Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes June 7, 2017

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Larry Ambroson, R.Ph.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Brian Couse, M.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
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 9:37 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 5, 2017 meeting were reviewed. Daniel Gillette motioned to accept them, Brian Couse seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting, a recommendation letter from the P&T Committee regarding development of PA criteria for Exondys 51, and a letter from Advocates for Opioid Recovery were also reviewed. There will be no changes to buprenorphine/naloxone prior authorization criteria and quantity limits at this time, but they will be reviewed at a future meeting.

IME Pharmacy Update

The Iowa legislature made a change to the P&T Committee and DUR Commission code language, which states: “When making recommendations or determinations regarding beneficiary access to drugs and biological products for rare diseases as defined in the Federal Orphan Drug Act of 1983, publication number 97-414, and drugs and biological products that are genetically targeted, the committee shall request and consider information from individuals who possess scientific or medical training with respect to the drug, biological product, or rare disease.” The IME is currently working on a new process for the committees, which will most likely result in drug discussions being delayed. Information will be brought to the committees once finalized, and it will also be provided on the website. The legislature is also requiring DHS to review the use of step therapy protocols and the application of step therapy override exceptions in the Iowa Medicaid program. In the review the Department may consider the use of step therapy protocols and the application of step therapy override exceptions as provided in Chapter 514F.7 if enacted by 2017 Iowa Acts House File 233 and the potential for improving the quality of life of Medicaid members and increasing efficiencies in the Medicaid program. The Department shall report findings of the review and recommendations to the individuals designated in this Act for submission of reports by November 15, 2017. 514F.7 has to do with those providers that are under the jurisdiction of the insurance commissioner, and

Medicaid is not. House File 233 was enacted as part of the legislation under the insurance division section, and defines step therapy as a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular covered person, are covered under a pharmacy or medical benefit by a health carrier, health benefit plan, or utilization review organization, including self-administered drugs and drugs administered by a health care professional. Both the IME Pharmacy and Medical benefits will be reviewing this. From a Pharmacy benefit perspective, it would impact the sequence requiring someone to try a preferred medication before allowing them to take a non-preferred medication, as well as some of the established criteria in the PA criteria. IME will be looking at the current process versus the process that is defined in the House File to see if any changes or improvements need to be made, or if requirements are already being met. IME has a relatively transparent process for how it does things, compared to what some of the other insurers do. Any resulting recommended changes will be brought back to the Commission at the next meeting in August. Pam Smith presented Brian Couse and Larry Ambroson with letters and certificates signed by the Medicaid Director in thanks for their service, as this was their last meeting.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a three-and-a-half-minute overview for fee-for service statistics from March through April 2017, including: total amount paid ($1,618,380), cost per user ($216.19), and number of total prescriptions dispensed (29,207). There were 7,486 unique users, which is 8.8% less than the total for January and February. There were no large changes on the top 100 pharmacies by prescription count report, given the small FFS population. All ranking changes on the top 100 pharmacies by paid amount report were understandable given the number of members, prescriptions, and drugs dispensed. On the top 100 prescribing providers by prescription count report, the prescribing practices of the top 5 prescribers were all in line with their specialties. Pam Smith also looked further into the prescribers that had a high prescription per member count. There was nothing out of the ordinary on the top 100 prescribing providers by paid amount report. The top 5 therapeutics classes by paid amount were: Antipsychotics – Atypicals; Anticonvulsants; Anti-Inflammatories, Non-NSAID; Stimulants – Amphetamines – Long Acting; and Diabetic – Insulin. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics - Miscellaneous, Antipsychotics – Atypicals, and Beta-Lactams/Clavulanate Combos. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Latuda, methylphenidate hcl er, Strattera, Humalog, Humira Pen, Lantus, Advair Diskus, Norditropin Flexpro, and Onfi. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg, Tramadol 50mg, fluoxetine 20mg, clonidine 0.1mg, and Ventolin HFA. 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 $98,475,984 was spent in total for 250,777 unique users who had 1,306,567 prescriptions.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided a two-and-a-half-minute overview for Amerigroup's statistics from March through April 2017, 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. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, Antidiabetics, Antiasthmatic and Bronchodilator Agents, Antipsychotics/Antimanic Agents, and Antivirals. Vyvanse was the #1 most expensive medication, followed by methylphenidate er, Latuda, Humira Pen, and Humalog. The Bi-Monthly Statistics report reflected that expenditures totaled $35,408,088, a 3.5% decrease from January and February. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Analgesics – Opioid. Hydrocodone-acetaminophen has been the drug with the highest prescription count since April 1, 2016, followed by: escitalopram, omeprazole, and Ventolin HFA. After the last meeting, Sandy Pranger checked with report analysts to confirm that reversed claims are not included in the reports. They had been previously included, but the issue has now been corrected.

United Healthcare Community Plan: Karrie Hansotia spoke for 3 and a half minutes and provided written summaries that included United's statistics from March through April 2017, including: total paid amount, unique users, and cost per user. She noted that not much changed from the January/February reporting period to the March/April period. 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 and 4 Walgreens locations made up the top 5. ARJ Infusion Services 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; Antihemophilic Factors; Adrenergics, Aromatic, Non-Catecholamine; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; and Tx for Attention Deficit-Hyperactivity ADHD)/Narcolepsy. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Analgesics, Narcotics; Penicillins; and NSAIDs, Cyclooxygenase Inhibitor-Type Analgesics. The most expensive drugs were Novoseven RT, Vyvanse, methylphenidate er, Harvoni, Humira Pen, and Humalog, while hydrocodone/apap, amoxicillin, omeprazole, Lisinopril, and levothyroxine sodium had the top 5 prescription counts.

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a four-minute overview for AmeriHealth's statistics from March through April 2017, including: total paid amount ($35,111,886 - not much change from the previous reporting period), unique users (92,364), average cost per user ($380.15), total prescriptions (495,639), utilization by age and gender (age 19-64 category highest for both genders), top 100 pharmacies by prescription count (Walgreens, Mercy Family, and Broadlawns had the highest counts), top 100 pharmacies by paid amount (predominantly specialty pharmacies at the top of the list), top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount (top 4 similar to last reporting period). The top 5 therapeutics classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin

Antagonist; Adrenergics, Aromatic, Non-Catecholamine; Anticonvulsants; and Tx for Attention Deficit-Hyperactivity (ADHD)/Narcolepsy. The top 5 therapeutic classes by prescription count were: Anticonvulsants; SSRIs; Proton-Pump Inhibitors; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; and Penicillins. The most expensive drugs were Vyvanse, methylphenidate er, Latuda, Humalog, and Lantus, whereas omeprazole, hydrocodone-acetaminophen, amoxicillin, lisniopril, and levothyroxine sodium had the highest prescription counts.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comments from the speakers listed below.

Name	Representing	Drug/Topic
Robert Lyon	Genentech	Xolair
Greg Kitchens	Artia Solutions/PTC Therapeutics	Emflaza
Kerri Hoernemann	Novartis	Entresto
Nancy Bell	Pfizer	Eucrisa
Anthony Pudlo	Iowa Pharmacy Association	AMA principles for PA
Jason Lurk	Novo Nordisk	Xultophy 100/3.6

Retrospective Claims Analysis

Concomitant Use of Benzodiazepines and Opioids: The Commission wanted to know how many providers would be affected, and what percentage of all opioid users had concomitant use with a benzodiazepine. They suggested including patient information on informational letters to improve rate of response and impact. Pam Smith with work with the MCOs to define parameters and letter substance and bring more information back to the next meeting.

ProDUR Edits

Injectable Anticoagulant Quantity Limits: After discussion at the April 5, 2017 DUR meeting, a recommendation was made to implement ProDUR quantity limits on the injectable anticoagulants listed below, allowing for twice daily dosing to prevent incorrect quantities billed or excessive dosing. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

Drug	Proposed Quantity Limit per 30 Days
Fragmin 2,500 u/0.2 mL; Fragmin 5,000 u/0.2 mL	12 mL
Fragmin 7,500 u/0.3 mL	18 mL
Fragmin 10,000 u/mL; Fragmin 25,000 u/mL	60 mL
Fragmin 12,500 u/0.5 mL	30 mL

Fragmin 15,000 u/0.6 mL	36 mL
Fragmin 18,000 u/0.72 mL	43.2 mL
Lovenox 30 mg/0.3 mL	18 mL
Lovenox 40 mg/0.4 mL	24 mL
Lovenox 60 mg/0.6 mL	36 mL
Lovenox 80 mg/0.8 mL; Lovenox 120 mg/0.8 mL	48 mL
Lovenox 100 mg/mL Lovenox 150 mg/mL	60 mL
Lovenox 300 mg/3mL	180 mL

Prior Authorization

Prior Authorization Process:

i. **American Medical Association Prior Authorization and Utilization Management Reform Principles:** After reviewing the document provided at https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf, the Commission agreed these were good points to keep in mind when creating criteria, but most of them were already being followed. Number 19 is not possible with the current IME systems, as provider specialty designation is only optional with enrollment. Pam Smith will look into how other states identify outlying prescribers.

ii. **Iowa House File 233 – Step Therapy Protocols for Prescription Drugs:** Commission members were provided a copy of House File 233 that Susan Parker discussed in the IME Updates section above. Pam Smith believes the language found in section 3b would be most application to the DUR Commission. It states "a step therapy override exception shall be approved by the health carrier, health benefit plan, or utilization review organization if any of the following circumstances apply:

1. The prescription drug required under the step therapy protocol is contraindicated pursuant to the drug manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:
   (a) Cause an adverse reaction to a covered person.
   (b) Decrease the ability of a covered person to achieve or maintain reasonable functional ability in performing daily activities.
   (c) Cause physical or mental harm to a covered person.
2. The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person, such as the covered person's adherence to or compliance with the covered person's individual plan of care, and any of the following:
   (a) The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer's prescribing information for the drug.

(b) The health care professional's medical judgment based on clinical practice guidelines or peer-reviewed journals.
(c) The covered person's documented experience with the prescription drug regimen.

3. The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the covered person's health care professional due to lack of effectiveness.
4. The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while under the covered person's current or previous health benefit plan. This subparagraph shall not be construed to encourage the use of a pharmaceutical sample for the sole purpose of meeting the requirements for a step therapy override exception.

Pam Smith noted that the IME already gives a lot of consideration for the situations listed above through prior authorization, specifically to b1 and b3, when proper documentation is provided. b2 and b4 could also be considered if valid clinical information is provided. Medicaid can only reimburse for medications for a medically accepted indication, so this would open the door for potential off-label use. Medicaid regulations would still have to be followed in addition to the new House File regulations. Pam Smith also pointed out that Medicaid does not always pay for the most convenient drug, either. In terms of grandfathering, the P&T Committee will sometimes determine when that will be used when they review medications and there is a PDL status change. However, their use of grandfathering is very specific and not just applicable to classes of drugs in general. Commission members were asked to review this legislation based on the current process of handling what IID language considers an "exception" as was discussed and to bring back any recommendations for changes/enhancements to processes to the August meeting.

Deflazacort (Emflaza): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and*
2. *Patient is within the FDA labeled age; and*
3. *Patient experienced onset of weakness before 5 years of age; and*
4. *Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and*

5. *Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose; and*
6. *Is dosed based on FDA approved dosing.*
   The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Larry Ambroson motioned to accept the criteria as amended, and Daniel Gillette seconded. 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.

Hepatitis C Treatments: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of chronic hepatitis C; and*
2. *Patient's age and/or weight is within the FDA labeled age and/or weight; and*
3. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
4. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
5. *Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and*
6. *Viral load will be submitted by prescriber 12 weeks after completion of therapy; and*
7. *Patient has advanced liver disease corresponding to a Metavir score of 2 or greater fibrosis as confirmed by one of the following:*
   - *Liver biopsy confirming Metavir score ≥ F2; or*
   - *Transient elastography (FibroScan) score ≥ 7.5kPa; or*
   - *FibroSURE (FibroTest) score ≥ 0.48; or*
   - *APRI score > 0.7; or*
   - *Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or*
   - *Physical findings or clinical evidence consistent with cirrhosis; or*
   - *Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis.*

8. *Patient's prior treatment history is provided (treatment naïve or treatment experienced); and*
9. *If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and*
10. *Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and*
11. *For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and*
12. *HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and*
13. *For patients on a regimen containing ribavirin, the following must be documented on the PA form:*
    a) *Patient is not a pregnant female or male with a pregnant female partner; and*
    b) *Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and*
    c) *Monthly pregnancy tests will be performed during treatment; and*
14. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.*
15. *Documentation is provided for patients who are ineligible to receive ribavirin.*
16. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
17. *Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.*
18. *If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.*
19. *Lost or stolen medication replacement requests will not be authorized.*
20. *The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.*

Mark Graber said looking at epidemiology, about 10% of patients per year with F2 Metavir criteria go on to F3. People with F1 may not progress. Given this information, the members would like to modify the PA criteria to include those with a Metavir score of F2 or greater. Additionally, according to the guidelines, patients with a limited life expectancy that cannot be remediated by treating HCV, transplantation, or other directed therapy do not require treatment, as little evidence exists to support initiation of treatment in patients

with limited life expectancies (less than twelve months) owning to non-liver-related comorbid conditions. Brett Faine motioned to accept the criteria as amended, and Larry Ambroson 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. New agents are expected to be released soon, so this will likely be reviewed again at future meetings.

Omalizumab (Xolair): The Commission feels that the medication should be limited to the Medical benefit based on the black box warning and the fact that the package insert further states "Administer Xolair only in a healthcare setting by healthcare providers prepared to manage anaphylaxis that can be life-threatening." Brett Faine motioned to remove coverage through the pharmacy benefit, and Larry Ambroson seconded. The decision was unanimous. The recommended removal of coverage from the Pharmacy benefit will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Crisaborole (Eucrisa): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of mild to moderate atopic dermatitis; and*
2. *Patient is within the FDA labeled age; and*
3. *Patient has failed to respond to good skin care and regular use of emollients; and*
4. *Patient has documentation of an adequate trial and therapy failure with two preferred medium to high potency topical corticosteroids for a minimum of 2 consecutive weeks; and*
5. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
6. *Patient will continue with skin care regimen and regular use of emollients.*
7. *Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.*

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 criteria, and Daniel Gillette seconded. 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.

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. *Patient is without a gallbladder.*
    b. *Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction.*
    c. *Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day.*
    d. *A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction).*
    e. *Severe hepatic impairment (Child-Pugh Class C).*
    f. *Severe constipation or sequelae from constipation.*
    g. *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.

Kellen Ludvigson motioned to accept the criteria, and Larry Ambroson seconded. 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.

New to Market Drugs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for newly marketed drugs. Payment will be considered for patients when the following criteria are met:

1. *Patient has an FDA approved or compendia indication for the requested drug; and*
2. *If the requested drug falls in a therapeutic category/class with existing prior authorization criteria, the requested drug must meet the criteria for the same indication; or*

3. *If no clinical criteria are established for the requested drug, patient has tried and failed at least two preferred drugs, when available, from the Iowa Medicaid Preferred Drug List (PDL) for the submitted indication; and*
4. *Request must adhere to all FDA approved labeling.*

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

Once newly marketed drugs are reviewed by the Pharmaceutical & Therapeutics Committee, they will be placed on the PDL which will dictate ongoing PA criteria, if applicable.

Daniel Gillette motioned to accept the criteria as modified, and Brett Faine seconded. 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.

High Dose Opioid (≥ 90 MME/day): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for use of high-dose opioids ≥90 morphine milligram equivalents (MME) per day. (See CDC Guideline for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. *Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and*
2. *Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and*
3. *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*
4. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and*
5. *There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and*
6. *Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and*
7. *Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and*
8. *Chart notes from a recent office visit for pain management is included documenting the following:*

a. *Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and*
b. *Treatment goals; and*

9. *Patient has been informed of the risks of high-dose opioid therapy; and*
10. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and*
11. *The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and*
12. *A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and*
13. *The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and*
14. *Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and*
15. *Patient has been educated on opioid overdose prevention; and*
16. *Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and*
17. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and*
18. *A documented dose reduction is attempted at least annually.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. *High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and*
2. *Patient has not experienced an overdose or other serious adverse event; and*
3. *Patient is not exhibiting warning signs of opioid use disorder; and*
4. *The benefits of opioids continue to outweigh the risks; and*
5. *A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and*
6. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and*

7. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.*
8. *Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and*
9. *Patient has been reeducated on opioid overdose prevention; and*
10. *Patient's household members have been reeducated on the signs of opioid overdose and how to administer naloxone.*

Given the additional burden this will create for the MCOs, the Commission agreed to initially only apply the criteria for new starts, and let existing users continue on their existing regimens for now, potentially addressing them in a future DUR focus study. They also suggested letters and calls to providers and members along with the customary informational letter. Pam Smith and the MCO representatives looked into how many members and providers will be impacted after the last meeting. Fee-for-service had 47 members (and 46 providers), AmeriHealth Caritas 904 members, Amerigroup 1694 members (and 612 providers), and United Healthcare 735 members. Susan Parker said a legislative opioid commission is being created to seek input from organizations and states and provide a report, and it could potentially suggest additional criteria or quantity limits. Since the data reported varied by program, Pam Smith will work with the MCOs to define parameters to ensure all four programs use the same data points. The information will be brought back to the next meeting for further discussion.

GLP-1 Agonist/Basal Insulin Combinations: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products. Payment will be considered for patients when the following criteria are met:

1. *A diagnosis of type 2 diabetes mellitus; and*
2. *Patient is 18 years of age or older; and*
3. *The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and*
4. *Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and*
5. *Will not be used concurrently with prandial insulin; and*
6. *Clinical rational is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and*
7. *Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of:*
    a. *Soliqua below 15 units or over 60 units, or*
    b. *Xultophy persistently below 16 units or over 50 units.*

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

Calcifediol (Rayaldee): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for calcifediol (Rayaldee). Initial requests will be considered for patients when the following criteria are met:

1. *Patient is 18 years of age or older; and*
2. *Patient is being treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) as documented by a current glomerular filtration rate (GFR); and*
3. *Patient is not on dialysis; and*
4. *Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL within the past 3 months; and*
5. *Patient has documentation of a previous trial and therapy failure at a therapeutic dose with a preferred vitamin D analog for a minimum of 3 months.*
6. *Initial requests will be considered for a dose of 30 mcg once daily for 3 months.*

Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to need to be treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) documented by a current glomerular filtration rate (GFR); and*
2. *Patient has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and a serum phosphorus below 5.5 mg/dL.*

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

Lesinurad (Zurampic): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for lesinurad (Zurampic). Requests for doses above the FDA approved dose will not be considered. Requests will be considered for patients when the following criteria are met:

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of hyperuricemia associated with gout; and*
3. *Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least 3 months; and*
4. *Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and*

5. *Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and*
6. *Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor.*
    a. *If taking allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min); and*
7. *Patient does not have a contraindication to therapy including any of the following:*
    a. *Severe renal impairment (eCrCl <30 mL/min),*
    b. *End stage renal disease,*
    c. *Kidney transplant recipient,*
    d. *On dialysis,*
    e. *Tumor lysis syndrome, or*
    f. *Lesch-Nyhan syndrome.*

If criteria for coverage are met, initial requests will be given for 6 months. Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to take medication in combination with a xanthine oxidase inhibitor.*
    a. *If allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min)*
2. *Patient has an eCrCl > 45 mL/min; and*
3. *Patient does not have a contraindication to therapy including any of the following:*
    a. *Severe renal impairment (eCrCl <30 mL/min),*
    b. *End stage renal disease,*
    c. *Kidney transplant recipient,*
    d. *On dialysis,*
    e. *Tumor lysis syndrome, or*
    f. *Lesch-Nyhan syndrome.*
4. *Documentation of a positive clinical response to lesinurad.*

The required trials may be overridden when documented evidence is provided that use of the agent(s) 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.

Sapropterin (Kuvan): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met:

1. *Patient has a diagnosis of phenylketonuria (PKU); and*
2. *Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and*
3. *Patient has a baseline blood Phe level ≥360 micromol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sapropterin therapy (attach lab results); and*
4. *Patient's current weight is provided; and*
5. *Request is for an FDA approved starting dose (10mg/kg/day for patients 1 month to 6 years and 10-20mg/kg/day for patients 7 years and older); and*
6. *Blood Phe levels will be measured after 1 week of therapy and at least one other time during the first month of therapy.*

Initial requests will be considered for 1 month to assess response to therapy.
Continuation of therapy will be considered when the following criteria are met:

1. *Patient's current weight is provided; and*
2. *Patient continues on a Phe restricted diet; and*
3. *For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for 1 month to assess response to therapy.*
4. *For patients initiated at a dose of 20mg/kg/per day or those increased to this dose after 1 month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease after 1 month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved.*
5. *Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at 6 month intervals. Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.*

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 29, Number 3. There were not recommended changes. The DUR Digest will be posted to the DUR website.

MedWatch: The Commission members received FDA announcements concerning new

Black Box Warnings.

At 11:55, Larry Ambroson motioned to adjourn the meeting and Daniel Gillette and Brian Couse both 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 2, 2017, at the Learning Resource Center in West Des Moines.