covered by Iowa Medicaid.

Prior Authorization

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

A prior authorization is required for duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™). 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.

Opioid use must be decreased and/or discontinued upon approval of these agents. A plan to decrease opioid use must be provided prior to consideration for patients with current opioid use as seen in pharmacy claims.

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.

Pam Smith, R.Ph. will finalize revisions to the criteria as requested by the Commission, removing tramadol as a trial option for fibromyalgia and diabetic peripheral neuropathy and muscle relaxants as a trial for fibromyalgia and bring the revised criteria back to the June meeting.

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. *Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and*
4. *Patient is not a pregnant female or a male with a pregnant female partner; and*
5. *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*
6. *Documentation that routine monthly pregnancy tests are performed during*

this time; and

7. *Documentation is provided that patient has been educated on how to prevent further liver damage and patient will abstain from alcohol use; and*
8. *Medication is prescribed by an infectious disease specialist, gastroenterologist, or hematologist.*
9. *Non-FDA approved combination therapy regimens will not be approved.*

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 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 peg-interferon alfa and ribavirin. A maximum 12 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.*
- *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.*

The criteria will be sent to specialists for their input, and Pam Smith will look at what other states and common insurers have been doing. Given the high costs and addiction issues involved, the Commission agreed access to these medications, especially Sovaldi, should be restricted as much as possible. Larry Ambroson, R.Ph. motioned to accept the criteria as amended, and Kellen Ludvigson, Pharm.D. 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 one preferred generic SNRI; 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.

Larry Ambroson, R.Ph. motioned to accept the criteria, and Brian Couse, M.D. seconded. The decision was unanimous. Additionally, quantity limits of 30 units per 30 days will be put in place for both levomilnacipran and voritoxetine.

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: 551D, 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.*

Larry Ambroson, R.Ph. motioned to accept the criteria, and Kellen Ludvigson, Pharm.D. seconded. All members were in favor.

Anti-Diabetics, Non-Insulin Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for preferred anti-diabetic, non-insulin agents subject to clinical criteria. Payment will be considered under the following conditions:

1. *A diagnosis of Type 2 Diabetes Mellitus, and*
2. *Patient is 18 years of age or older, and*
3. *The patient has not achieved HgbA1C goals after a minimum three month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated.*

Payment for a non-preferred anti-diabetic, non-insulin agent subject to clinical criteria will be authorized only for cases in which there is documentation of previous trials and therapy failures with metformin, a preferred DPP-4 Inhibitor and a preferred Incretin Mimetic at maximally tolerated doses, unless evidence is provided that use of these agents would be medically contraindicated.

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 continued improvement in HgbA1C.

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

Trametinib (Mekinist): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient is 18 years of age or older; and*
2. *Patient has a documented diagnosis of unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutation as detected by an FDA-approved test; and*
3. *Patient has not received prior therapy with a BRAF-inhibitor; and*
4. *Prescriber is an oncologist.*

If the criteria for coverage are met, authorizations will be given at three (3) month intervals. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued.

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

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 26, Number 3. No changes were recommended. As this was the initial review, it will be brought back to the June meeting for a second review.

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

A unanimous roll call vote was made at 12:35 to adjourn the meeting and move to closed session (motion by Larry Ambroson, R.Ph. second by Kellen Ludvigson, Pharm.D.).

The next meeting will be held at 9:30 a.m. on Wednesday, June 4, 2014, at the Learning Resource Center in West Des Moines.