# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes December 3, 2014

**Attendees:**

| **Commission Members** |
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| Mark Graber, M.D., FACEP, MSHCE; Laurie Pestel, Pharm.D.; Gregory Barclay, M.D.; Kellen Ludvigson, Pharm.D.; Larry Ambroson, R.Ph.; Brett Faine, Pharm.D.; Brian Couse, M.D.; Jason Wilbur, M.D.; and Susan Parker, Pharm.D. |

| **Staff** |
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| Pam Smith, R.Ph. |

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

## Welcome & Introductions

Mark Graber called the meeting to order at 9:32 a.m. at the Learning Resource Center in West Des Moines. The minutes from the October 1, 2014 meeting were reviewed. Brian Couse motioned to accept them, and Kellen Ludvigson and Gregory Barclay seconded simultaneously. All members were in favor. The recommendation letter sent to DHS after the last meeting, the letter sent to the P&T Committee by the DUR Commission recommending niacin products be made non-preferred on the PDL, and the annual Federal and State DUR reports were also reviewed.

## IME Updates

As of December 1, 2014, Iowa Medicaid is now covering an additional 9,700 members previously enrolled in CoOportunity under the Iowa Health and Wellness Plan (IHAWP), as CoOportunity has withdrawn participation in the Marketplace. The State is currently working with CMS to establish ongoing options for these individuals that had been enrolled in the Marketplace Choice Plan, but these members will remain in the Wellness Plan until options are explored with CMS. Prescribers and members have received notification. DHS is working on budget issues, and the legislative session starts in mid-January. As requested at the last meeting, Pam Smith provided more information as to how the IME Lock-in department identifies members for their program. Parameters include: the number of controlled substances, different prescribers of controlled substances, multiple pharmacies, number and days supply of the controlled substances, exclusivity of short-acting opioids, multiple ER visits, along with other things such as diagnosis of poisoning by a prescribed controlled substance or if the member is seeing multiple providers for the same diagnosis. Diagnoses and eligibility are also incorporated into the score algorithm, and members are locked in for 24 months once they have been identified. Members with a malignancy or tumor are excluded. There are currently about 1800 members in the lock-in program.

## Prevalence Report Summary

Statistics from September though October 2014 were discussed, including: cost per user ($298.51), number of total prescriptions dispensed (an increase of 9.4% compared to the previous reporting period), average cost per prescription ($60.27), and generic utilization (83.7%). The total paid amount increased by 8.4% from the previous reporting period. There were 198,167 unique users, which is 8.4% more than the total for July and August. 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, Lantus, Focalin XR, Cymbalta, Advate, Ventolin HFA, Advair Diskus, and Strattera.

## Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $11,496.61 pre-rebate (state and federal).

## Public Comment

| Name | Representing | Drug/Topic |
|---|---|---|
| Paul Miner | Gilead | Sovaldi and Harvoni |
| Kendig Bergstresser | Celgene | Otezla |
| Michael Voight | Patient Representative | Hepatitis C PA Criteria |
| Antonio Sanchez | University of Iowa Liver Transplant Center | Harvoni |
| Donald Hilldebrand | UnityPoint (Gilead and Abbvie Speaker Bureaus) | Harvoni |
| Jennifer Stoffel | Janssen | Olysio |
| Tyler Whisman | Novartis | Zykadia and Exjade |

## Focus Studies

***Three or More Antiepileptics with a Seizure Diagnosis:*** This was a follow-up discussion. Fifty-three (53) of the 291 members identified changed therapy, for an annualized cost savings of $255,021.08 (state and federal, pre-rebate) as a result of the 751 surveys sent out to prescribers and pharmacies. A total of 312 (41.54%) surveys were returned.

***Three or More Antiepileptics without a Seizure Diagnosis:*** This was a follow-up discussion. Ten (10) of the 25 members identified changed therapy, increasing the annual cost by $3,832.96 (state and federal, pre-rebate) due to pre-rebate costs being reported, as a result of the 73 surveys sent out to prescribers and pharmacies. A total of 29 (39.73%) surveys were returned.

***Memantine Utilization without a Valid Diagnosis:*** This was a follow-up discussion. Nineteen (19) of the 51 members identified changed therapy, for an annualized cost savings of $42,567.64 (state and federal, pre-rebate) as a result of the 108 surveys sent out to prescribers and pharmacies. A total of 48 (44.44%) surveys were returned.

***Duloxetine Dose Greater than 120mg per Day:*** This was a follow-up discussion. Both of the members identified lost Medicaid eligibility since October 1, 2013. Four surveys had been sent out to prescribers and pharmacies, but only 1 (25%) of the surveys was returned.

***High Dose Stimulants in Children:*** The providers of members exceeding 40mg per day of immediate-release amphetamine salt combo tablets will be contacted to ask if the dose could be decreased to a maximum of 40mg per day. Additionally, the providers of members exceeding 60mg per day of immediate-release methylphenidate tablets will be contacted to ask if the dose could be decreased to a maximum of 60mg per day. The Commission suggested looking into all stimulants, including long-acting, or those on combinations of long and short acting. Pam Smith agreed that the quantity limits on the long-acting stimulants needed to be adjusted, and will bring recommendations back to the next meeting.

***Benzodiazepine Dosing:*** Letters will be sent to the prescribers of members combining two or more benzodiazepines concomitantly, and also those prescribing benzodiazepines without an SSRI or SNRI in patients that have an anxiety diagnosis. Pam Smith will break down the claims data to help determine appropriate quantity limits. She will also look at alprazolam usage to determine the impact of these limits. Erin Halverson suggested lowering the quantity limits slowly prior to adding a duplicate edit to control access to multiple strengths.

**Public Comment**

There were no additional public speakers.

**Prior Authorization**

***Hepatitis C Agents:*** 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. *Documentation of viral load taken within 6 months before beginning therapy; and*
4. *Viral load will be submitted by prescriber 12 weeks after completion of therapy; and*
5. *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*
6. *For patients on a regimen containing ribavirin, the following must be documented on the PA form:*
   a) *Patient is not a pregnant female or a male with a pregnant female partner;*

*and*

   b) *Women of childbearing potential and their male partners must use two forms of effective contraception (non-hormonal contraception for patients taking Sovaldi™) during treatment and for at least 6 months after treatment has concluded; and*
   c) *Documentation that routine monthly pregnancy tests are performed during this time; and*

7. *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*
8. *Prescriber is an infectious disease specialist, gastroenterologist, hepatologist or other hepatitis specialist.*
9. *Where applicable, 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; or a history of preexisting unstable cardiac disease.*
10. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
11. *If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on established length of therapy for the particular treatment (defined below).*
12. *Lost or stolen medication replacement requests will not be authorized.*
13. *The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.*

***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; and*
- *Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and*
- *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; and*
- *Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and*
- *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 advanced liver disease stage 3 or greater fibrosis as confirmed by one of the following indicators related to staging of liver fibrosis (attach test results/documentation):*
  - *Liver biopsy confirming a Metavir score ≥ F3; or*
  - *Transient elastography (FibroScan) score ≥ 9.5kPa; or*
  - *FibroSURE (FibroTest) score ≥ 0.58; or*
  - *APRI score > 1.5; or*
  - *Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); and*
  - *Physical findings or clinical evidence consistent with cirrhosis.*
- *Dosing and length of therapy will be based on the following:*
  - ***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.*

***Harvoni***

- *Patient has documentation of hepatitis C genotype 1a or 1b; and*
- *The patient is not receiving dialysis or does not have a CrCl < 30 mL/min; and*
- *Patient is not co-infected with hepatitis B or HIV; and*
- *Patient does not have decompensated liver disease; and*
- *Patient has a contraindication to a preferred peg-interferon alfa plus ribavirin based regimen (e.g. sofosbuvir + peg-interferon + ribavirin); and*
- *Documentation the patient has advanced liver disease as confirmed by one of the following indicators related to staging of liver fibrosis (attach test results/documentation):*
  - *Liver biopsy confirming a Metavir score ≥ F3; or*
  - *Transient elastography (FibroScan) score ≥ 9.5kPa; or*
  - *FibroSURE (FibroTest) score ≥ 0.58; or*
  - *APRI score > 1.5; or*
  - *Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); and*
  - *Physical findings or clinical evidence consistent with cirrhosis.*
- *Dosing and length of therapy will be based on the following:*
  - *Patient is treatment-naïve without cirrhosis and has a documented pre-treatment baseline HCV RNA less than 6 million IU/mL. A maximum 8 weeks of therapy will be allowed; or*
  - *Patient is treatment-naïve with or without cirrhosis and has a documented pre-treatment baseline HCV RNA greater than 6 million IU/mL. A maximum 12 weeks of therapy will be allowed; or*
  - *Patient is treatment-experienced without cirrhosis and experienced failure with a previous treatment regimen that included either peg-interferon alfa + ribavirin or an HCV protease inhibitor + peg-interferon alfa + ribavirin. A maximum 12 weeks of therapy will be allowed; or*
  - *Patient is treatment-experienced with cirrhosis and experienced failure with a previous treatment regimen that included either peg-interferon alfa + ribavirin or an HCV protease inhibitor + peg-interferon alfa + ribavirin. A maximum 24 weeks of therapy will be allowed.*

Jason Wilbur motioned to accept the criteria as modified, and Brian Couse seconded. All members were in favor. Criteria will be sent to the medical and pharmacy associations for comment.

***Deferasirox (Exjade):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for deferasirox. Payment will be considered under the following conditions:*

1. *Patient does not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance <40mL/min; and*
2. *Patient does not have a poor performance status; and*
3. *Patient does not have a high-risk myelodysplastic syndrome; and*
4. *Patient does not have advanced malignancies; and*
5. *Patient does not have a platelet count <50 x $10^9$/L.*

***Transfusional Iron Overload***

*Initiation of Therapy*

1. *Patient is 2 years of age or older; and*
2. *Patient has documentation of iron overload related to anemia (attach documentation); and*
3. *Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overload; and*
4. *Serum ferritin is consistently >1000 mcg/L (attach lab results dated within the past month); and*
5. *Starting dose does not exceed 20mg/kg/day. Calculate dose to the nearest whole tablet.*
6. *Initial requests will be considered for up to 3 months.*

*Continuation of Therapy*

1. *Serum ferritin has been measured within 30 days of continuation of therapy request (attach lab results); and*
2. *Ferritin levels are >500mcg/L; and*
3. *Dose does not exceed 40mg/kg/day.*

***Non-Transfusional Iron Overload***

*Initiation of Therapy*

1. *Patient is 10 years of age or older; and*
2. *Patient has documentation of iron overload related to anemia (attach documentation); and*
3. *Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and*
4. *Serum ferritin levels are >300mcg/L.*
5. *Liver iron concentration (LIC) are >3mg Fe/g dw; and*
6. *Dose does not exceed 10mg/kg/day (if LIC is <15mg Fe/g dw), or 20mg/kg/day (if LIC is >15mg Fe/g dw).*
7. *Initial authorization will be considered for up to 6 months.*

*Continuation of Therapy*

1. *Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and*
2. *Serum ferritin levels are >300mcg/L; and*
3. *Liver iron concentration (LIC) is >3mg Fe/g dw; and*

4. *Dose does not exceed 10mg/kg/day (if LIC is 3 to 7mg Fe/g dw) or 20mg/kg/day (if LIC is >7mg Fe/g dw).*

Kellen Ludvigson motioned to accept the criteria as modified, and Brian Couse seconded. All members were in favor. Criteria will be sent to the medical and pharmacy associations for comment.

***Vorapaxar (Zontivity):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for vorapaxar (Zontivity™). Payment will be considered under the following conditions:*

1. *Patient has a history of myocardial infarction (MI) or peripheral artery disease; and*
2. *Patient does not have a history of stroke, transient ischemic attack (TIA), intracranial bleeding, or active peptic ulcer; and*
3. *Patient has documentation of an adequate trial and therapy failure with aspirin plus clopidogrel; and*
4. *Patient will use vorapaxar concurrently with aspirin and/or clopidogrel.*

*The required trials may be overridden when documented evidence is provided that the use of this agent would be medically contraindicated.*

Brett Faine and Kellen Ludvigson simultaneously motioned to accept the criteria as modified, and Brian Couse seconded. All members were in favor. Criteria will be sent to the medical and pharmacy associations for comment.

***Ceritinib (Zykadia):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for ceritinib (Zykadia™). Payment will be considered under the following conditions:*

1. *Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test (attach copy of results); and*
2. *Patient is 18 years of age or older; and*
3. *Prescribed by a oncologist; and*
4. *Patient has documentation of treatment with crizotinib and the disease has progressed while on treatment or is intolerant to treatment.*
5. *Liver function tests (ALT, AST, and total bilirubin) will be monitored at least monthly while on ceritinib.*

*If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered with documentation patient has not experienced disease progression or unacceptable toxicity.*

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

**ProDUR Edit**

***Antipsychotics – Age Edit and Duplicate Therapy Edit:*** The DUR Commission also discussed the Mental Health Advisory Group's (MHAG) comments on the recommendations the DUR Commission initially made in April 2012 to implement ProDUR edits on antipsychotics in members less than 18 years of age. Specifically, the recommendation was to: 1) implement an age edit on risperidone for members less than five (5) years of age and an age edit on all other antipsychotics for members less than six (6) years of age; and 2) apply a duplicate therapy edit to all antipsychotics. The MHAG wondered if the age edits on haloperidol and chlorpromazine should be lowered to 3 years of age and six months of age respectively, to match the FDA standards. After discussion, the Commission continues to support implementation of the aforementioned ProDUR edits, tentatively scheduled for implementation in the summer of 2015. The members feel the age edits should not be lowered for haloperidol and chlorpromazine, and that requiring prior authorization for cases in which the prescribers want to use these medications for young children would be a good idea to confirm appropriate use. Prior to initiation of these edits, an informational letter will be sent to all providers, to encourage changes to drug regimen or submission of a PA prior to implementation of the edits and prior to discharge. Soft edits will also be programmed into the Point of Sale (POS) system indicating the claim(s) will deny for a PA at the specific date indicated, which should prompt the pharmacy to notify the prescriber. A draft of a FAQ document, which will likely be attached to the upcoming informational letter, was also provided. It covered topics such as how the ProDUR edits work in the POS system, the prior authorization process, and which antipsychotic medications would require prior authorization due to the new ProDUR edits. Chronic concurrent use will be considered on a case by case basis, but should be avoided if possible. A POS edit for a 30 day grace period to allow for tapering is being explored to decrease the need for PA when transitioning from one agent to another.

**Miscellaneous**

***DUR Digest:*** The Commission members reviewed the draft for DUR Digest Volume 27, Number 2. No changes were recommended. It will be brought back to the next meeting for final review.

***MedWatch:*** The Commission members received FDA announcements regarding: methylphenidate hcl er tablets made by Mallinckrodt and Kudco; FDA approval of extended-release, single-entity hydrocodone product with abuse-deterrent properties; warning of case of rare brain infection PML with Tecfidera; and FDA approval of first combination pill to treat hepatitis C.

***New York Times Article – Cystic Fibrosis Foundation:*** The Commission members received copies of this recent article detailing the Cystic Fibrosis Foundation deal that allows for the foundation to receive 3.3 billion from selling the rights to royalties of drugs developed for the lung disease.
http://www.nytimes.com/2014/11/19/business/for-cystic-fibrosis-foundation-venture-

yields-windfall-in-hope-and-cash.html

A unanimous roll call vote was made at 11:50 to adjourn the meeting and move to closed session (motion by Brian Couse, second by Jason Wilbur).

**The next meeting will be held at 9:30 a.m. on Wednesday, February 4, 2015, at the Learning Resource Center in West Des Moines.**