# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes June 6, 2012

**Attendees:**

| **Commission Members** |
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| Mark Graber, M.D., FACEP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brett Faine, Pharm.D.; and Susan Parker, Pharm.D. |

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

| **Guests** |
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| Chuck Wadle, D.O., Magellan; Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; Megan Smith, Pharm.D.; and Melissa Biddle, IME. |

## Welcome & Introductions

Dr. Graber called the meeting to order at 9:35 a.m. at Magellan Health Services in West Des Moines. The minutes from the April 4, 2012 meeting were reviewed. Dr. Schutte-Schenck motioned to accept them, and Craig Logemann seconded. The vote was unanimous.

## IME Updates

The IME has written a proposal, currently posted on the IME website for public comment, to share savings with CMS for dual eligible members. Savings will be generated in multiple ways over the next three years beginning in January of 2013, by use of the health homes, expansion of the disease management programs, and focusing on home and community based programs over institutional care. The IME has submitted its State Plan Amendment for health homes for people with chronic diseases to CMS, where approval is pending. Interested providers are being allowed to enroll in health homes, and can now also enroll members as of June 1st with payments to begin on July 1st. The legislature passed the appropriations bill changing the reimbursement from Average Wholesale Price to Average Acquisition Cost (AAC), and DHS is currently performing a cost of dispensing survey. The AAC will be effective January 1, 2013, and letters and surveys will go out this week. CMS has also been required to launch a retail price survey, releasing two documents on May 31st in regards to this National Drug Average Acquisition Cost. Myers and Stauffer have been contracted to perform monthly surveys of retail community pharmacies and generate an average acquisition cost, similar to what's being proposed on the state level. The CMS draft methodology document is posted on their website. Pam Smith provided a summary of the last Federal Annual DUR report, which included the overall cost and savings of the DUR program. She will supply a copy of the Federal Fiscal Year 2011 report once it's completed. This will be the last DUR Commission meeting for Dr.Schutte-Schenck and Craig Logemann, as their second terms will be expiring this month. Pam Smith thanked them for their 8 years of service, and presented certificates and letters of appreciation

signed by Medicaid Director Jennifer Vermeer. Jason Wilbur, M.D., and Kellen Ludvigson, Pharm.D., will be taking over those Commission seats beginning July 1st.

**Prevalence Report Summary**

Statistics from March though April 2012 were discussed, including: cost per user ($269.68), number of total prescriptions dispensed (an increase of 1.1% compared to the previous reporting period), average cost per prescription ($64.47), and generic utilization (77.5%). The total paid amount increased by 4.0% from the previous reporting period. There were 164,680 unique users, which is 0.6% less than the total for January and February 2012. Lists of the top 20 therapeutic classes were provided. Atypical Antipsychotics were the most expensive, 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. Eight of the ten most expensive medications were mental health drugs.

**Case Studies**

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $3,434.43 pre-rebate (state and federal).

**Public Comment**

Don Iacobellis from Eli Lilly spoke about Cymbalta.

**Hepatitis C Triple Therapy Adherence analysis**

This was initially presented at the April meeting, and the Commission had wanted to know how many unique prescribers there were. Pam Smith presented updated claims data. She had also contacted the prescriber identified as having the highest prescription count for input, and inquired if there was a monitoring system in place. The prescriber stated that members needed to be in a good place, both physically and mentally, in order to begin this therapy, and she makes sure to emphasize to the patient how important it is to take these expensive medications on a regular basis, and that it's wasteful if they don't. She does not allow any refills on any of these medications, so when she gets a refill request from the pharmacy, she checks lab work, and requires the patients to come in for office visits monthly at first, as well. She questions them about their compliance, and is usually alerted by unchanging hemoglobin levels if they are not compliant. She prefers to use US Bioservices, one of the specialty pharmacies, for all of her patients, if their plan allows it, as they track the patients as well. She also works with Iowa Department of Public Health. She sometimes gives out samples of these medications, which could explain the gaps in therapy on patient profiles. The prescriber felt that letters were unnecessary as they were already following the steps detailed above. There were a total of 25 physicians with submitted claims for these medications, mostly in Des Moines, Fort Dodge, or at the University of Iowa. Dr. Graber mentioned that the CDC had just put out a recommendation that everyone in a certain age group be tested for Hepatitis C, so utilization will likely increase. The Commission agreed that letters were not necessary at this time, however.

**Prior Authorization**

***Buprinorphine (Suboxone):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for buprenorphine/naloxone (Suboxone®). Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Payment will be considered for patients when the following is met:*

1. *Patient has a diagnosis of opioid dependence and is 16 years of age or older; AND*
2. *Prescriber meets qualification criteria to prescribe buprenorphine/naloxone (Suboxone®) for opioid dependence and has an "X" DEA number; AND*
3. *Patient is participating in formal substance abuse counseling/psychosocial therapy; AND*
4. *A projected treatment plan is provided, including:*
   - *anticipated induction/stabilization dose,*
   - *anticipated maintenance dose,*
   - *anticipated taper schedule,*
   - *expected frequency of office visits, and*
   - *expected frequency of counseling/psychosocial therapy visits.*
5. *Requests for renewal must include:*
   - *An updated treatment plan, including last date of dose taper,*
   - *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request,*
   - *Documentation of a current, negative drug screen,*
   - *Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.*
6. *Requests for buprenorphine will only be considered for pregnant patients.*

Dr. Wadle said that the usage should be capped at 8mg, and allowed for 6 months at the higher dose, for up to a year once lowered. Positive drug screens need to be verified. If a member has a negative drug screen and negative PMP, then the PA could be renewed. The initial PA will be approved for 3 months, and then reviewed for renewal. Craig Logemann referred to North Carolina's criteria as a recommendation for the length of treatment. A draft PA form will be brought to the next meeting.

***Vemurafenib (Zelboraf):*** The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient is 18 years of age or older; and*
2. *Has a diagnosis of unresectable or metastatic melanoma with $BRAF^{V600E}$ mutation as detected by an FDA-approved test; and*
3. *Prescriber is an oncologist.*

Dr. Graber and Brett Faine will attempt to contact an oncologist at the University of Iowa for input, as Pam Smith received no response in regards to her inquiry regarding the criteria. They will then email Pam, and she will bring the comments back to the next

meeting so that length of therapy can be determined. The Commission has suggested either 3 months or 12 weeks.

***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, 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 antidepressant.*

   *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.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary. The criteria will be sent to DHS for their consideration and implementation.

***Sedative/Hypnotics Non-Benzodiazepines:*** The Commission reviewed the prior authorization criteria as follows:

*Preferred agents are available without Prior Authorization (PA). Although intermittent therapy is recommended, quantity limits will allow 30 tablets per 30 days supply without PA for preferred medications.*

*Prior authorization is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when there is:*

1) *A diagnosis of chronic insomnia (insomnia lasting ≥ 6 months,*
2) *Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued,*
3) *Enforcement of good sleep hygiene is documented.*
4) *All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses*
5) *Patient has a documented trial and therapy failure with zaleplon.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary. The criteria will be sent to DHS for their consideration and implementation.

***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. *Patients is 6 years of age or older; and*
2. *Has a diagnosis of cystic fibrosis with a G551D mutation in the CFTR gene as detected by an FDA-cleared CF mutation test; and*
3. *Prescriber is a CF specialist or pediatric pulmonologist; and*
4. *Patient does not have one of the following infections: Burkholderia cenocepacia, dolosa, or Mycobacterium abcessus.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary. Craig Logemann had suggested removing requirement #4, but the Commission decided to leave it included for now unless more PA requests are received. The criteria will be sent to DHS for their consideration and implementation.

***Lost, Stolen, Destroyed Medication Overrides:*** The Commission reviewed the prior authorization criteria as follows:

*Non-controlled medications that are lost, stolen, or destroyed are limited to a one time override allowance per 12 month period. Overrides for the first occurrence of a lost, stolen, or destroyed medication can be obtained by contacting the POS Helpdesk at 1-877-463-7671 or locally at 515-256-4608.*

*Replacement of lost, stolen, or destroyed controlled substances and tramadol containing products will not be approved. In addition, no allowances will be provided for patients residing in a long term care (LTC) facility.*

*Requests exceeding the one time override allowance for non-controlled lost, stolen and destroyed medications may be considered with additional documentation. Requests for stolen medications must include a copy of a police report.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary. The criteria will be sent to DHS for their consideration and implementation.

***Crizotinib (Xalkori):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for Xalkori® (crizotinib). Payment will be considered for patients when the following is met:*

1. *Diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test (Please attach copy of test results); and*
2. *Is prescribed by an oncologist.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary. The criteria will be sent to DHS for their consideration and implementation.

**Public Comment**

There were no public comments.

**Focus Studies**

***Bipolar Depression:*** This was a follow-up discussion, and the Commission had no further comments.

***Topiramate in Women of Childbearing Age:*** This was a follow-up discussion, and the Commission had no further comments.

***Stimulant Use in Children Less than 4 Years Old:*** As this involves a very small percentage of the population, it will be published as a DUR Digest article, including the AAP Guidelines.

***Clonidine plus Guanfacine Duplicate Therapy:*** Letters will be sent to the prescribers of the 299 members combining immediate-release clonidine with immediate-release guanfacine, pointing out the duplication and asking if one medication could be discontinued.

**Miscellaneous**

***DUR Digest:*** The Commission members had no further changes or additions to the

draft for DUR Digest Volume 24, Number 3. It will be posted on the website.

**SMAC Updates:** The Commission members were given a copy of the SMAC changes that had gone into effect since March.

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

A unanimous vote was made at 11:27 to adjourn the meeting and move to closed session (motion by Craig Logemann, second by Dr. Schutte-Schenck).

**The next meeting will be held at 9:30 a.m. on Wednesday, August 1, 2012, at the Learning Resource Center in West Des Moines.**