Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 1, 2012

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Gregory Barclay, M.D.; Casey Clor, M.D.; Kellen Ludvigson, Pharm.D.; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brett Faine, Pharm.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
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 the Learning Resource Center in West Des Moines. The minutes from the June 6, 2012 meeting were reviewed. Larry Ambroson motioned to accept them, and Dr. Barclay seconded. Annual conflict of interest forms were requested to be given to Pam Smith. The vote was unanimous. Laurie Pestel nominated Dr.Graber to remain Commission Chairperson. Brett Faine seconded this, and all members were in favor. Dr. Graber then nominated Laurie Pestel to remain Vice-Chairperson. Dr. Clor seconded, and there were no objections.

IME Updates

The IME State Plan Amendment for health homes for people with chronic diseases has been approved by CMS. Ten health home entities, with 40 locations in 11 counties, have enrolled so far, almost 500 providers total. Approximately 700 members have enrolled. Another SPA focusing on members with serious mental illness and emotional disturbances is in process, based upon the integrated health home model piloted by Magellan. Managed care facilities are now available in Clinton, Muscatine, and Benton counties, with Linn County coming online September 1, 2012. The ICD-10 team has recently completed a crosswalk of over 59,000 ICD-9 and ICD-10 codes. The Medicaid Integrated Data Administration (MIDAS) project has been launched, and will overhaul the MMIS and POS systems over the next several years. Iowa's readmissions from 2010 were 7.2% overall in 30-day readmissions, compared to the 18 state average of 8.8%. Cost of dispensing surveys have been sent out to providers, and are due back August 13th. DHS hopes to set the new pharmacy dispensing fee in October, to be effective January 1, 2013, contingent upon SPA approval from CMS. Average Actual Acquisition Cost (AAC) surveys will go out to pharmacies in October to set preliminary rates for posting by the end of November or beginning of December. The new AAC will also be implemented on January 1, 2013.

Prevalence Report Summary

Statistics from May and June 2012 were discussed, including: cost per user ($267.80), number of total prescriptions dispensed (a decrease of 5.8% compared to the previous reporting period), average cost per prescription ($62.77), and generic utilization (78.1%). The total paid amount decreased by 8.0% from the previous reporting period. There were 152,042 unique users, which is 7.4% less than the total for March and April. 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 $3,609.35 pre-rebate (state and federal).

Public Comment

There were no public speakers.

Prior Authorization

Annual Review of PA Criteria: The Commission members would like to discuss the following:

ADD/ADHD – The members want to discuss options for controlling adult prescriptions, perhaps at least on short-acting medications. Claims data, along with other states' criteria for comparison, will be brought to the next meeting.

Pre-filled Insulins – Larry Ambroson had heard that manufacturers wanted to discontinue the vials, but Susan Parker said DHS has not received notification of that. Vials are still less expensive at this point. The Commission wanted to know what percentage of the population is currently utilizing pre-filled pens.

Chronic Pain Syndromes – The form needs to be restated to include Lyrica's new indication for management of neuropathic pain associated with spinal cord injury. Erin Halverson suggested creating a general neuropathy section.

Synagis – The Commission asked if statistics since the PA criteria change were available. It is too soon for Iowa stats, but other states that switched sooner have not noted large changes in hospitalization or deaths. Pam Smith will compare annual costs before and after the change, and update Dr. Biczak's document.

Smoking Cessation Therapy – There have been members with multiple Chantix trials, using the maximum every year, which may require a limit be put in place. On average, it takes 7 attempts to successfully quit smoking. A question needs to be added to the PA form to address concomitant use of antidepressants and antipsychotics. More information will be brought back to a future meeting.

Xolair – The criteria needs to be more specific, based on the package insert. This will be brought back to the next meeting.

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. Initial request will be considered for 3 months at which time a dose reduction must be attempted for doses greater than 8mg per day. Thereafter a dose reduction attempt will be required every 3 months until a maintenance dose of 8mg per day is achieved. 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 and compliant with 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.*
7. *Requests for Suboxone® film will only be considered upon a previous trial and therapy failure with Suboxone® sublingual tablets.*

Pam Smith will look at the studies to find data on relapse rates so that allowed treatment duration can be determined at the next meeting. Concomitant use of controlled substances (tramadol, opioids, and hypnotics) will be prohibited, with the exception that benzodiazepines will be allowed 30 days per 12 months.

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.*

If the criteria for coverage are met, authorizations will be given at three month intervals, and updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued.

Dr. Clor motioned to accept the revised criteria, and Larry Ambroson seconded. The motion passed with no objections. The criteria will be sent to the medical and pharmacy associations for their comment and brought back to the next meeting.

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

Prior authorization is required for biologicals used for arthritis. Patients initiating therapy with a biological agent must 1) be screened for hepatitis B and C (patients with active hepatitis B and C will be excluded); 2) have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; 3) not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and 4) be screened for latent TB infection. Payment will be considered under the following conditions:

A diagnosis of rheumatoid arthritis (RA) (Humira, Enbrel, Actemra, Cimzia, Kineret, Orencia, Remicade, Simponi)

- *A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxycholoroquine, sulfasalazine, leflunomide, or minocycline).*
- *Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions.*

A diagnosis of moderate to severe psoriatic arthritis (Enbrel, Humira, Remicade, Simponi)

- *A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated).*

A diagnosis of moderate to severe juvenile idiopathic arthritis (Enbrel, Humira, Actemra, Orencia)

- *A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated).*

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

Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents.

Dr. Clor motioned to accept the revised criteria, and Brett Faine seconded. The motion passed with no objections. The criteria will be sent to the medical and pharmacy associations for their comment and brought back to the next meeting.

Public Comment

Christina Soltwedel from Abbott Labs spoke of her concerns about the Biologicals for Arthritis PA form. In response, Pam will contact the specialist who had recommended that radiographic damage be added to the criteria as a measure of severity.

Focus Studies

Aspirin plus Ibuprofen or Naproxen: This was a follow-up discussion, and the Commission had no further comments.

Aspirin plus NSAIDs with GERD/PUD: This was a follow-up discussion, and the Commission had no further comments.

Drospirenone-containing Oral Contraceptives and Risk of Blood Clots: The prescribers of the 45 members identified as having the largest risk will be contacted. There will also be a future DUR Digest article which addresses the risks of all oral contraceptives.

Low Dose Quetiapine: The prescribers of the 109 members identified as having a claim for immediate-release quetiapine at a total daily dose less than or equal to 150mg per day between January and April 2012 will be contacted. Additional data on off-label use of second generation antipsychotics will be brought back to the next meeting.

Miscellaneous

DUR Digest: The Commission members had no further changes or additions to the draft for DUR Digest Volume 25, Number 1. It will be brought back to the next meeting for the second review.

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

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

A unanimous vote was made at 11:41 to adjourn the meeting and move to closed session (motion by Dr.Clor, second by Brett Faine).

The next meeting will be held at 9:30 a.m. on Wednesday, October 3, 2012, at the Learning Resource Center in West Des Moines.