Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes June 1, 2016

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brian Couse, M.D.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Jason Wilbur, M.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

Mark Graber called the meeting to order at 9:32 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 6, 2015 meeting were reviewed. Larry Ambroson motioned to accept them, and Daniel Gillette seconded. All members were in favor. The DUR recommendation letter sent to DHS after the last meeting and a letter from the P&T Committee to the DUR Commission regarding prior authorization criteria for Nucala were also reviewed.

IME Pharmacy Update

Susan Parker encouraged those that hadn't already signed up for the Iowa Medicaid Newsletter to do so, as these bi-monthly newsletters contain much useful information regarding managed care and fee for service issues. Pam Smith reviewed her findings on how other states were attempting to control opioid abuse.

Prevalence Report Summary

Statistics from March though April 2016 were discussed, including: cost per user ($238.48), number of total prescriptions dispensed (a decrease of 43.9% compared to the previous reporting period), average cost per prescription ($70.54), and generic utilization (86.3%). The total paid amount decreased by 43.5% from the previous reporting period. There were 174,211 unique users, which is 19.2% less than the total for January and February. This is the first prevalence report since the switch to managed care on April 1, 2016, which accounts for the significant changes. Lists of the top 20 therapeutic classes were provided. SSRIs had the highest prescription count, and Anticonvulsants came in second. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, Abilify, methylphenidate hcl er, Harvoni, Lantus, Focalin XR, Humalog, Strattera, Latuda, and Advate.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $1,043.41 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	Anticoagulants
Julie McDavid	Boehringer-Ingelheim	Pradaxa
Jennifer Stofel	Janssen	Xarelto

Focus Studies

Members Exceeding Proposed Benzodiazepine Quantity Limits: This was a follow-up discussion. Ninety-one (91)A t of the 213 members identified changed therapy, for an annualized cost savings of $11,404.20 (state and federal, pre-rebate) as a result of the 431 surveys sent out to prescribers and pharmacies. A total of 176 (40.84%) surveys were returned.

Duplicate Beta-Blockers: This was a follow-up discussion. Seventeen (17) of the 34 members identified changed therapy, for an annualized cost savings of $5,364.12 (state and federal, pre-rebate) as a result of the 104 surveys sent out to prescribers and pharmacies. A total of 44 (42.31%) surveys were returned.

Vimpat Dose Greater than 400mg: This was a follow-up discussion. Two of the 19 members identified changed therapy, for an annualized cost savings of $4,707.23 (state and federal, pre-rebate) as a result of the 46 surveys sent out to prescribers and pharmacies. A total of 23 (50.00%) surveys were returned.

Anticholinergics with Second Generation Antipsychotics: This was a follow-up discussion. A total of 183 of the 724 members identified changed therapy, for an annualized cost savings of $24,517.72 (state and federal, pre-rebate) as a result of the 1,745 surveys sent out to prescribers and pharmacies. A total of 607 (34.79%) surveys were returned.

Methadone Utilization: Following a letter from Congress to CMS asking that state Medicaid programs look into this, it was discussed at the prior DUR meeting in April. Pam Smith then researched how other states were responding, and reported her findings, along with the possible conversion ratio issues involved with implementing morphine equivalent quantity limits. Jason Wilbur motioned to recommend that the P&T Committee make methadone non-preferred, and Brian Couse seconded. Brett Faine opposed, but all of the other members were in favor, so the motion passed. A check box to note usage for opioid dependence will be added to the prior authorization form. Quantity limits were discussed again, but none will be implemented at this time.

ProDUR Edits

Tramadol Utilization in Members under 18 Years of Age: An age edit was recommended to restrict usage to members 18 years of age and older due to issues with slowed breathing in children (motion by Brett Faine, second by Jason Wilbur, unanimous decision).

Prior Authorization

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.

Jason Wilbur motioned to accept the criteria as modified, and Kellen Ludvigson 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.

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 twice daily dosing for 21 days followed by once daily dosing*
- *20mg tablets – 30 tablets per 30 days*

Brett Faine motioned to accept the amended criteria, along with the proposed quantity limits, and Brian Couse seconded. The decision was unanimous. 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.

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.

Brian Couse motioned to accept the criteria, and Jason Wilbur seconded. The decision was unanimous. 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.

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

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

1. *Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term 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, NSAIDs, or selected antidepressants and anticonvulsants)*
4. *There is documentation of previous trial and therapy failure with one preferred long-acting opioid at a maximally tolerated dose, and*
5. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization, and*
6. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and determine if use of a long-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*
7. *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.*
8. *Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered.*

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 long-acting opioid is appropriate for this member.*

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.

Adalimumab (Humira): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals FDA approved for the treatment of Hidradenitis Suppurativa (HS). Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and*
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 biologic agent; and*
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. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

1. *Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and*
2. *Patient is 18 years of age or older; and*
3. *Patient has at least three (3) abscesses or inflammatory nodules; and*
4. *Patient has documentation of adequate trials and therapy failures with the following:*
    a. *Daily treatment with topical clindamycin;*
    b. *Oral clindamycin plus rifampin;*
    c. *Maintenance therapy with tetracyclines (doxycycline or minocycline).*

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

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.

Rifaximin (Xifaxan): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for rifaximin. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. *A diagnosis of travelers' diarrhea*
    a. *Patient is 12 years of age or older; and*
    b. *Patient has a diagnosis of travelers' diarrhea not complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli; and*

c. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred generic fluoroquinolone or azithromycin.*
d. *A maximum 3 day course of therapy (9 tablets) of the 200mg tablets per 30 days will be allowed.*

2. *A diagnosis of hepatic encephalopathy*
   a. *Patient is 18 years of age or older; and*
   b. *Patient has a diagnosis of hepatic encephalopathy; and*
   c. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with lactulose.*
3. *A diagnosis of irritable bowel syndrome with diarrhea*
   a. *Patient is 18 years of age or older; and*
   b. *Patient has a diagnosis of irritable bowel syndrome with diarrhea; and*
   c. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred antispasmotic agent (dicyclomine, hyoscyamine); and*
   d. *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with amitriptyline and loperamide.*
   e. *If criteria for coverage are met, a single 14-day course will be approved.*
   f. *Subsequent requests will require documentation of recurrence of IBS-D symptoms. A minimum 10 week treatment-free period between courses is required.*
   g. *A maximum of 3 treatment courses of rifaximin will be allowed per lifetime.*

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.

Ivabradine (Corlanor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ivabradine. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and*
3. *Patient has documentation of a left ventricular ejection fraction ≤35%; and*
4. *Patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; and*
5. *Patient has documentation of blood pressure ≥90/50 mmHg; and*
6. *Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol*

50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily), or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and

7. *Patient has documentation of a trial and continued use with a preferred ACE inhibitor or preferred ARB at a maximally tolerated dose.*

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.

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

Prior authorization is required for deferasirox. Requests will only be considered for FDA approved dosing. Payment will be considered under the following conditions:

1. *Patient does not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance < 40mL/min; and*
2. *Patient does not have a poor performance status; and*
3. *Patient does not have a high-risk myelodysplastic syndrome; and*
4. *Patient does not have advanced malignancies; and*
5. *Patient does not have a platelet count < 50 x 10^9/L.*

Transfusional Iron Overload

Initiation of Therapy

1. *Patient is 2 years of age or older; and*
2. *Patient has documentation of iron overload related to anemia (attach documentation); and*
3. *Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overload; and*
4. *Serum ferritin is consistently > 1000mcg/L (attach lab results dates within the past month); and*
5. *Starting dose does not exceed: Exjade - 20mg/kg/day OR Jadenu - 14mg/kg/day. Calculate dose to the nearest whole tablet.*
6. *Initial requests will be considered for up to 3 months.*

Continuation of Therapy

1. *Serum ferritin has been measured within 30 days of continuation of therapy request (attach documentation); and*
2. *Ferritin levels are > 500mcg/L; and*
3. *Dose does not exceed: Exjade - 40mg/kg/day OR Jadenu - 28mg/kg/day.*

Non-Transfusional Iron Overload

Initiation of Therapy

1. *Patient is 10 years of age or older; and*
2. *Patient has documentation of iron overload related to anemia (attach documentation); and*
3. *Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and*

4. *Serum ferritin levels are > 300mcg/L; and*
5. *LIC are > 5mg Fe/g dw; and*
6. *Dose does not exceed: Exjade - 10mg/kg/day (if LIC is ≤ 15mg Fe/g dw), or 20mg/kg/day (if LIC is > 15mg Fe/g dw); OR Jadenu - 7mg/kg/day (if LIC is ≤ 15mg Fe/g dw), or 14mg/kg/day (if LIC is > 15mg Fe/g dw).*
7. *Initial authorization will be considered for up to 6 months.*

Continuation of Therapy

1. *Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and*
2. *Serum ferritin levels are ≥ 300mcg/L; and*
3. *LIC is ≥ 3mg Fe/g dw.*
4. *Dose does not exceed: Exjade - 10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is > 7mg Fe/g dw); OR Jadenu - 7mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 14mg/kg/day (if LIC is > 7mg Fe/g dw).*

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

Eluxadoline (Viberzi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older*
2. *Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)*
3. *Patient does not have any of the following contraindications to therapy:*
   a. *Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction*
   b. *Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day*
   c. *A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction)*
   d. *Severe hepatic impairment (Child-Pugh Class C)*
   e. *Severe constipation or sequelae from constipation*
   f. *Known or suspected mechanical gastrointestinal obstruction*
4. *Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following:*
   a. *A preferred antispasmodic agent (dicyclomine or hyoscyamine)*
   b. *A preferred antidiarrheal agent (loperamide)*

If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following:

1. *Patient has not developed any contraindications to therapy (defined above)*

2. *Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following:*
    a. *Improvement in abdominal cramping or pain*
    b. *Improvement in stool frequency and consistency.*

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 and made changes 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 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.

Brett Faine motioned to accept the updated criteria, and Larry Ambroson and Daniel Gillette both seconded simultaneously. All members were in favor. Since the criteria was changed, the newly recommended criteria will be sent to the medical/pharmacy associations for their comment and brought back to the next DUR meeting.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 28, Number 3. As this was the second review, it will be posted to the DUR website.

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

At 10:58, Jason Wilbur motioned to adjourn the meeting and Kellen Ludvigson 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, August 3, 2016, at the Learning Resource Center in West Des Moines.