Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes April 3, 2013

Attendees:

Commission Members
Laurie Pestel, Pharm.D.; Jason Wilbur, M.D.; Gregory Barclay, M.D.; Kellen Ludvigson, 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

Laurie Pestel called the meeting to order at 9:33 a.m. at the Learning Resource Center in West Des Moines. The minutes from the February 6, 2013 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Dr. Wilbur seconded. The vote was unanimous.

IME Updates

There are now 23 health home entities, with more than 560 providers, enrolled in the health homes for people with chronic diseases program, which began July 1, 2012. Almost 3,000 members are in health homes so far. The IME has recently submitted a State Plan Amendment in coordination with Magellan for the next phase of the health home project, health homes for people with serious and persistent mental illness and serious emotional disturbances. The tentative start date for this project is July 1, 2013. The legislature has passed a bill to strengthen Iowa Medicaid's program integrity, with provisions designed to eliminate fraud, waste, and abuse in the program; the Governor's signature is pending. Among other things, the new legislation would improve Medicaid's ability to collect and retain funds due to the state, and regulate the participation of individuals with histories of fraud or abuse. The IME successfully applied for a grant to assist in implementing the core adult quality measures and to institute some quality improvement projects to improve Iowa Medicaid's performance on some of them, and is in the early stages of getting the project mobilized. IME has applied for a CMS innovation model design grant to develop a multi-payer ACO model based on existing private payer and Medicare efforts already forming in the state. The model should also specifically address long term care services, and will focus on engaging members in their own health. The grant is a six month design project, after which the State will submit to CMS a state model innovation plan and a model testing proposal.

Prevalence Report Summary

Statistics from January though February 2013 were discussed, including: cost per user ($237.83), number of total prescriptions dispensed (a decrease of 2.9% compared to the previous reporting period), average cost per prescription ($58.00), and generic utilization (83.9%). The total paid amount decreased by 4.8% from the previous reporting period. There were 161,645 unique users, which is 2.8% less than the total for November and December. 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 Beta-Lactams/Clavulanate Combinations came in second. The top 100 drugs were also reviewed. The ten most expensive medications were: *Abilify*, *Vyvanse*, methylphenidate hcl er, *Synagis*, *Focalin XR*, *Adderall XR*, *Advate, Cymbalta, Tamiflu*, and *Advair Diskus*.

Case Studies

Pam Smith presented 4 case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of $837.52 pre-rebate (state and federal).

Public Comment

Nancy Bell from Pfizer spoke about Janus Kinase Inhibitors. Ruchir Parikh from Boehringer-Ingelheim spoke about *Pradaxa*. Kelly Quigley from Merck spoke about *Zetia* and *Vytorin*. Chris Draheim from Genzyme spoke about *Abagio*.

P&T Referral of Zetia/Vytorin

At the March 14th P&T Committee Meeting, *Zetia* and *Vytorin* underwent an evidence review to discuss whether they should be changed to non-preferred for lack of clinical outcomes. Per the prescribing information of both products, limitations of use include that the effect on CV morbidity and mortality have not been established (or with *Vytorin*, over and above that demonstrated with simvastatin monotherapy). After reviewing the prepared analysis, the P&T Committee agreed with the recommendation that these medications be referred to the DUR Commission for review and creation of prior authorization criteria. Dr. Barkin suggested that multiple trials on statins with survival advantages should be required prior to approval of *Vytorin* or *Zetia*. However, the DUR Commission did not feel prior authorization criteria were necessary at this time due to the limited number of claims, though the numbers will be run and brought to the June meeting for further consideration. This could possibly be a future focus study topic.

Prior Authorization

Repository Corticotropin Injection (H.P. Acthar Gel): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for repository corticotropin injection. Payment will be considered under the following conditions:

1. *Patient is under two years of age and*

2. *Patient has a diagnosis of infantile spasms.*

Treatment of compendia indicated steroid-response conditions will only be considered upon documented contraindications or intolerance to corticosteroids not expected to occur with the use of repository corticotropin injection. Requests will be considered for up to 30 days for all indications, when criteria for coverage are met.

Larry Ambroson motioned to accept the criteria as amended, and Brett Faine seconded. The motion passed with all in favor.

Janus Kinase (JAK) Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. *The patient is 18 years of age or older; and*
2. *Has a diagnosis of moderate to severe rheumatoid arthritis; and*
3. *Has a documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, leflunomide, or minocycline) ; and*
4. *Has a documented trial and inadequate response to preferred biological DMARD; and*
5. *The patient is not using or planning to use tofacitinib in combination with biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and*
6. *Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and*
7. *Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to manufacturer labeling; and*
8. *Patient does not have a history of malignancy (other than a successfully treated non-melanoma skin cancer); and*
9. *Patient is not at an increased risk of gastrointestinal perforation.*

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

Dr. Wilbur motioned to accept the criteria as amended, and Larry Ambroson seconded. The motion passed with all in favor.

Dabigatran (Pradaxa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for dabigatran (Pradaxa®). Payment will be considered for patients under the following conditions:

1. *Patient has a diagnosis of non-valvular atrial fibrillation; and*
2. *Documentation of a previous trial and therapy failure with warfarin; and*
3. *Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 2; and*
4. *Patient does not have a mechanical prosthetic heart valve; and*

5. *Patient does not have active pathological bleeding; and*
6. *Patient does not have severe renal impairment (CrCl < 15mL/min) or is not on dialysis.*

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

Additionally, a quantity limit of 60 capsules per 30 days for both strengths will be put in place, and the $CHADS_2$ scoring table will be added to the PA form. Brett Faine motioned to accept the criteria, and Kellen Ludvigson seconded. The motion passed with all in favor.

Sodium Oxybate (Xyrem): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 years of age or older under the following conditions:

1. *A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline.*
2. *Patient is enrolled in the Xyrem® Success Program.*
3. *A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.*
4. *Patient has been instructed to not drink alcohol when using Xyrem®.*
5. *Requests for patients with a prior history of substance abuse, concurrent use a sedative hypnotic, or a semialdehyde dehydrogenase deficiency will not be considered.*

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

As this was the second review of these criteria, no motion was necessary.

Oral Multiple Sclerosis Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for fingolimod (Gilenya™) or teriflunomide (Aubagio®). Payment will be considered for patients 18 years of age and older under the following conditions:

1. *A diagnosis of relapsing forms of multiple sclerosis, and*
2. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*

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

For patients initiating therapy with fingolimod (Gilenya™), documentation of the following must be provided:

- *Patient does not have a recent (within the past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure.*
- *Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.*
- *Patient does not have a baseline QTc interval ≥ 500 ms.*
- *Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.*

For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:

- *Patient does not have severe hepatic impairment.*
- *A negative pregnancy test for females of childbearing age.*
- *Use of a reliable form of contraception for females of childbearing age.*
- *Patient is not taking leflunomide.*

As this was the second review of these criteria, no motion was necessary.

Public Comment

There were no public comments.

Focus Studies

Guanfacine plus Clonidine: This was a follow-up discussion. One-hundred sixty-two (162) of the 299 members identified changed therapy, for an annualized cost savings of $6,490.60 (state and federal, pre-rebate) as a result of the 689 surveys sent out to prescribers and pharmacies. Three-hundred sixteen (316) (45.86%) of those surveys were returned.

Duplicate Antidepressants: Letters will be sent to the prescribers of patients taking an antidepressant in the same drug class to inquire about the duplicate therapy and ask if one of the antidepressants could be discontinued. Letters will also be sent to the prescribers of the two patients combining an MAOI with an SSRI or TCA to inform the provider of the contraindication. Additionally, letters will be sent to the prescribers of the patients combining three or more antidepressants to ask if one or more of the medications could be discontinued.

Topical Testosterone without an Indicated Diagnosis: Clinical prior authorization criteria will be developed for topical testosterone products. Potential criteria, to be brought to the June DUR meeting, includes:

- *Patient is male*
- *Diagnosis of hypogonadism*
- *Serum testosterone level (two morning pre-treatment levels)*
- *Symptoms and signs of hypogonadism; more than one symptom? Combination of specific and non-specific symptoms and signs? (Iowa Medicaid does not authorize payment of medications for sexual dysfunction or infertility)*

- *Exclude members from treatment with any contraindication to topical testosterone treatment*
- *Initial authorization for 3 to 6 months. Upon renewal require*
    - *Follow-up testosterone level*
    - *Assessment of how patient's specific symptoms have responded to therapy*
    - *Assessment of adverse effects to topical testosterone therapy*
    - *Assessment of adherence to therapy*

Zolpidem Dose: Numbers will be rerun to use March data, as the Commission felt that many prescribers may have already changed to the new lower recommended dose. Letters will then be sent to the prescribers of the female patients taking more than 5mg of immediate release zolpidem or more than 6.25mg of zolpidem ER at bedtime to inform them of the lower FDA recommended dose and ask if the dose can be decreased.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 25, Number 3. There is an open physician position since Dr. Clor left; an internist or family medicine physician would be ideal.

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 Kellen Ludvigson).

The next meeting will be held at 9:30 a.m. on Wednesday, June 5, 2013, at the Iowa State Capitol, Room 116, in Des Moines.