Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes October 3, 2012

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Gregory Barclay, M.D.; Jason Wilbur, 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 9:30 a.m. at the Learning Resource Center in West Des Moines. The minutes from the August 1, 2012 meeting were reviewed. Dr. Jason Wilbur motioned to accept them, and Dr. Gregory Barclay seconded. The vote was unanimous.

IME Updates

The new program for health homes for people with chronic diseases began July 1st. Thirty (30) health home entities, with 40 locations in 11 counties, have enrolled so far, almost 500 providers total. Approximately 1500 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, is hoped to be up and running for 2013. Managed care facilities are now available in Clinton, Muscatine, Benton, and Linn counties, with Polk and Blackhawk counties coming online in November. The Medicaid Integrated Data Administration (MIDAS) project has been launched, and will overhaul the MMIS and POS systems over the next several years. DHS is evaluating the cost of dispensing surveys returned by the pharmacies and hopes to set the new pharmacy dispensing fee in October, to be effective January 1, 2013, contingent upon SPA approval from CMS. Multiple informational letters have been sent out, including the latest one sent on September 19th. Average Actual Acquisition Cost (AAC) surveys went out to half of the enrolled pharmacies on October 1st, and the other half will complete theirs in six months. The P&T Committee will have their annual meeting in November, at which time potential PDL changes for 2013 will be discussed. The draft PDL is posted on the website, though some things might change due to AAC information collected. Dr. Clor has resigned from the DUR Commission, leaving an opening for another physician. Pam Smith summarized the “Because Minds Matter” conference that she, Susan Parker, Dr. Kessler, and Dr. Wadle had recently attended. Foster children, specifically their associated trauma, had been a topic of discussion.

Prevalence Report Summary

Statistics from July though August 2012 were discussed, including: cost per user ($269.47), number of total prescriptions dispensed (an increase of 1.0% compared to the previous reporting period), average cost per prescription ($62.19), and generic utilization (78.7%). The total paid amount decreased by 2.2% from the previous reporting period. There were 151,920 unique users, which is 0.4% less than the total for May and June. Lists of the top 20 therapeutic classes were provided. Atypical Antipsychotics were the most expensive (though the percentage of the budget is decreasing due to release of multiple generics), 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. The ten most expensive medications were: Abilify, Singulair, Vyvanse, Advate, Concerta, Adderall XR, methylphenidate hcl er, Focalin XR, Lexapro, and Cymbalta.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $630.74 pre-rebate (state and federal).

Public Comment

Jennifer Stoffel from Johnson & Johnson spoke about PA criteria for Biologics, including Remicade and Symponi.

ProDUR Edit

Topical Pediculicides: The DUR Commission discussed criteria to be used for a ProDUR edit on spinosad (Natroba). The DUR Commission recommends that two applications of the preferred pediculicide (permethrin lotion 1% or pyrethrins-piperonyl butoxide) be tried within 30 days before Natroba would be allowed to pay without prior authorization. An informational letter will be sent to providers, educating them on proper billing and days supply.

Prior Authorization

Buprenorphine (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.*

The Commission requested that a requirement regarding anticipated discontinuation date/discontinuation discussion be added to the PA form. This medication will be discussed at the annual P&T Meeting in November, as the manufacturer will discontinue the sublingual tablet dosage form within 6 months. Brett Faine motioned to accept the above criteria, and Kellen Ludvigson seconded. There were no objections.

Mifepristone (Korlym): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for mifepristone (Korlym®). Payment will be considered for patients when the following is met:

1. *The patient is 18 years of age or older; and*
2. *Has a diagnosis of endogenous Cushing's Syndrome with hyperglycemia secondary to hypercortisolism in patients with Type 2 Diabetes or glucose intolerance; and*
3. *Patient must have failed surgery or is not a candidate for surgery; and*
4. *Female patients of reproductive age must have a negative pregnancy test confirmed within the last 7 days and must use a non-hormonal method of contraception during treatment and for one month after stopping treatment.*

This medication must be prescribed by an endocrinologist to qualify for prior authorization. Also, a quantity limit of 120 tablets per 30 days will be implemented. Dr. Jason Wilbur motioned to accept the above criteria, and Brett Faine seconded. The motion passed with all in favor.

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 (3) month intervals. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued.

The DUR Commission also recommends a quantity limit of 240 tablets per 30 days. As this was the second review of these criteria, no motion was necessary.

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 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.

Brett Faine motioned to accept the criteria as modified above, and Larry Ambroson seconded. All members were in favor.

Public Comment

There were no public comments.

Focus Studies

Concurrent Muscle Relaxants: This was a follow-up discussion, and the Commission had no further comments.

Chronic Muscle Relaxant: This was a follow-up discussion, and the Commission had no further comments.

Quetiapine and QT Prolongation: This was a follow-up discussion, and the Commission had no further comments.

Stimulant Utilization in Adults: The PA form will be updated to match the DSM-IV criteria, and require childhood onset with documentation, such as noted dysfunction at school, as well as documented improvement in function at home or work for treatment continuance. Prescribers will be contacted regarding the members identified as taking a stimulant or atomoxetine without an appropriate diagnosis in their medical claims history.

Appropriate Use of Second Generation Antipsychotics: The DUR members wish to contact the prescribers of the 459 members using a SGA without any mental health diagnosis and ask the rationale for its use and if the patients condition has been recently evaluated to support the continued use of this medication for a potential "off-label" use. Prescribers of members taking two or more second generation antipsychotics concurrently over the six month time period will also be contacted. Additionally, this will appear as a DUR Digest article. Dr. Wadle asked about looking at minimum doses prescribed.

Miscellaneous

DUR Digest: The Commission members offered additions to the draft for DUR Digest Volume 25, Number 1. Dr. Clor will be added to the outgoing member section, and a picture of Dr. Ludvigson will appear next to his bio on the final version.

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 11:18 to adjourn the meeting and move to closed session (motion by Dr. Jason Wilbur, second by Larry Ambroson).

The next meeting will be held at 9:30 a.m. on Wednesday, December 5, 2012, at the Learning Resource Center in West Des Moines.