# Iowa Medicaid Drug Utilization Review Commission
## Meeting Minutes October 5, 2011

**Attendees:**

| Commission Members |
| --- |
| Mark Graber, M.D., FACEP; Casey Clor, M.D. ; 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.; Gregory Barclay, M.D.; and Susan Parker, Pharm.D. |

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

| Guests |
| --- |
| Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; and Melissa Biddle, IME. |

**Welcome & Introductions**

Dr. Graber called the meeting to order at 9:36 a.m. at the Learning Resource Center in West Des Moines. The minutes from the August 3, 2011 meeting were reviewed. Dr. Schutte-Schenck motioned to accept them, and Dr. Clor seconded. The vote was unanimous.

**IME Updates**

Iowa is participating in a multi-state study through the Center for Healthcare Strategies, which is aiming to reduce disparities and improve the level of care provided to women and children enrolled in Medicaid and Hawk-I. Program Integrity initiatives have saved $23 million in the last year. House File 649 requires DHS to come up with a replacement for AWP reimubusement, which was eliminated on September 29, 2011 by First Data Bank. A public meeting is scheduled for October 25th in Capitol Room 116 to discuss this issue. This will be posted on the www.iowamedicaidpdl.com website on the Latest News page, and an email has been sent to the various manufacturers and other entities involved. An information letter will also be going out to providers. A recommendation is due to the legislature by December 15, 2011. The POS RFP proposals are in, and oral presentations scheduled. Awards should be announced in December. Pam Smith read through the public comment policy, specifically concerning the new addition of a deadline; this is posted on the www.iadur.org website.

**Prevalence Report Summary**

Statistics from July though August 2011 were discussed, including: cost per user ($258.77), number of total prescriptions dispensed (a decrease of 2.3% compared to the previous reporting period), average cost per prescription ($60.99), and generic utilization (76.7%). The total paid amount decreased by 0.8% from the previous reporting period. There were 149,038 unique users, which is 2.4% less than the total for May and June. Lists of the top 20 therapeutics 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, including 3 different strengths of Abilify.

**Case Studies**

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $1,327.73 pre-rebate (state and federal).

**Public Comment**

| ***Speaker*** | ***Topic*** |
|---|---|
| Felicia Williams from Merck | Januvia |
| Karen Loihl from the IA Psych Society | 15 Days Supply List |
| Susan Harrell (no manufacturer affiliation) | Synagis |
| Jeremy Franklin from MedImmune | Synagis |

**Ivermectin (*Stromectol*) Utilization**

At the last meeting, the Commission had asked if the claims data provided included topical compounds in addition to oral ivermectin. There was only one claim that was submitted as a compound over the 5-year span, but it's possible that they billed for the ivermectin and then compounded after the fact, as pharmacies are not reimbursed for the other excipients that go into the compound. Utilization will be monitored, and there will also be a DUR Digest article with regards to the treatment of head lice.

**Prior Authorization**

***Annual Review of PA Criteria:*** The Commission would like to re-evaluate PA criteria for the following categories: Angiotensin Receptor Blockers, Antihistamines, DPP-4 Inhibitors, Erythropoiesis Stimulating Agents, Nicotine Replacement Therapy, and Sedative/Hypnotics-Non-Benzodiazepines. Larry Ambroson motioned that these categories be addressed at upcoming meetings, and Brett Faine seconded. All members were in favor of the motion.

***Nicotine Replacement Therapy:*** The Commission reviewed quantity limits for the addition of nicotine nasal spray and nicotine inhaler to the list of covered products. The added criteria are as follows:

> *Requests for non-preferred nicotine replacement products will be considered after documentation of previous trials and intolerance with a preferred oral and preferred topical nicotine replacement product. A maximum quantity of 168 nicotine inhalers or 40ml of nicotine nasal spray may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4-week supply at 336 nicotine inhalers or 80ml of nicotine nasal spray.*

Larry Ambroson motioned to accept the above criteria, and Brett Faine seconded. The decision was unanimous.

***AntiAcne:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for all prescription topical acne products. Payment for the treatment of mild to moderate acne vulgaris will be considered under the following conditions:*

1. *Previous trial and therapy failure with a preferred over-the-counter benzoyl peroxide product, which is covered by the program without prior authorization.*
2. *Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity.*
3. *If the patient presents with a preponderance of comedonal acne, topical retinoid products may be utilized as first line agents with prior authorization (see Topical Retinoids PA form).*
4. *Requests for non-preferred combination products may only be considered after documented separate trials and therapy failures with the individual ingredients.*

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

Brett Faine motioned to accept the above criteria, and Craig Logemann seconded. The decision was unanimous.

***Topical Retinoids:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for all prescription topical retinoid products. Payment for prescription topical retinoid products will be considered under the following conditions:*

1. *Previous trial and therapy failure with a preferred over-the-counter benzoyl peroxide product, AND*
2. *Previous trials and therapy failures with two topical and/or oral antibiotics for the treatment of mild to moderate acne (non-inflammatory and inflammatory), and drug-induced acne.*
3. *Payment for non-preferred topical retinoid products will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent.*
4. *Trials and therapy failure will not be required for those patients presenting with a preponderance of comedonal acne.*
5. *Skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive automatic approval for lifetime use of topical retinoid products.*
6. *Requests for non-preferred combination products may only be considered after documentation of separate trials and therapy failures with the individual ingredients.*
7. *Requests for Tazorac for a psoriasis diagnosis may only be considered after documentation of a previous trial and therapy failure with a preferred topical antipsoriatic agent.*

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

Brett Faine motioned to accept the above criteria, and Larry Ambroson seconded. The decision was unanimous.

***Dextromethorphan/Quinidine (Nuedexta):*** The Commission reviewed the prior authorization criteria as follows:

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

1. *Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS).*
2. *A trial and therapy failure at a therapeutic dose with amitriptyline and an SSRI.*
3. *Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire.*
4. *Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.*

Dr. Clor motioned to accept the above criteria, and Dr. Schutte-Schenck seconded. The decision was unanimous.

***Roflumilast (Daliresp):*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for roflumilast (Daliresp). Payment will be considered for patients 18 years of age or older when the following is met:*

1. *A diagnosis of severe COPD with chronic bronchitis as documented by spirometry results, and*
2. *A smoking history of ≥ 20 pack-years, and*
3. *Currently on long-acting bronchodilator in combination with an inhaled corticosteroid with documentation of inadequate control of symptoms, and*
4. *A history of at least one exacerbation in the past year requiring treatment with oral glucocorticosteroids.*

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

Dr. Clor motioned to accept the above criteria, and Brett Faine seconded. The decision was unanimous.

***Palivizumab (Synagis):*** The Commission reviewed the following prior authorization criteria, which incorporated the full 2009 AAP RSV Guidelines:

*Prior authorization is required for therapy with palivizumab. Prior authorizations will be approved for a maximum of five doses per patient. No allowances will be made for a sixth dose. Payment for palivizumab will be considered for patients who meet one of the following criteria:*

*Chronic Lung Disease (CLD)*

- *Patient is less than 24 months of age at start of therapy and has chronic lung disease of prematurity (i.e. bronchopulmonary dysplasia) requiring medication (bronchodilator, corticosteroid, or diuretic therapy) or oxygen within six months before the anticipated start of RSV season.*

*Prematurity*

- *Patient is less than 12 months of age at start of therapy with a gestational age less than 29 weeks.*
- *Patient is less than 6 months of age at start of therapy with a gestational age of 29 weeks through 31 weeks.*

- *Patient is less than 3 months of age at start of therapy or born during the RSV season with a gestational age of 32 weeks through 34 weeks and has one of two risk factors. Risk factors include: day care attendance or siblings less than 5 years of age in household. Doses will be limited to a maximum of 3 doses or until patient reaches 90 days of age, which ever comes first.*

*Severe Neuromuscular Disease or Congenital Abnormalities*

- *Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital abnormalities of the airway that compromises handling of respiratory secretions.*

*Congenital Heart Disease (CHD)*

- *Patient is less than 24 months of age at start of therapy and has hemodynamically significant congenital heart disease further defined by any of the following: receiving medication to control congestive heart failure, moderate to severe pulmonary hypertension, or cyanotic congenital heart disease.*

*Severe Immunodeficiency*

- *Patient is less than 24 months of age at start of therapy and has severe immunodeficiencies (e.g., severe combined immunodeficiency or advanced acquired immunodeficiency syndrome).*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary.

***Oxycodone ER/CR (OxyContin):*** The Commission reviewed the prior authorization criteria as follows:

*Extended release oxycodone/OxyContin® is non-preferred except for patients being treated for cancer related pain. Prior authorization at any dose twice daily for cancer related pain will be approved. For all other diagnoses, payment will be considered under the following conditions:*

1. *There is documentation of previous trials and therapy failures with two (2) chemically distinct preferred long-acting narcotics (such as morphine sulfate ER and methadone) at therapeutic doses, and*
2. *A trial and therapy failure with fentanyl patch at maximum tolerated dose, and*
3. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization.*
4. *Requests will only be considered for 12 hour dosing.*

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

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary. However, a previously published DUR Digest article outlining proper methadone dosing and guidelines will be referenced on the PA form.

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

*Prior authorization is required for all oral hepatitis C protease inhibitors. Payment will be considered under the following conditions:*

1. *A diagnosis of hepatitis C genotype 1.*

2. *Patient is 18 years of age or older.*
3. *Administered in combination with peginterferon alfa and ribavirin.*
4. *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™).*

*HCV-RNA results are required at treatment week 8, 12, and 24 (including lead in period) for boceprevir (Victrelis™) and patient must not be a prior null responder to standard treatment. 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 40 weeks of therapy with boceprevir (Victrelis™) based on response.*

The Commission had no further changes. As this was the second review of these criteria, no motion was necessary.

**Public Comment**

| ***Speaker*** | ***Topic*** |
|---|---|
| Leah McWilliams from IOMA | *OxyContin* and the methadone trial |

**Focus Studies**

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

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

***Multiple Concurrent Anticonvulsants:*** This was a follow-up discussion, and the Commission had no further comments.

***Members with CHF:*** This was a follow-up discussion, and the Commission had no further comments.

***Members Using Clopidogrel:*** This was a follow-up discussion, and the Commission had no further comments.

***Initial Treatment with Multiple Antidepressants:*** This topic will be addressed in a future DUR Digest article.

***Effective Use of Oral Antidiabetic Medications to Achieve A1C Goals:*** Dr. Graber noted that control cannot be established in two months, as hemoglobin doesn't stabilize for three months. The Commission believes this to be a non-issue, and no action will be taken at this time.

***Potential Complications with Daily Aspirin Regimen:*** Letters will be sent to the prescribers of the members with heart disease or cerebrovascular disease taking daily aspirin with ibuprofen or naproxen informing them that the cardioprotective benefits of

aspirin may be reduced. Letters will also be sent to the prescribers of the members who are taking daily aspirin and NSAIDs who also have a GERD or PUD diagnosis. This topic will be addressed as a DUR Digest article, as well. In addition, it was requested that the claim profiles of the members identified as combining a daily aspirin regimen with ibuprofen or naproxen be checked for chronic use.

## Miscellaneous

***DUR Digest:*** The Commission members offered changes and additions to the draft for DUR Digest Volume 24, Number 1.

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

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

A unanimous vote was made at 11:30 to adjourn the meeting and move to closed session (motion by Brett Faine).

**The next meeting will be held at 9:30 a.m. on Wednesday, December 7, 2011 at the Learning Resource Center in West Des Moines.**