Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 7, 2018

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).
Staff
Pam Smith, R.Ph.
Guests
David Smith, M.D., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Brett Faine called the meeting to order at 9:32 a.m. at the State Capitol in Des Moines. The minutes from the August 1, 2018 meeting were reviewed. Jason Kruse motioned to accept them, and Mark Graber seconded. The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Pharmacy Update

CMS has approved the dispensing fee increase from $10.02 to $10.07 effective November 1, 2018. The federal Support of Patients and Community Act recently passed will impact the Medicaid program, specifically drug utilization review committees, with section 1004. The new regulations include claims review limitations and safety edits on opioids, concurrent use of opioids with benzodiazepines and/or antipsychotics, monitoring antipsychotic medications in children, fraud and abuse, and use of the PMP.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from July through August 2018, including: total amount paid ($1,879,743), cost per user ($249.77), and number of total prescriptions dispensed (30,092). There were 7,526 unique users, which is 1.1% less than the total for May and June. The top 5 therapeutics classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Antiretroviral Combinations; and Diabetic – Insulin Penfill. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics – Miscellaneous; Antipsychotics – Atypicals; and Antihypertensives – Central. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Epclusa, Concerta, Humira Pen, Enbrel Sureclick, Hemlibra, Latuda, Emflaza, Novolog Flexpen, and Humalog. The five drugs with the highest prescription count were: hydrocodone/apap, gabapentin, sertraline hcl, lisinopril, and trazodone hcl. Pam Smith also created a report that compared the FFS stats above with those from each MCO

below. Its side-by-side statistics showed that $93,956,512 was spent in total for 233,801 unique users who had 1,303,808 prescriptions.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from July through August 2018, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. The Bi-Monthly Statistics report reflected that expenditures totaled $32,225,801, a 1.0% decrease from May and June. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Imflammatory. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, Antihypertensives, and Ulcer Drugs. Vyvanse was the most expensive medication, followed by Humira Pen, Latuda, Concerta, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and gabapentin.

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from July through August 2018, including: total paid amount ($59,850,968.45), unique users (151,325), and cost per user ($395.51). There was also a handout showing utilization by age and gender; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, Broadlawns, U of I Ambulatory Care, and 3 Walgreens locations made up the top 5. U of I Ambulatory Care was the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; and Anticonvulsants. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Proton-Pump Inhibitors; Antihyperlipidemic – HMG COA Reductase Inhibitors; and NSAIDs, Cyclooxygenase Inhibitor – Type Analgesics. The most expensive drugs were Vyvanse, Concerta, Humira Pen, Latuda, and Humalog, while omeprazole, lisinopril, levothyroxine sodium, atorvastatin calcium, and sertraline hcl had the top 5 prescription counts.

Public Comment

In addition to the written public comments provided to Commission members as part of their meeting material, they heard oral public comment from the speakers listed below.

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	Annual Class Review, Eucrisa
Leslie Zanetti	Sarepta	Exondys 51
Jamie Vora	Abbvie	Orilissa
Josh Bishop	Allergan	Vraylar

ProDUR Edits

Duplicate Antipsychotics in Adults: Pam Smith could not find clear information as to how Medicare handles duplicate antipsychotics, which had been requested at the last meeting. Letters will be sent to the prescribers of members on 3 or more antipsychotics concurrently after final recommendation is sent to DHS. A POS edit was recommended to be put into place allowing 2 unique chemical entities, with no 30-day grace period for a third agent. Jason Wilbur motioned to accept this recommendation, and Jason Kruse seconded. The decision was unanimous. Quantity limits may also be utilized in the future to address the members on multiple strengths of the same medication. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

CNS Stimulants and Atomoxetine Concurrent Therapy ProDUR Edit: A recommendation was made to allow one unit of a short-acting stimulant with a long acting stimulant for members under 21 years of age. This would be accomplished by implementing a quantity limit on all short-acting stimulants to one unit per day (i.e., 30 units per 30 days). Kellen Ludvigson motioned to accept these recommendations, and Jason Kruse seconded. Jason Wilbur opposed, and Mark Graber abstained. All others were in favor, and the motion passed. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

CNS Stimulants and Atomoxetine Age Edit: A recommendation was made to implement ProDUR age edits on stimulants. The minimum FDA approved ages will be followed for brand and generic agents, and prior authorization criteria updated to reflect this. Mark Graber motioned to accept this change and Jason Kruse seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Prior Authorization

Annual Review of Prior Authorization Criteria: Changes were suggested for the following categories, to be discussed at upcoming meetings:

PA Category	Recommended Changes
Becaplermin (Regranex)	Check trials to see if 2 weeks allows for adequate response time to wound debridement and topical moist dressing.
Benzodiazepines	Add criteria for concomitant use with opiates, and look into creating a ProDUR edit to catch the concomitant preferred agents.
Buprenorphine/Naloxone	Remove #5 and potentially #3, and define negative drug screen.
Feboxostat (Uloric)	Keep an eye out for a future Black Box Warning.
Growth Hormone	Create pathway for continuity of care for renewals for #5 and #6. Check compendia for use in adults.

Long-Acting Opioids	Remove PMP link from #6, and add criteria for concomitant use of benzodiazepines.
Lupron Depot – Adult	For #3, clarify concurrent therapy with NSAIDs.
Narcan (Naloxone) Nasal Spray	No update is needed but a suggestion was made to monitor for naloxone claims but no opioids in claims.
Short Acting Opioids	Remove PMP link and add criteria for concomitant use of benzodiazepines.
Sodium Oxybate	Adjust age range to include new pediatric indication for ages 7 and older.

Kalydeco (Ivacaftor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Has a diagnosis of cystic fibrosis; and*
3. *Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST/ALT) are provided.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. *Adherence to ivacaftor therapy is confirmed; and*
2. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

Mark Graber motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Orkambi (Lumacaftor/Ivacaftor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Has a diagnosis of cystic fibrosis; and*
3. *Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and*
4. *Baseline liver function tests (AST/ALT) and bilirubin levels are provided and*
5. *Prescriber is a CF specialist or pulmonologist.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. *Adherence to lumacaftor/ivacaftor therapy is confirmed; and*
2. *Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.*

Jason Kruse motioned to accept the criteria as amended, and Mark Graber seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Hematopoietics/Chronic ITP (Thrombopoeitin Receptor Agonists): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hematopoietics/chronic ITP agents. Request must adhere to all FDA approved labeling. Payment for a non-preferred hematopoietic/chronic ITP agent will be considered following documentation of a recent trial and therapy failure with a preferred hematopoietic/chronic ITP agent when applicable, unless such a trial would be medically contraindicated. Payment will be considered under the following conditions:

1. *A diagnosis of thrombocytopenia with chronic immune thrombocytopenia (ITP) (Promacta, Nplate, or Tavalisse)*
    a. *Patient has documentation of an insufficient response to a corticosteroid, immunoglobulin, or splenectomy.*
2. *A diagnosis of severe aplastic anemia (Promacta)*
    a. *Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and*
    b. *Patient has a platelet count less than or equal to 30 x10^9/L.*
    c. *If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.*
3. *A diagnosis of thrombocytopenia with chronic liver disease in patients who are scheduled to undergo a procedure (Mulpleta)*
    a. *Patient has a platelet count less than 50 x 10^9/L; and*
    b. *Dosing will begin 8 to 14 days prior to a scheduled procedure; and*
    c. *Patient is scheduled to undergo a procedure within 2 to 8 days after the last dose; and*
    d. *A platelet count will be obtained no more than 2 days before starting treatment.*

Jason Kruse motioned to accept the criteria as amended, and Melissa Klotz seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Elagolix (Orilissa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for gonadotropin-releasing hormone (GnRH)

antagonists. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of moderate to severe pain associated with endometriosis; and*
2. *Pregnancy has been ruled out; and*
3. *Patient does not have osteoporosis; and*
4. *Patient does not have severe hepatic impairment; and*
5. *Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine and gemfibrozil); and*
6. *Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and*
7. *Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.*
8. *Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose.*

Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.

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

Melissa Klotz motioned to accept the criteria as amended, and Jason Kruse seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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

Prior authorization is required for oral constipation agents subject to clinical criteria. Payment for non-preferred oral constipation agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred oral constipation agent. Payment will be considered under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Patient must have documentation of adequate trials and therapy failures with both of the following:*
    a. *Stimulant laxative (senna) plus saline laxative (milk of magnesia); and*
    b. *Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); and*
3. *Patient does not have a known or suspected mechanical gastrointestinal obstruction; and*
4. *Patient has one of the following diagnoses:*
    a. *A diagnosis of chronic idiopathic constipation (Amitiza®, Linzess™, Trulance®)*
        i. *Patient has less than 3 spontaneous bowel movements (SBMs) per week; and*

ii. *Patient has two or more of the following symptoms within the last 3 months:*
    1. *Straining during at least 25% of bowel movements;*
    2. *Lumpy or hard stools for at least 25% of bowel movements; and*
    3. *Sensation of incomplete evacuation for at least 25% of bowel movements; and*
iii. *Documentation the patient is not currently taking constipation causing therapies*

b. *A diagnosis of irritable bowel syndrome with constipation (Amitiza®, Linzess™, Trulance®)*
    i. *Patient is female (Amitiza® only); and*
    ii. *Patient has recurrent abdominal pain on average at least 1 day per week in the last 3 months associated with two (2) or more of the following:*
        1. *Related to defecation;*
        2. *Associated with a change in stool frequency; and/or*
        3. *Associated with a change in stool form*

c. *A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™, Relistor®, or Symproic®)*
    i. *Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and*
    ii. *Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:*
        1. *Hard to very hard stool consistency;*
        2. *Moderate to very severe straining; and/or*
        3. *Having a sensation of incomplete evacuation*

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Jason Wilbur motioned to accept the criteria as amended, and Mark Graber seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Desmopressin Acetate Nasal Spray (Noctiva): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Noctiva (desmopressin acetate). Payment will be considered for patients when the following criteria are met:

1. *Patient is 50 years of age or older; and*

2. *Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine production occurring at night; and*
3. *Patient wakens at least 2 times at night to void; and*
4. *Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and*
5. *Patient is not taking a diuretic in the evening; and*
6. *Patient does not have any of the following contraindications:*
    a) *Current or previous history of hyponatremia; and*
    b) *Primary nocturnal enuresis; and*
    c) *Polydipsia; and*
    d) *Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and*
    e) *Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and*
    f) *Estimated glomerular filtration rate < 50 mL/min/1.73 m^2; and*
    g) *Illnesses that can cause fluid or electrolyte imbalance; and*
    h) *New York Heart Association (NYHA) Class II-IV congestive heart failure; and*
    i) *Uncontrolled hypertension.*

Initial requests will be considered for 3 months. Requests for continuation of therapy will require the following:

1. *Patient continues to meet above criteria; and*
2. *Patient has experienced a decrease in nocturnal voiding; and*
3. *There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).*

Jason Kruse motioned to accept the criteria as amended, and Melissa Klotz seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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

For patients initiating therapy with a preferred oral agent, a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *Patient meets the FDA approved age; and*
3. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*
4. *Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.*

For patients initiating therapy with fingolimod (Gilenya™):

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

For patients initiating therapy with teriflunomide (Aubagio®):

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

For patients initiating therapy with dimethyl fumarate (Tecfidera™):

1. *Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.*
2. *Upon renewal, documentation of an updated CBC.*

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

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

Janus Kinase 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. *Patient meets the FDA approved age and*
2. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and*
3. *Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and*
4. *Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and*
5. *Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and*
6. *Patient is not at an increased risk of gastrointestinal perforation; and*

7. *Patient does not have an active, serious infection, including localized infections; and*
8. *Medication will not be given concurrently with live vaccines; and*
9. *Follows FDA approved dosing based on indication; and*
10. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis with*
        i. *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, or leflunomide); and*
        ii. *A documented trial and inadequate response to two preferred biological DMARDs; OR*
    b. *Psoriatic arthritis with*
        i. *A documented trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
        ii. *Documented trial and therapy failure with two preferred biological agents used for psoriatic arthritis; OR.*
    c. *Patient has a diagnosis of moderately to severely active ulcerative colitis, and*
        i. *Has a documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
        ii. *Has a documented trial and inadequate response with a preferred biological DMARD; and*
        iii. *If requested dose is for 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit.*

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

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

Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for CGRP Inhibitors. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of migraine as defined by one of the following:*
    a. *Chronic Migraine*
        i. *≥ 15 headache days per month for a minimum of 3 months; and*
        ii. *≥ 8 migraine headache days per month for a minimum of 3 months; or*
    b. *Episodic Migraine*
        i. *4 to 14 migraine days per month for a minimum of 3 months; and*

2. *Patient meets the FDA approved age; and*
3. *Patient has been evaluated for and does not have medication overuse headache; and*
4. *Patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadalol, propranolol, timolol], antidepressants, [amitriptyline, venlafaxine]); and*
5. *The requested dose does not exceed the maximum FDA labeled dose; and*
6. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days).

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

No further changes were recommended. 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 conducted the second review of the draft DUR Digest Volume 31, Number 1. The final document will be posted to the DUR website.

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

Articles of Interest: The Commission members were provided a link to an article recently published regarding empathy as a foundation for legislative medical policy.

At 12:32, Kellen Ludvigson motioned to adjourn, and Mark Graber seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, February 6, 2019, at the Department for the Blind in Des Moines.