Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes February 5, 2014

Attendees:

Commission Members
Laurie Pestel, Pharm.D.; Mark Graber, M.D., FACEP (via phone); Jason Wilbur, M.D. (via phone); Kellen Ludvigson, Pharm.D. (via phone); Larry Ambroson, R.Ph. (via phone); Brett Faine, Pharm.D. (via phone); Brian Couse, M.D. (via phone); and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Chuck Wadle, D.O., Magellan; Jason Kessler, M.D., IME; Megan Smith, Pharm.D., IME; and Melissa Biddle, IME.

Welcome & Introductions

Laurie Pestel called the meeting to order at 9:33 a.m. at the Learning Resource Center in West Des Moines. Six Commission members attended via phone, allowable as attending in person was impractical due to inclement weather. The minutes from the December 4, 2013 meeting were reviewed. Dr. Wilbur motioned to accept them, and Larry Ambroson seconded. A roll call vote was done since most of the Commission members were on the phone. All members were in favor.

IME Updates

In the spring of 2014, IME is planning to update the chronic condition health home program, addressing some of the barriers that may have slowed the progression of the provider and member participation. 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 Iowa Health and Wellness Plan was implemented on January 1, 2014, providing coverage to many members who were previously enrolled in the IowaCare program, which ended on December 31, 2013. Those that fell between 0% and 100% of the federal poverty level were enrolled in the Wellness Plan, and those between 101% and 133% were enrolled in the Iowa Marketplace Choice Plan or instructed to visit the Health Insurance Marketplace to find coverage if IME could not verify their income.

Prevalence Report Summary

Statistics from November though December 2013 were discussed, including: cost per user ($260.73), number of total prescriptions dispensed (a decrease of 4.1% compared to the previous reporting period), average cost per prescription ($61.00), and generic utilization (83.3%). The total paid amount decreased by 0.5% from the previous reporting period. There were 148,507 unique users, which is 3.3% less than the total for September and October. 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: *Vyvanse, Abilify, Synagi*s, methylphenidate hcl er, *Focalin XR, Advate, Cymbalta, Adderall XR, Lantus*, and *Strattera*.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $534.80 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	Lyrica, Chronic Pain Syndromes PA
Rebecca Blair	Herself (NP at pain management clinic)	Opiates and non-opiates prior auth criteria
Steven Lukan	Director, Iowa Office of Drug Control Policy	Chronic Pain Syndromes PA criteria

Focus Studies

Duplicate SSRI: This was a follow-up discussion. Twenty-three of the 50 members identified changed therapy, for an annualized cost savings of $10,549.96 (state and federal, pre-rebate) as a result of the 126 surveys sent out to prescribers and pharmacies. Sixty (47.62%) of those surveys were returned.

Duplicate TCA: This was a follow-up discussion. Eight of the 13 members identified changed therapy, for an annualized cost savings of $2,079.72 (state and federal, pre-rebate) as a result of the 34 surveys sent out to prescribers and pharmacies. Twenty (58.82%) of those surveys were returned.

Prescriber Trends in Opiate Prescribing: Findings will be plotted on a graph to illustrate opioid units per day and morphine sulfate equivalents per day, along with provider types to identify outliers. Pam Smith will make the graphs and send them to the Commission members for feedback.

Chronic Short-Acting Opioid Use without a Long-Acting Opioid: Data will be re-run to look at TCAs (amitriptyline), gabapentin, and tramadol used in combination with short-acting opioids, short-acting opioids by percent of opioid utilization and if there are multiple prescribers. Results will be broken out by type and drug, and include all required trials on the Chronic Pain Syndromes prior authorization form. Pam Smith will also look into what other states are doing.

Butalbital Utilization: Data will be run to see how many members would be impacted if a quantity limit of 30 or 60 per 30 days was implemented, if the limit could be applied to the GPI, and if an accumulator edit could restrict limits for 6 months or a year as well.

Those on high does could be allowed time to taper though the prior authorization process. This will be re-evaluated at the April meeting.

Public Comment

There were no public comments.

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™). 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 three drugs from three distinct therapeutic classes from the following: tricyclic antidepressant, muscle relaxant, SSRI/SNRI, tramadol, or gabapentin, 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 at least two drugs from two distinct therapeutic classes from the following: tricyclic antidepressant, topical lidocaine, valproate, carbamazepine, or gabapentin.
3. *A diagnosis of diabetic peripheral neuropathy (Cymbalta® and Lyrica®)*

    A trial and therapy failure at a therapeutic dose with at least two drugs from two distinct therapeutic classes from the following: tricyclic antidepressant, topical lidocaine, tramadol, or gabapentin.
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.

Pam Smith will send out the electronic version of the comparison studies she spoke about. Mark Graber suggested reducing the musculoskeletal pain trials to two. This topic will be tabled until April to see if generic *Cymbalta* becomes less expensive.

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. *Medication is prescribed by an infectious disease specialist, gastroenterologist, or hematologist.*

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.*
- *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.*
- *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.*
- *Patient has a documented diagnosis of hepatitis C genotype 4 and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed.*
- *Patient has a documented diagnosis of hepatitis C genotype 1 with HIV co-infection and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed.*
- *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.*
- *Patient has a documented diagnosis of hepatitis C genotype 1 who is peg-interferon ineligible and is used in combination with ribavirin. A maximum 24 weeks of therapy will be allowed. Requests for patients with a documented diagnosis of hepatitis C genotype 1 without HIV co-infection and are peg-interferon eligible will not be considered.*

Dr. Graber suggested splitting out criteria by genotype since drugs did not have equal effectiveness on all of them, and he pointed out that the older regimens have more side effects that might not merit the cost of the medications. Information regarding educating the patient about alcohol abuse will be added to the PA form. Pam Smith will research, and bring her findings back to the April meeting. The P&T Committee will have created

a draft PDL for its own April meeting by then which should assist the DUR in developing criteria for the newer agents.

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.

Dr. Graber motioned to accept the criteria, and Dr, Wilbur seconded. A roll call vote was done since most of the Commission members were on the phone. All members were in favor.

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. *Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.*
6. *Requests for patients with concurrent use a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.*
7. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gove/IAPMPWebCenter/ prior to requesting prior authorization.*

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 with be sent to the Department for consideration.

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

Prior authorization is required for anti-diabetic, non-insulin agents. Payment for preferred agents 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 agent 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.

The first two lines will be revised to clarify that the statement is not intended for all agents, even those that wouldn't require prior authorization, and then this will be brought back to the next meeting.

Proton Pump Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day. Requests for PPIs exceeding one unit per day for a diagnosis of gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with concomitant use of once daily PPI dosing and a bedtime dose of a histamine H2-receptor antagonist. Upon failure of the combination therapy, subsequent requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a retrial of the recommended once daily dosing will be required. A trial of the recommended once daily dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day.

Requests for twice daily dosing for a diagnosis of Helicobacter pylori will be considered for up to 14 days of treatment with documentation of an active

infection.

Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products.

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

Miscellaneous

DUR Digest: The Commission member reviewed the draft for DUR Digest Volume 26, Number 2 for a second time. No changes were recommended. The DUR Digest 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 11:54 to adjourn the meeting and move to closed session (motion by Dr. Graber, second by Larry Ambroson).

The next meeting will be held at 9:30 a.m. on Wednesday, April 2, 2014, at the Learning Resource Center in West Des Moines.