Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 3, 2016

Attendees:

Commission Members
Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brian Couse, M.D.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
C. David Smith, M.D., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Laurie Pestel called the meeting to order at 9:35 a.m. at the Learning Resource Center in West Des Moines. The minutes from the June 1, 2016 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Larry Ambroson seconded. The decision was unanimous. Members were asked to complete their annual conflict of interest disclosures. However, they decided to postpone the chairperson and vice-chairperson elections until the October meeting when all members should be present (motion by Kellen Ludvigson, second by Daniel Gillette, with all members in favor). The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Pharmacy Update/News Relevant to Medicaid

Pam Smith reviewed her findings on how other states were attempting to control opioid abuse, as well as a report done by Kaiser regarding the most costly Medicaid outpatient drugs (pre-rebate). The top 10 most expensive drugs were: Abilify, Sovaldi, Vyvanse, Harvoni, Truvada, Lantus, methylphenidate er, Atripla, Advair Diskus, and Lantus Solostar. Susan Parker explained why the cost of dispensing fee would be going back down to $10.02, pending CMS approval. During the initial cost of dispensing survey in 2012, there was a shortage of pharmacists and salaries had escalated, resulting in a higher dispensing fee. The response rate was also higher with the most recent survey, contributing to an average cost of dispensing fee much closer to the national average of $10.50.

Prevalence Report Summary

This was the first complete set of statistics since the change to managed care, May through June 2016, were discussed, including: cost per user ($232.02), number of total prescriptions dispensed (a decrease of 91.6% compared to the previous reporting period), average cost per prescription ($64.63), and generic utilization (84.5%). The total paid amount decreased by 92.3% from the previous reporting period. There were 13,757 unique users, which is 92.1% less than the total for March and April. Lists of the top 20

therapeutic classes were provided. The highest prescription count continues to come from the SSRI category, with Anticonvulsants still in second place. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, methylphenidate hcl er, Abilify, Strattera, Alphanate/Von Willebrand, Focalin XR, Humalog, Lantus, Advair Diskus, and Adderall XR.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $2,654.54 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Judy Kelloway	GlaxoSmithKline	Nucala PA
Julie McDavitt	Boehringer-Ingelheim	NOACs - Pradaxa
Steven Woods	Relypsa	Potassium Binders - Veltassa
Nancy Bell	Pfizer	ProDUR edit for MME
Jennifer Stoffel	Janssen	NOACs - Xarelto
Melissa Laurie	Bristol-Myers Squibb	NOACs - Eliquis

Focus Studies

Metoclopramide Utilization Greater than 90 Days: This was a follow-up discussion. Thirty-two (32) of the 95 members identified changed therapy, for an annualized cost savings of $3,899.12 (state and federal, pre-rebate) as a result of the 222 surveys sent out to prescribers and pharmacies. A total of 97 (43.69%) surveys were returned.

Modafanil Utilization in Members under 21 Years of Age: This was a follow-up discussion. Three of the nine members identified changed therapy, for an annualized cost savings of $34,836.44 (state and federal, pre-rebate) as a result of the 23 surveys sent out to prescribers and pharmacies. A total of 10 (43.48%) surveys were returned.

Duplicate Antidepressants, Four or More Agents: This was a follow-up discussion. Four of the 11 members identified changed therapy, increasing annualized costs by $3,702.72 (state and federal, pre-rebate) due to dose consolidation on a more expensive agent. A total of 27 surveys were sent out to prescribers and pharmacies, and 10 (37.04%) of those surveys were returned.

Duplicate SSRIs: This was a follow-up discussion. Three of the 21 members identified changed therapy, for an annualized cost savings of $607.56 (state and federal, pre-rebate) as a result of the 67 surveys sent out to prescribers and pharmacies. A total of 27 (40.30%) surveys were returned.

Duplicate SNRIs: This was a follow-up discussion. Three of the 15 members identified changed therapy, for an annualized cost savings of $12,092.48 (state and federal, pre-

rebate) as a result of the 54 surveys sent out to prescribers and pharmacies. A total of 29 (53.70%) surveys were returned.

Duplicate Antidepressants, SSRI plus SNRI: This was a follow-up discussion. Thirty-eight (38) of the 162 members identified changed therapy, for an annualized cost savings of $5,781.44 (state and federal, pre-rebate) as a result of the 414 surveys sent out to prescribers and pharmacies. A total of 153 (36.96%) surveys were returned.

ProDUR Edits

Morphine Equivalent Dosing (MED) Limits: After discussing the limits that have been implemented in other states, the Commission decided to look into how many members would be affected prior to implementing anything in Iowa. Pam Smith and the MCO representatives will run reports to check the impact at both 90mg and 120mg morphine milligram equivalents per day, along with number of prescriptions with less than and greater than a 15 day supply. It is also likely that a State task force will be developed for this issue, so demonstrated proactive measures are advisable. The first step might be educational releases to providers, to provide adequate warning prior to POS changes and time for tapering. Pam Smith will also check the 2017 Medicare Part D guidelines for comparison.

Loperamide Quantity Limits: The FDA released a Drug Safety Communication in June 2016 regarding serious heart problems with high doses of loperamide, including abuse or misuse of the drug. Based on this warning, a quantity limit of 120 per 30 days was recommended for loperamide 2mg tablet and capsule, and 1200ml per 30 days for loperamide 1mg/5ml solution. Larry Ambroson motioned to accept the proposed limits, and Kellen Ludvigson and Brett Faine seconded simultaneously. All members were in favor.

Prior Authorization

Lupron Depot Pediatric: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot-Ped. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of central precocious puberty (CPP); and*
2. *Patient has documentation of onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males; and*
3. *Patient is currently < 11 years of age for females or < 12 years of age for males; and*
4. *Confirmation of diagnosis by a pubertal response to a gonadotropin-releasing hormone (GnRH) stimulation test is provided (attach results); and*
5. *Documentation of advanced bone age (defined as greater than or equal to two standard deviations above the gender/age related mean); and*
6. *Baseline evaluations including the following have been conducted and/or evaluated:*
   a. *Height and weight measurements; and*

b. *Sex steroid (testosterone or estradiol) levels have been obtained; and*
c. *Appropriate diagnostic imaging of the brain has been conducted to rule out an intracranial tumor; and*
d. *Pelvic/testicular/adrenal ultrasound has been conducted to rule out steroid secreting tumors; and*
e. *Human chorionic gonadotropin levels have been obtained to rule out a chorionic gonadotropin secreting tumor; and*
f. *Adrenal steroid levels have been obtained to rule out congenital adrenal hyperplasia; and*

7. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.*

When criteria for coverage are met, an initial authorization will be given for 6 months.

Additional approvals will be granted at 6 month intervals until the patient is ≥ 11 years of age for females and ≥ 12 years of age for males. If therapy beyond the aforementioned ages is required, documentation of medical necessity will be required.

Brian Couse motioned to accept the new criteria, and Daniel Gillette seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Lupron Depot Adult: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
3. *Patient has a diagnosis of endometriosis for whom therapy with NSAIDs and at least one preferred 3 month course of a continuous hormonal contraceptive has failed; or*
4. *Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or*
5. *Patient has a diagnosis of advanced prostate cancer.*

Therapy will be limited as follows:

- *Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant*

norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.

- *Uterine leiomyomata – 3 month approval.*
- *Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).*

Brian Couse motioned to accept the new criteria, and Daniel Gillette and Brett Faine seconded simultaneously. Larry Ambroson was out of the room during this vote, but otherwise all members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Short-Acting Opioids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting opioids. Payment will be considered under the following conditions:

1. *Patient has pain severe enough to require opioid treatment; and*
2. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen or NSAIDs); and*
4. *Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and*
5. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring program website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
6. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at*

https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a short-acting opioid is appropriate for this member.

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

Daniel Gillette motioned to accept the new criteria, and Brian Couse seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Buprenorphine/Naloxone: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day 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 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, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. 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 for opioid dependence and has a "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; AND*
5. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
6. *Requests for buprenorphine will only be considered for pregnant patients.*

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.*
- *Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.*

Kellen Ludvigson motioned to accept the new criteria, and Brett Faine seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Topical Acne and Rosacea Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

1. *Documentation of diagnosis.*
2. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid for moderate to severe acne.*
3. *Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid).*
4. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent.*
5. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products.*
6. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis.*
7. *Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.*
8. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) 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. The recommendation will be sent to the Department for consideration.

NOACs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is not required for preferred novel oral anticoagulants (NOACs). Prior authorization is required for non-preferred NOACs. Requests for doses

outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications under the following conditions:

1. *Patient does not have a mechanical heart valve; and*
2. *Patient does not have active bleeding; and*
3. *For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1; and*
4. *A recent creatinine clearance (CrCl) is provided; and*
5. *A recent Child-Pugh score is provided; and*
6. *Patient's current body weight is provided; and*
7. *Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs.*
8. *For requests for edoxaban, documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).*

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

In addition to the above PA criteria the DUR Commission made the recommendation to implement the following ProDUR quantity limits on rivaroxaban (Xarelto):

- *10mg tablet – 30 tablets per 30 days*
- *15mg tablets – allow bid dosing for 21 days followed by once daily dosing*
- *20mg tablets – 30 tablets per 30 days*

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Patiromer (Veltassa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for non-preferred potassium binders. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of chronic hyperkalemia; and*
3. *Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.*

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. The recommendation will be sent to the Department for consideration.

Mepolizumab (Nucala): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for mepolizumab (Nucala). Requests will not be considered with concurrent use of omalizumab. Payment will be considered under the following conditions:

1. *Patient is 12 years of age or older; and*
2. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype; and*
3. *Patient has a pretreatment blood eosinophil count of ≥150 cells per mcL within the previous 6 weeks or blood eosinophils of ≥300 cells per mcL within 12 months prior to initiation of therapy; and*
4. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and*
5. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus an LABA and LTRA; and*
6. *A pretreatment forced expiratory volume in 1 second (FEV_1) <80% predicted; and*
7. *Prescriber is an allergist, immunologist, or pulmonologist; and*
8. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.*

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

1. *Patient continues to receive therapy with both an ICS, LABA and LTRA; and*
2. *Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath, or*
3. *Patient has experienced a decrease in administration of rescue medication (albuterol); or*
4. *Patient has experienced a decrease in exacerbation frequency; or*
5. *Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline.*

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

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 1. A disclaimer will be added noting that the Medicaid Statistics for Prescription Claims are for fee for service members only, and do not include those for MCO members when reporting future statistics.

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

At 11:32, Daniel Gillette motioned to adjourn the meeting and Larry Ambroson seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, October 5, 2016, at the Learning Resource Center in West Des Moines.