

# Iowa Medicaid Drug Utilization Review Commission

## Meeting Minutes December 2, 2009

### Attendees:

#### **Commission Members**

Rick Rinehart, M.D.; Bruce Alexander, R.Ph., Pharm.D., BCPP; Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Casey Clor, M.D.; Mark Graber, M.D., FACEP; and Susan Parker, Pharm.D.

#### **Staff**

Chad Bissell, R.Ph., Pharm.D.; and Pam Smith, R.Ph.

#### **Guests**

Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Nick Ford, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

### **Welcome & Introductions**

Chairman Dr. Mark Graber called the meeting to order at 9:30 a.m. at the Learning Resource Center in West Des Moines. Commission members, guests, and observers were welcomed and introduced.

The minutes from the November 4, 2009 meeting were approved following a spelling correction from Bruce Alexander. (Motion by Dr. Casey Clor, second by Larry Ambroson, unanimous approval by voice vote.)

### **Iowa Medicaid Enterprise Updates**

There were none.

### **Case Studies**

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$6,071.61 pre-rebate (state and federal).

### **Annual Smoking Cessation Report**

The Commission was presented with a copy of the current year's draft report. Their additional recommendations will be added, and a revised report will be brought to the next meeting in February.

### **MMWR – State Medical Coverage for Tobacco-Dependence Treatments**

The Commission members reviewed this report created by the Centers for Disease Control and Prevention (CDC).

### **Varenicline Safety**

Recent varenicline (Chantix) utilization within the Iowa Medicaid program was reviewed to evaluate use in patients with underlying mental health disorders, as

well as those who develop new mental health disorders after starting varenicline. Commission members had expressed interest in this at a previous meeting. They also were curious if these prescribing practices resulted in an increased number of hospitalizations for psychiatric reasons. Additionally, a query was conducted of other state Medicaid programs asking what type of specific criteria restrictions were in place for varenicline when a past history of psychiatric disorders is present or if it is left to the discretion of the prescriber. Seventeen states responded, of which 15 states leave it to the discretion of the prescriber. Two states, Indiana and Washington, have restrictions specific to psychiatric disorders. Indiana currently denies a claim if the member has a diagnosis of depression, suicidal behavior/attempt, or psychosis and has not previously tried both NTR and bupropion in the past two years, unless otherwise contraindicated. Washington has specific criteria based on FDA labeling and denies claims if there is history of a psychiatric disorder. Two analyses were performed looking at paid, non-reversed Iowa Medicaid pharmacy claims over a recent six month time frame (May 1, 2009 through October 31, 2009). The first analysis looked at members who were taking an antidepressant and added varenicline. The second analysis looked at members who started varenicline who then added an antidepressant shortly thereafter. Medical claims were also reviewed during this time to identify how many members required hospitalization for psychiatric illness shortly after starting varenicline. A total of 1,207 unique members were on varenicline during this time frame. One hundred eleven of them added an antidepressant (SSRI, SNRI, TCA, and/or MAOI) after starting varenicline, and three new varenicline starters had a hospitalization for a psychiatric reason. Claims data will be re-evaluated to search for psychiatric breaks and/or mood stabilizing medications, and the prescribers of these 111 members will be contacted.

### **Public Comment**

Nancy Bell from Pfizer spoke about Chantix and fibromyalgia PA criteria. Eric Burns from Alcon Labs spoke about ophthalmic antibiotic criteria changes, and Farid Manshadi, a physician, spoke about Savella and fibromyalgia criteria.

### **Pro-DUR Edits**

***Armodafinil – Proposed Age Limit:*** On August 1, 2007, the DUR Commission voted in favor of following an age restriction per the package insert of modafinil (*Provigil*) restricting use to members 16 years of age and older to prevent off-label use. Since implementation, there have been no issues regarding the age edit on modafinil. There have been several requests for off-label use of the drug in children to treat ADHD. To prevent off label use of armodafinil (*Nuvigil*), it is being proposed to add an age edit to restrict use to members 17 years of age and older. Bruce Alexander motioned to accept this recommendation, and Larry Ambrosion seconded. The motion passed with no objections.

***Brand Ophthalmic Fluoroquinolone Products - Proposed Age Edit:*** The P&T Committee had voted in favor of changing the status of brand ophthalmic fluoroquinolone products to non-preferred for members less than 18 years of

age. This was in response to the DUR Commission's recommendation from September 3, 2009, requesting the P&T Committee consider making all ophthalmic fluoroquinolones non-preferred on the PDL, to shift utilization towards less expensive, first-line treatment options when treating bacterial conjunctivitis since ophthalmic fluoroquinolones are not considered first line options. The DUR Commission disagreed with the P&T Committees recommendation, and again proposed that all ophthalmic fluoroquinolones be non-preferred for children 18 years of age and younger. Dr. Schutte-Schenck suggested DUR staff contact pediatric ophthalmologists to get their opinion on how this will affect their practice. This topic will be taken back to the next P&T Committee meeting.

### **PA Criteria**

***Bupropion SR for Smoking Cessation:*** The Commission reviewed the prior authorization criteria as follows:

*Prior Authorization is required for varenicline (Chantix™) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:*

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.*
- 2) Confirmation of enrollment and ongoing participation in the Quitline Iowa counseling program is required for approval and continued coverage.*
- 3) Approvals will only be granted for patients eighteen years of age and older.*
- 4) The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period.*
- 5) Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.*
- 6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.*

No motion was necessary as this was the second review of the topic. The criteria will now be forwarded to the Department of Human Services (DHS).

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

*Prior authorization is not required for the preferred proton pump inhibitors (PPI) for a cumulative 60 days of therapy per 12-month period. Prior authorization will be required for all non-preferred proton pump inhibitors as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. 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. Prior authorization is required for any PPI usage longer than 60 days or more frequently than one 60-day course per 12-month period. The 12-month period is patient specific and begins 12 months before the requested date of prior authorization.*

*Payment for usage beyond these limits will be authorized for cases in which there is a diagnosis of:*

- 1. Specific Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas).*
- 2. Barrett's esophagus.*
- 3. Erosive esophagitis*
- 4. Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses.*
- 5. Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of Helicobacter pylori treatment or a negative Helicobacter pylori test result.*

*Prior authorization is NOT required for Prevacid SoluTabs for children age 8 years old or younger for the first 60 days of therapy. Prior authorization is required for Prevacid SoluTabs for patients over 8 years of age beginning day one of therapy. Authorization for Prevacid SoluTabs will be considered for those patients who cannot tolerate a solid oral dosage form.*

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

No motion was necessary as this was the second review of the topic. The criteria will now be forwarded to DHS.

**Biologicals for Ankylosing Spondylitis:** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for biologicals used for ankylosing spondylitis.*

*Payment will be considered following inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum doses unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, and intramuscular gold.*

*Prior authorization is required for all non-preferred biologicals for ankylosing spondylitis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.*

*Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of a previous trial and therapy failure*

*with a preferred agent.*

No motion was necessary as this was the second review of this topic. The criteria will now be forwarded to DHS.

**Short-Acting Narcotics:** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for all non-preferred short acting narcotics. Payment will be considered for cases in which there is documentation of previous trial(s) and therapy failures with three (3) chemically distinct preferred short acting narcotics (based on narcotic ingredient only) at therapeutic doses, unless evidence is provided that the use of these products would be medically contraindicated.*

No motion was necessary as this was the second review of this topic. The criteria will now be forwarded to DHS.

**Biologicals for Arthritis:** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for biologicals used for arthritis.*

*Payment will be considered following an inadequate response to a preferred disease modifying antirheumatic drug such as hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, or minocycline.*

*Prior authorization is required for all non-preferred biologicals for arthritis as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy.*

*Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.*

Dr. Graber volunteered to speak to some rheumatologists to get their input on the new criteria. The topic will then be revisited.

**Cymbalta, Lyrica, Savella:** The Commission reviewed the prior authorization criteria as follows:

*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 a tricyclic antidepressant (such as amitriptyline), AND*
  - b. a trial and therapy failure at a therapeutic dose with a preferred muscle relaxant (such as cyclobenzapriue), AND*

- c. at least **two** trials and therapy failures at a therapeutic dose from the following agents: SSRI, tramadol, or gabapentin, **AND**
  - d. documented non-pharmacologic therapies (cognitive behavior therapies, exercise etc.), **AND**
  - e. 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)  
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, or gabapentin.
  3. A diagnosis of diabetic peripheral neuropathy (Cymbalta and Lyrica)  
The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: 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)

*\*PA required for new starts only.*

The Commission members thought this wording might be confusing for providers, and had an extensive clinical discussion as to the appropriateness of the criteria. Pam Smith will edit and bring a rearranged version to the next meeting for further deliberation.

**DPP-4 Inhibitors:** The Commission reviewed the prior authorization criteria as follows:

*Prior Authorization is required for dipeptidyl peptidase-4 (DPP-4) inhibitors. Payment will be considered under the following conditions:*

- 1) A diagnosis of Type 2 diabetes mellitus,
- 2) Patient is 18 years of age or older,
- 3) The patient has not achieved HbgA1C goals using insulin or a combination of two or more antidiabetic medications (metformin, sulfonylurea, or thiazolidinedione) at maximum tolerated doses unless otherwise 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 improvement in HbgA1C since the beginning of the initial prior authorization period.*

Craig Logemann motioned to accept the proposed criteria, and Bruce Alexander seconded. The motion passed with no objections.

**Lidocaine Patch:** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for topical lidocaine patches (Lidoderm). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure or contraindications with a preferred agent at therapeutic dose from one of the following: tricyclic antidepressant, opioid, or gabapentin.*

In addition, the Commission decided to limit the quantity to 30 for the first fill, and also limit to 90 patches per 30 days. There will be no limit on duration of therapy, however, as post-herpetic neuralgia is a chronic condition. Dr. Casey Clor motioned to accept the proposed criteria and quantity limits. Dr. Rick Rinehart seconded, and the motion passed unanimously.

**Ergotamine Derivatives:** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for preferred ergotamine derivatives used for migraine headache treatment for quantities exceeding 18 unit doses of tablets, injections, or sprays per 30 days. Payment for ergotamine derivatives for migraine headache treatment beyond this limit will be considered on an individual basis after review of submitted documentation. Prior authorization will be required for all non-preferred ergotamine derivatives beginning the first day of therapy. Payment for non-preferred Ergotamine agents will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. For consideration, the following information must be supplied:*

- 1. The diagnosis requiring therapy.*
- 2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.*

It was proposed that these criteria be removed due to low utilization of this category and higher utilization of Triptans for acute treatment of migraine. For SFY 2009, there was one approved PA out of a total of five PA requests. Six months after removal of the PA, a follow-up will be done to monitor utilization of this drug class. Bruce Alexander motioned to accept the recommendation, and Craig Logemann seconded. All members voted in favor of the motion.

### **Public Comment**

Dr. Geoff Wall spoke about the Biologicals for Arthritis criteria.

### **Focus Studies**

**Drugs that cause Edema:** The purpose of this study was to identify instances where prescribers were prescribing medications that typically cause edema as a side effect in disease states that often have edema present as a symptom. Edema is defined as palpable swelling as a result of interstitial fluid volume expansion. There are many different clinical conditions that can cause edema

such as heart failure, cirrhosis, and nephrotic syndrome. Certain medications can also cause edema as a side effect. When used in patients with peripheral edema, the addition of these drugs can cause worsening symptoms of edema such as swollen legs, difficulty walking, increased abdominal girth, and shortness of breath due to pressure on the diaphragm. These patients become high utilizers of prescribers offices and emergency departments seeking medical care for the discomfort caused by the worsening edema. An analysis was performed to identify instances where prescribers were prescribing medications that typically cause edema as a side effect in Iowa Medicaid members who have disease states that commonly cause edema. At the September meeting, the Commission had asked that these findings be re-run and remove members who have had a hospital admission for heart failure, and/or those already on diuretics. They reviewed the updated report, but later decided to send letters to all prescribers of members that had appeared in the initial query results.

***Abilify for Depression without Antidepressants:*** The purpose of this study was to determine the extent to which aripiprazole (*Abilify*) is being used as monotherapy to treat major depression. Aripiprazole is an atypical antipsychotic that was first approved for use in schizophrenia in 2002. Unlike other atypical antipsychotics that bind to D<sub>2</sub> receptors in the nigrostriatal pathway, aripiprazole acts as a partial agonist at the D<sub>2</sub> receptors. In 2008, the FDA approved the use of aripiprazole as adjunctive treatment of major depressive disorder. This indication was based on two short-term (6 weeks) placebo-controlled trials of adult patients who met the DSM-IV criteria for MDD who had an inadequate response to venlafaxine ER, paroxetine CR, fluoxetine, escitalopram, or sertraline. In both trials, aripiprazole was superior to placebo in reducing the mean Montgomery-Asberg Depression Rating Scale scores. At a recent DUR Commission meeting, some concern was expressed as to the possibility that providers were using aripiprazole to treat MDD as monotherapy instead of as adjunctive therapy. This was based on observations made during profile reviews and observations in practice. An analysis was performed looking at paid pharmacy claims over a six month time period (3/1/09 through 8/31/09) to identify members using aripiprazole with and without SSRIs or SNRIs concurrently. For those identified as using aripiprazole as monotherapy, anyone with a diagnosis for schizophrenia or bipolar disorder was removed. Concurrent therapy was defined as having two or more fills for aripiprazole while also receiving prescriptions for an SSRI or an SNRI. Three thousand seventy-eight unique members were using aripiprazole for depression, of which 1,974 used a SSRI or SNRI in combination, and 1,104 (36%) were using aripiprazole (*Abilify*) as monotherapy. Forty-three of those 1,104 members were using a drug from the Tricyclic Antidepressant or MAO Inhibitor PDL category. The Commission asked that the report be rerun to look for GAD, mood stabilizers, and second-generation antipsychotics as well.

***Chronic Use of Transdermal Scopolamine:*** The purpose of this study was to determine the extent to which Iowa Medicaid members are using transdermal scopolamine (*Transderm Scōp*) on a chronic basis and/or in combination with oral medications. Transdermal scopolamine is a belladonna alkaloid that is FDA

indicated to prevent motion sickness and nausea and vomiting associated with anesthesia following surgery. It is compendia indicated for excessive salivation. Transdermal scopolamine is a small flat patch that is applied behind the ear at least four hours before the prevention of nausea and vomiting is required, typically four hours before travel. Transdermal scopolamine comes in boxes of four patches, and each patch lasts for 3 days. The most common use for transdermal scopolamine is to prevent motion sickness prior to air, car, or boat travel. Transdermal scopolamine is a preferred product on the Preferred Drug List, and is not subject to clinical prior authorization criteria, quantity limits, or ProDUR edits of any kind. Based on marketshare data for State Fiscal Year 2009, there were 659 prescriptions billed for *Transderm Scōp* for an average of 6 units per prescription at a cost of \$50.82 (state and federal dollars, pre-rebate) per prescription. When compared to other therapies used for motion sickness, this average cost per prescription is considerably higher due to SMAC prices on the other products. For example, the average cost per prescription for meclizine is \$5.64 (state and federal dollars, pre-rebate) for an average of 52 tablets per prescription. Through the usual course of profile reviews, it has been noticed there are members using transdermal scopolamine on both a regular basis and in combination with other oral medications. To evaluate the extent of this practice, an analysis was done over a three month timeframe (7/1/09 through 9/30/09) to determine how many members were using transdermal scopolamine chronically, who had previous trials with meclizine, who was taking other oral medications, and who was receiving quantities greater than four. Twenty-eight unique members had more than two fills on the claim histories. This data will be rerun to remove cancer patients, and then letters will be sent to the prescribers involved.

***Long-Term Use of Short-Acting Opioids:*** The purpose of this study was to determine the number of members using four or more doses per day of a short acting opioid for an extended period of time without using a long acting opioid. Potential benefits of switching to a long acting opioid in chronic non-cancer pain could provide members with a more consistent control of pain, improved adherence, and lower risk of addiction or abuse. There are no clear guidelines for use of short-acting opioids versus long-acting opioids, as there is insufficient evidence comparing the two. There is a lack of studies that support a recommendation of as-needed versus around-the-clock dosing of opioids. The decision to switch to a long-acting opioid should be based on outcomes of a trial with a short-acting opioid lasting several weeks to a few months. An example of outcomes to consider would include progress toward meeting therapeutic goals, presence of adverse effects, changes in the underlying pain condition, changes in psychiatric or medical comorbidities, identification of aberrant drug-related behaviors, addiction, or diversion. It is important to note that although neuropathic and non-neuropathic pain conditions appear to respond to chronic use of long-acting opioids, evidence that supports efficacy of these products for conditions such as chronic low back pain, daily headache, and fibromyalgia are lacking. An analysis was preformed looking at paid pharmacy claims over a six month time period (4/1/09 through 9/30/09). Members who had four or more doses per day for 90 days or longer of any drug from the Narcotics -

Miscellaneous PDL category without claims for any drug in the Narcotics - Long Acting PDL category during the same time period were identified. If members are using short-acting opioids on a chronic basis for non-cancer pain, it is thought that they should be considered for a trial with a preferred long-acting opioid. One thousand three hundred five members were identified as using four or more doses of a short-acting opioid per day for more than 90 days without claims for a long-acting narcotic. Their average length of therapy was five months. Letters will be sent to prescribers with patients on two or more short-acting opioids. If Maine's new restrictive PA criteria (members having 90 days of opiates in the past 100 days would require a PA to ensure appropriate indication, non-pharmacologic and non-opioid treatments have been considered and/or tried, an opiate/controlled substance contract exists, and review of a monitoring plan, i.e. urine drug screens and pill counts, if necessary) for this category proves effective, it could possibly be adopted in Iowa in the future.

### **Miscellaneous**

***SMAC Update:*** The Commission members were given a copy of the SMAC changes effective November 25, 2009.

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

A unanimous vote was made at 12:04 p.m. to adjourn the meeting and move to closed session (Motion by Bruce Alexander, second by Craig Logemann).

**The next meeting will be held at 9:30 a.m. on Wednesday, February 3, 2010 at the Learning Resource Center in West Des Moines, IA.**