

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes February 3, 2010

Attendees:

Commission Members
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 Ambrosion, R.Ph.; Casey Clor, M.D.; and Susan Parker, Pharm.D.
Staff
Chad Bissell, Pharm.D.; and Pam Smith, R.Ph.
Guests
Chuck Wadle, D.O., Magellan; Colleen Kacher, IME; Laura Wiggins, IME; Sandy Pranger, R.Ph., IME; and Melissa Biddle, IME.

Welcome & Introductions

Vice-Chairperson Laurie Pestel called the meeting to order at 9:30 a.m. at the Learning Resource Center in West Des Moines. Commission members and guests were welcomed and introduced.

The minutes from the December 2, 2009 meeting were approved following several corrections from Commission members. (Motion by Bruce Alexander, second by Larry Ambrosion, unanimous approval by voice vote.)

Iowa Medicaid Enterprise Updates

Vendors bidding for IME contracts gave oral presentations to DHS last week. Decisions should be announced to the public next week. With the contract re-negotiation, there will only be 6 DUR meetings per year, every other month, starting in August. The next P&T Meeting will be April 8th at the Botanical Center in Des Moines.

Case Studies

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$17,791.48 pre-rebate (state and federal).

Quarterly Management Reports (Summary)

For the second quarter of State Fiscal Year 2010, the average amount paid per claim was \$59.81, which was a subtle decrease from the previous quarter. Total dollars paid for the quarter was up to \$64.2 million. The number of paid claims, along with the number of eligible members, also continues to trend upwards. There were 373,114 eligible Medicaid members in the second quarter. The average number of claims per utilized member was 5.39, and percent of controlled substances was 18.67%. *ProAir HFA* (albuterol) continues to be the top drug by number of prescriptions, and *Synagis* (palivizumab) was the top drug

by dollars spent. Brand single source drugs made up 22.87% percent of paid claims, while generic utilization was up to 72.11%. Lastly, the average amount paid per generic claim was \$13.09.

Annual Smoking Cessation Report

The Commission was presented with a copy of the current year's draft report, which had been updated with their additional recommendations from the last meeting. Larry Ambrosion motioned that this finalized version be forward to the Department of Human Services. Craig Logemann seconded, and the motion passed with no objections.

Public Comment

Rose Mullen, Outcome Liaison Consultant and Dr. Donna Bahls, Lecture Bureau Speaker, representing Eli Lilly spoke of *Cymbalta* and fibromyalgia PA criteria. Nancy Bell from Pfizer spoke about fibromyalgia PA criteria. Kristin Crouch from Forest Labs spoke about *Savella* and fibromyalgia criteria. Sarah Sullivan from Merck reviewed the American Association of Clinical Endocrinologists consensus statement regarding DPP-4 Inhibitors.

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 amodafinil (*Nuvigil*), it is being proposed to add an age edit to restrict use to members 17 years of age and older. This was the second review of this topic, and the Commission had no further comments. This will now be forwarded to DHS.

PA Criteria

PEG 3350 Utilization: Pam Smith followed up on the days supply edit that had been placed on PEG 3350 to allow for the colonoscopy in children. A review of claims for the past six months identified only one member using this drug for something other than a colonoscopy. Calls were made to the pharmacy and the doctor's office, and they've been asked to correct this. It has not been filled since November 2009.

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.

As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

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 a combination of two or more antidiabetic medications (metformin, sulfonylurea, thiazolidinedione, or insulin) 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.

As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

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 with a preferred agent at therapeutic dose from one of the following: tricyclic antidepressant, opioid, or gabapentin. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

In addition, the commission decided to limit the quantity to 30 patches 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. As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

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 5 PA requests. Six months after removal of the PA, a follow-up will be done to monitor utilization of this drug class. As this was the second review of these criteria and the Commission had no further comment, this will now be forwarded to DHS.

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 three drugs from any of the following: tricyclic antidepressant, muscle relaxant, SSRI, 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)*

The patient must have previous trials and therapy failure at therapeutic doses with at least two of the following agents: tricyclic antidepressant, topical lidocaine, valproate, carbamazepine, 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*)

The Commission members thought the preferred medications should be listed on the PA form for the convenience of prescribers. The draft PA form will be brought to the next meeting.

Public Comment

There were no speakers in this public comment section.

Focus Studies

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. 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. A total of 3,078 unique members were identified as using aripiprazole for depression, of which 1,974 used a SSRI or SNRI in combination, and 1104 (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. At the December 2009 DUR meeting, it was requested the data be re-run, removing members with a diagnosis of generalized anxiety disorder, members using a mood stabilizer (lamotrigine, levetiracetam, divalproex, carbamazepine, topiramate, oxcarbazepine, and/or lithium), and to look to see if other antipsychotic medications are being used. Of the 1,104 members originally identified in the initial study, only 1,006 members were currently eligible when the data was re-run. One-hundred-sixty-four (164) of these members were identified as not meeting any of the criteria for use of aripiprazole (*Abilify*) based on their medical claims data. Letters will be sent to their prescribers. Dr. Casey Clor suggested that they be reminded that *Abilify* is very expensive compared to other alternatives. The letter could suggest other more cost efficient options they might prescribe instead.

Off-Label Utilization of Cholinomimetics: The purpose of this study was to determine the extent to which drugs approved for the treatment of Alzheimer's dementia are being used for off-label indications. In June 2007, the DUR Commission recommended to the Department that an age edit be placed on the cholinomimetic drugs used for Alzheimer's dementia due to the high prevalence

of off-label use in young members for diagnoses such as traumatic brain injury and autism. Since July 30 2007, claims for members under 40 years of age have required a prior authorization. These have been dealt with on a case-by-case basis. For those over 40 years of age, claims for cholinomimetics, specifically *Aricept* (donepezil) and *Namenda* (memantine), which are preferred drugs on the Preferred Drug List, have paid without a review of the member's diagnosis. Both drugs have been used off label in the treatment of attention-deficit/hyperactivity disorder (ADHD); behavioral syndromes in dementia; Lewy body dementia; treatment of mild-to-moderate vascular dementia; mild cognitive impairment; traumatic brain injury; autism; and stroke. A pharmacy claims analysis was performed looking at paid, non-reversed pharmacy claims between 6-1-09 and 11-30-09. Members who had two or more claims for *Aricept* (donepezil) and/or *Namenda* (memantine) were identified. A search of these members' medical claims histories was done to look for diagnosis codes corresponding with Alzheimer's dementia, dementia (senile, pre-senile, vascular, etc), amnesic disorder, and frontotemporal dementia. One-hundred-fifteen (115) unique members met the search criteria. Eighty-five (85) of them were found to have an off-label diagnosis in their pharmacy claims history. Their prescribers will be contacted. This topic will also appear as an article in an upcoming DUR Digest under a "dementia" header as requested.

Utilization of Multiple Oral Anti-Diabetic Agents without Use of Insulin: The purpose of this study was to determine the number of members using three or more oral anti-diabetic medications concurrently. Based on observations made during member-specific profile reviews, it was suspected that many Iowa Medicaid members with type 2 diabetes were prescribed multiple oral anti-diabetic products in various combinations as opposed to adding insulin after one or two oral medications failed to achieve glycemic goals. An analysis was performed looking at paid pharmacy claims over a three month time period (9/1/09 through 11/30/09). Members who were using multiple oral anti-diabetic agents were identified. Seventy-eight (78) unique members were identified as using 3 or more anti-diabetic active ingredients concurrently. None of them were taking insulin, and only 2 had claims for Byetta in their profiles. Letters will be sent to the prescribers of members on 4 or 5 anti-diabetic agents concurrently. This topic will also appear as an article in the DUR Digest.

Cholesterol-Lowering Medication Pre- and Post-MI: The purpose of this study was to determine the extent to which members at high risk for coronary heart disease events are being treated for dyslipidemia, and of those being treated, how compliant these members are with their drug regimen. Similar to other studies that have been performed by the Iowa DUR Commission looking at adherence to professional guidelines for post-MI patients, we were interested in looking to see how many Iowa Medicaid Members were being treated with a cholesterol lowering agent following a new diagnosis of MI, unstable angina, and/or acute coronary syndrome. Additionally, the report showed how compliant those members were with their medication regimen. A report was run looking at Iowa Medicaid members who had constant eligibility between 12/1/06 and 11/30/09. An analysis of their pharmacy claims history and medical claims history

were performed during this time period. Within the members' medical claims histories, we identified members who had new diagnoses of myocardial infarction, unstable angina, and/or acute coronary syndrome between 12/1/07 and 11/30/08. The drugs that were searched included drugs and drug combinations that can be used for lowering cholesterol (statins, fibrates, and niacin) as recommended by multiple professional guidelines. For those members we identified as using cholesterol lowering pharmacotherapy, a medication possession ratio (MPR) was performed to assess compliance. Twelve (12) members were identified as having used cholesterol-lowering medications prior to an episode, but then discontinued following the episode. Dr. Casey Clor asked that the data be rerun to focus on members with these diagnoses in their claims files but who were not taking a statin medication. The 3-year eligibility timeframe will not be used for the new data pull. Craig Logemann asked if it would be possible to obtain national data, for a benchmark comparison. The Commission decided to hold off on letters for now and discuss with Dr. Kline at the next meeting the possibility of the IME nurse care managers supervising these members in the future.

Antiviral Utilization: Commission members were provided with utilization data and trend charts for Tamiflu and Relenza usage between 9/1/09 and 11/30/09. The peak appeared to have occurred between 10/11/09 and 10/25/09. The week of 10/18/09 had the highest number of prescriptions: 1,998 for Tamiflu, and 15 for Relenza, for a total of 2,013. Polk County had the most members on antivirals during this time period: 644. The Commission members agreed that no further action was needed for this focus study.

Miscellaneous

DUR Digest: The Commission members offered changes and additions to the draft for DUR Digest Volume 22, Number 2.

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

A unanimous vote was made at 11:18 to adjourn the meeting and move to closed session (1st by Bruce Alexander, 2nd by Craig Logemann).

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