Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes December 5, 2012

Attendees:

Commission Members
Laurie Pestel, Pharm.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 9:31 a.m. at the Learning Resource Center in West Des Moines. The minutes from the October 3, 2012 meeting were reviewed. Dr. Barclay motioned to accept them (with a spelling correction), and Kellen Ludvigson seconded. The vote was unanimous.

IME Updates

Based on the legislative direction last session, DHS is moving to reimbursement through average actual acquisition cost (AAC). Cost of dispensing surveys were completed by the pharmacies, and the resulting recommended dispensing fee was $10.02. DHS is currently completing the development of the rates for the brand and generic and OTC drugs, and those should be available by mid-December. These will both be implemented at the same time. A general reimbursement methodology plan has been submitted to CMS, and approval could take up to 90 days, which has delayed the tentative effective date to February 1, 2013. An informational letter with updated information will go out shortly. The Commission was provided copies of Informational Letter 1191, documenting PDL changes that had come about after the November P&T Meeting. Pam Smith explained the new step therapy edit that would go into place for the Antiphsychotic medications. Tablet splitting will be required for Abilify.

Prevalence Report Summary

Statistics from September though October 2012 were discussed, including: cost per user ($240.85), number of total prescriptions dispensed (an increase of 3.4% compared to the previous reporting period), average cost per prescription ($57.66), and generic utilization (80.1%). The total paid amount decreased by 3.9% from the previous reporting period. There were 163,459 unique users, which is 7.5% more than the total for July and August. 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, methylphenidate hcl er, Vyvanse, Advate, Adderall XR, Singulair, Focalin XR, Lexapro, Cymbalta, and Advair Diskus.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $3,525.15 pre-rebate (state and federal).

Public Comment

Jennifer Stoffel from Johnson & Johnson spoke about Xarelto, and Don Iacobellis from Eli Lilly spoke about Strattera. There was also an email from the Iowa Osteopathic Medical Association, stating that IOMA found the newly proposed PA criteria for buprenorphine and mifepristone to be acceptable.

ProDUR Edit

Refill Tolerance: The current 85% refill tolerance allows an extra 48 days supply of medication per year, when claims are filled on the 26th day. The option of restricting only lock-in members was discussed, but the current POS system cannot be programmed in that manner, purely by drug class. However, this could be discussed again after the new system deploys in July of 2013, along with the possibility of programming a rolling average/accumulator. Larry Ambroson motioned to increase the refill tolerance to 90% for all categories, and Dr. Barclay seconded. The motion passed unanimously.

Prior Authorization

Omalizumab (Xolair): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Patient is 12 years of age or older; and*
3. *Pretreatment IgE level between 30 IU/mL and 700 IU/mL; and*
4. *Patient's weight is between 30 kg and 150 kg; and*
5. *History of positive skin or RAST test to a perennial aeroallergen; and*
6. *Patient is currently using a high dose inhaled corticosteroid AND long-acting beta-agonist, is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy.*

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to therapy.

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

A question asking if EpiPen is being prescribed concurrently will be added to the PA form, along with a prescriber requirement bullet as recommended. Brett Faine motioned to accept the criteria above, and Larry Ambroson seconded. The motion was unanimous.

ADHD/ADD/Narcolepsy: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for ADD/ADHD/Narcolepsy agents for patients 21 years of age or older under the following conditions:

1. *Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-IV criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before seven (7) years of age and there must be clear evidence of clinically significant impairment in two or more environments (social, academic, or occupational).*
2. *Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).*
3. *Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.*

*Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial if the preferred immediate release and extended release product of the same chemical entity is required.*

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

Dr. Barclay motioned to accept the criteria above, and Kellen Ludvigson seconded. The motion was unanimous.

Selected Brand Name Drug: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for selected brand-name drugs, as determined by the Department, for which there is available an "A" rated bioequivalent generic product as determined by the Federal Food and Drug Administration, unless the brand drug has been designated by the Department as preferred (payable) under the Iowa Medicaid Preferred Drug List (PDL).

For prior authorization to be considered, the prescriber must submit a completed Selected Brand Name PA form and Iowa Medicaid MedWatch form with:

1. *Documentation of trials and therapy failures with two different generic manufacturers of the same chemical entity. If an allergy to an inactive component is suspected, the second trial must be with a generic product that does not contain the allergen, if available.*
2. *Documentation of the failure must include the specific adverse reaction as defined by the FDA (See Section B of the MedWatch form). Intolerances, such as nausea or vomiting, to the generic drug will not be considered as a basis for approval.*

Trials may be overridden when evidence is provided that use of the generic product would be medically contraindicated.

The "other" check box will be removed from the PA form. Down the road, trials of multiple generics or another drug in the same category may be additional requirements prior to approval of the brand. Kellen Ludvigson motioned to accept the criteria above, and Brett Faine seconded. The motion was unanimous.

Topical Retinoids for Acne: Due to changes in Preferred Drug List (PDL) status of topical antipsoriatic agents, changes to the language on the Topical Retinoids Prior Authorization (PA) form are necessary, as follows:

Prior authorization is required for all prescription topical retinoid products. Payment for prescription topical retinoid products will be considered under the following conditions:

1. *Previous trial and therapy failure with a preferred over-the-counter benzoyl peroxide product, and*
2. *Previous trials and therapy failures with two preferred topical and/or oral antibiotics for the treatment of mild to moderate acne (non-inflammatory and inflammatory), and drug-induced acne.*
3. *Payment for non-preferred topical retinoid products will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent.*
4. *Trials and therapy failure will not be required for those patients presenting with a preponderance of comedonal acne.*
5. *Skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive automatic approval for lifetime use of topical retinoid products.*
6. *Requests for non-preferred combination products may only be considered after documentation of separate trials and therapy failures with the individual ingredients.*
7. *Trials and therapy failure with a preferred topical antipsoriatic agent will not be required for Tazorac for a psoriasis diagnosis.*

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

No motion was necessary, as these were required changes and provided to the Commission for informational purposes only.

Antihistamines: Due to changes in Preferred Drug List (PDL) status of several antihistamines, changes to the language on the Antihistamines Prior Authorization (PA) form are necessary. The nasal antihistamines will be removed from the Antihistamine

PA form and will not be considered as a preferred trial for use of a non-preferred oral antihistamine.

Prior authorization is required for all non-preferred oral antihistamines.

Patients 21 years of age and older must have three unsuccessful trials with oral antihistamines that do not require prior authorization, prior to the approval of a non-preferred oral antihistamine. Two of the trials must be with cetirizine and loratadine.

Patients 20 years of age and younger must have unsuccessful trials with cetirizine and loratadine prior to the approval of a non-preferred oral antihistamine.

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 these were required changes and provided to the Commission for informational purposes only.

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. Requests for maintenance doses above 16mg will not be considered on a long-term basis. Concomitant use with opioids, tramadol, and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. 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,*
   - *expected frequency of office visits, and*
   - *expected frequency of counseling/psychosocial therapy visits.*
5. *Requests for renewal must include:*
   - *An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale,*
   - *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.*

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

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. *Prescriber is an endocrinologist.*
5. *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.*

A quantity limit of 120 tablets per 30 days will be applied, when criteria for coverage are met.

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

Public Comment

There were no public comments.

Focus Studies

Simvastatin Drug-Drug Interactions: This was a follow-up discussion. 142 members changed therapy in response to the 564 surveys that were sent, of which 35% were returned. This study did not result in savings, but rather, increased costs by $2,172.39 per month, pre-rebate.

Duplicate Anxiolytics and Sedative/Hypnotics: Letters will be sent to the prescribers of the 470 members using duplicate anxiolytics and also to the prescribers of the 62 members using duplicate sedative/hypnotics to ask if one of the medications could be discontinued. The Commission did not want to create ProDUR edits at this time.

Butalbital Utilization: Letters will be sent to prescribers to inquire about the excessive use of butalbital-containing analgesics and ask if the patient can be limited to a maximum of 18 units per month to prevent tolerance, dependence, toxicity, and the development of medication overuse headache.

Miscellaneous

DUR Digest: The Commission members offered additions to the draft for DUR Digest Volume 25, Number 2. There is an open physician position since Dr. Clor left; an internist or family medicine physician would be ideal.

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

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

A unanimous voice vote was made at 11:28 a.m. to adjourn the meeting and move to closed session (motion by Brett Faine, second by Kellen Ludgivson).

The next meeting will be held at 9:30 a.m. on Wednesday, February 6, 2013, at the Learning Resource Center in West Des Moines.