Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 2, 2017

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Jason Wilbur, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; 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 June 7, 2017 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Brett Faine seconded. The decision was unanimous. Members were asked to complete their annual conflict of interest disclosures. However, they decided to postpone the chairperson and vice-chairperson elections until the October meeting when all members should be present. The recommendation letter sent to DHS after the last meeting was also reviewed.

Biologics and Genetically Targeted Drugs

With HF653, 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." Section 249.24 is directed more toward the DUR Commission, and requires that the individuals specified above be contacted prior to any recommendations and determinations. The IME has developed a new process, wherein the IME will request the information through a public notification posted to the website and through a listserv for both P&T and DUR. A public notification request for comment form is being drafted; it will direct anyone who has the specified qualifications to prepare their public comment, which can be given in person or provided in writing. Once completed, it will be sent out to the listserv and also posted to the website. All public comments received in response will be posted to the websites and available to the public. An informational letter will go out to providers and both the PDL and DUR websites will be updated in the near future.

Step Therapy Protocol for Prescription Drugs

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. Pam Smith believes the language found in Section 1, subsection 3b would be most applicable to the DUR Commission review. 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 consideration for the situations listed above through prior authorization.
   - Specifically, to subsection 3 b1 (contraindicated) and b3 (prior trial & failure), when proper medical documentation is provided.
   - For subsection 3 b2 (expected to be ineffective & compliance) and b4 (established) 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 determines when grandfathering will apply when they review medications and there is a PDL status change. However, their use of grandfathering is very specific and may not be applicable to classes of drugs in general.

At the June meeting, Commission members were provided a copy of House File 233 and asked to review this legislation based on the current process of handling what the Iowa Insurance Division (IID) language considers an "exception" as was discussed, and to bring back any recommendations for changes/enhancements to processes to the August meeting.

At the August meeting, Jason Wilbur commented that it appears the current PA forms generally cover all these bullet points and allow for exceptions as necessary. Mark Graber was unsure how patient adherence could be evaluated ahead of time; he thinks that while prescribers try to simplify the regimen anyway, that shouldn't be the primary moving force. Jason Wilbur agreed #2 could potentially be used to justify once a day treatment rather than twice a day, and Pam Smith reminded them that Medicaid doesn't always pay for the most convenient drug. Jason Kruse agreed that #2 was a bit of an overreach and creates a loophole for people who refuse to fill medications; he thought that entire section could be stricken. Mark Graber and Brett Faine commented that 2b provided an out for everybody. The Commission agreed that these exceptions under #2 completely undermine the concept of the Preferred

Drug List (PDL), and thus prior authorization criteria in general. Jason Kruse said that 2b, which essentially defers to physician preference, undermines the entire process, and that it should be removed if the intent was to keep the process intact. Mark Graber again reiterated that predicted non-compliance should not be an exception, and that members should be required to at least try the medication first. Laurie Anderson asked how 2c would apply to product samples, as she believed a submitted claim would be required. Pam Smith responded that trials completed prior to Medicaid coverage documented in chart notes could be taken into consideration, but samples usually were not. However, Erin Halverson added that there could also be circumstances where a sample trial was counted, such as if it was only 1 of 2 agents in the category and the member had a bad reaction with a sample trial. She reiterated that clinical judgment will always apply, and will be applied on an individual level. Susan Parker noted that when these exceptions are applied in private insurance there are consequences such as higher copays to the member that might prevent so many from skipping steps, whereas Medicaid cannot charge higher copays for higher tiers of drugs. Medicaid is also required to only cover usage for FDA approved indications, so copying the private insurer language directly to Medicaid with no changes may result in unintended consequences. DHS is developing a response and will incorporate the comments above; the DUR portion of the report draft version will be brought back to the DUR Commission for review and finalization.

IME Pharmacy Update

DUR Commission members Mark Graber and Kellen Ludvigson have also been appointed to the P&T Committee for the upcoming 2-year term.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an eleven-minute overview for fee-for service statistics from May through June 2017, including: total amount paid ($1,627,062), cost per user ($244.19), and number of total prescriptions dispensed (27,442). There were 6,663 unique users, which is 11.6% less than the total for March and April. 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; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; Anticonvulsants; Stimulants – Amphetamines – Long Acting; and Anti-Inflammatories, Non-NSAID. 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, Advate, Humalog, Strattera, Enbrel Sureclick, Ibrance, Advair Diskus, and Lantus. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg,

Tramadol 50mg, Ventolin HFA, fluoxetine 20mg, and trazodone 50mg. 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 $95,848,982 was spent in total for 240,777 unique users who had 1,294,601 prescriptions.

MCO Prevalence Report Summary and Updates

United Healthcare Community Plan: Karrie Hansotia spoke for six minutes and provided written summaries that included United's statistics from May through June 2017, including: total paid amount ($25,158,248.31), unique users (66,997), and cost per user ($375.51). She noted that not much changed from the March/April reporting period to the May/June 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. BriovaRx 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; Adrenergics, Aromatic, Non-Catecholamine; Hep C Virus – NS5B Polymerase & NS5A Inhibitor Combo; and Anti-Inflammatory Tumor Necrosis Factor Inhibitor. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Analgesics, Narcotics; NSAIDs, Cyclooxygenase Inhibitor-Type Analgesics; and Proton-Pump Inhibitors. The most expensive drugs were Vyvanse, Harvoni, Humalog, methylphenidate er, and Latuda, while hydrocodone/apap, omeprazole, lisinopril, levothyroxine sodium, and gabapentin had the top 5 prescription counts.

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a seven-minute overview for AmeriHealth's statistics from May through June 2017, including: total paid amount ($34,895,753 - not much change from the previous reporting period), unique users (87,273), average cost per user ($399.85), total prescriptions (491,768), 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 3 similar to last reporting period). The top 5 therapeutics classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Anticonvulsants; Adrenergics, Aromatic, Non-Catecholamine; and Tx for Attention Deficit-Hyperactivity (ADHD)/Narcolepsy. The top 5 therapeutic classes by prescription count were: Anticonvulsants; SSRIs; Proton-Pump Inhibitors; Antihistamines – Second Generation; and Antipsychotic, Atypical, Dopamine, Serotonin Antagonist. The most expensive drugs were Vyvanse, methylphenidate er, Latuda, Humalog, and Lantus, whereas omeprazole, hydrocodone-acetaminophen, lisinopril, levothyroxine sodium, and sertraline had the highest prescription counts.

Amerigroup: Sandy Pranger provided a three-and-a-half-minute overview for Amerigroup's statistics from May through June 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, Humira Pen, Latuda, and Harvoni. The Bi-Monthly Statistics report reflected that expenditures totaled $33,021,668, a 6.5% decrease from March and April. 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 gabapentin.

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
Nancy Bell	Pfizer	Eucrisa, smoking cessation agents
Donald Hillebrand	Unity Point	Hepatitis C treatments
Michelle Plugge	Regeneron	Dupixent

Retrospective Claims Analysis

Concomitant Use of Benzodiazepines and Opioids: At the last meeting, 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. The Fee-for-Service and AmeriHealth programs both ran numbers for all members, while Amerigroup and United only included those with 90 or more MME. Keeping that in mind, these were the resulting statistics:

Opioids plus Benzodiazepines January through March 2017								
	FFS		Amerigroup		AmeriHealth		United Healthcare	
	Member	Prescriber	Member	Prescriber	Member	Prescriber	Member	Prescriber
Benzo	630	523	210	238	7232	2737	550	512
Opioid	1069	1104	1675	1347	15047	5484	1413	998
Benzo + opioid 1-29 days	133	228	68	128	1256		98	123
Benzo + opioid 30+ days	34	53	142	110	866		452	389

AmeriHealth and United will look into whether the case managers are reviewing profiles for concurrent use, multiple prescribers, etc. Amerigroup says it already does. The Commission would like a letter sent to all identified prescribers, emphasizing use of the PMP and recent PMP access changes, and the dangers of concomitant use (especially at higher doses) as per the CDC guidelines. Pam Smith will work with the MCOs to define parameters and letter substance.

ProDUR Edits

Tramadol Age Edit: Due to the recent changes to the label of tramadol containing medications, the DUR Commission made a recommendation to implement an age edit on all tramadol containing medications. Brett Faine motioned to implement an age edit that would restrict tramadol use in members 18 years of age or older and not allow the 72-hour emergency override for members under 18 years of age. Jason Kruse seconded, all members were in favor.

Prior Authorization

Dupilumab (Dupixent): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
2. *Patient is within the FDA labeled age; and*
3. *Is prescribed by or in consultation with a dermatologist; and*
4. *Patient has failed to respond to good skin care and regular use of emollients; and*
5. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
6. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
7. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
8. *Patient will continue with skin care regimen and regular use of emollients; and*
9. *Dose does not exceed an initial one-time dose of 600mg and maintenance dose of 300mg thereafter given every other week.*

If criteria for coverage are met, initial authorizations will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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

Jason Kruse motioned to accept the criteria as amended, and Kellen Ludvigson seconded. The decision was unanimous. The recommendation will be sent to the medical/pharmacy groups for comment and will be brought back to the next meeting for further discussion.

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

Prior authorization is required for oral buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids, tramadol and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of opioid dependence and is 16 years of age or older: AND*
2. *Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND*
3. *Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND*
4. *A projected treatment plan is provided, including:*
   - *Anticipated induction/stabilization dose,*
   - *Anticipated maintenance dose,*
   - *Expected frequency of office visits, and*
   - *Expected frequency of counseling/psychosocial therapy visits; AND*
5. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
6. *Requests for buprenorphine will only be considered for pregnant patients.*

Requests for renewal must include:

- *An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale,*
- *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request,*
- *Documentation of a current, negative drug screen,*
- *Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.*

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

The Commission reviewed current criteria taking into account the Advocates for Opioid Recovery letter supplied as a part of the meeting materials. They did not feel criteria

needed to be changed based on the suggestions in the letter but felt a revision to remove "…is 16 years of age or older" and replacing it with a general statement for the FDA approved age was warranted. Pam Smith will revise the criteria as suggested and bring it back to the next meeting for a vote.

Smoking Cessation Therapy, Oral & Nicotine Replacement Therapy: The Commission reviewed the prior authorization criteria as follows:

Smoking Cessation Therapy – Oral

Prior Authorization is required for varenicline (Chantix®) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:

1. *Diagnosis of nicotine dependence and referral for counseling 1) to Quitline Iowa program for Medicaid Fee-for service members or 2) through the Managed Care Organization program for managed care members.*
2. *Confirmation of enrollment and ongoing participation in the counseling program is required for approval and continued coverage.*
3. *Approvals will only be granted for patients eighteen years of age and older.*
4. *The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period.*
5. *Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.*
6. *The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation*

Nicotine Replacement Therapy

Prior Authorization is required for over-the-counter nicotine replacement patches, gum, or lozenges, and prescription nicotine nasal spray or inhaler. Requests for authorization must include:

1. *Diagnosis of nicotine dependence and referral for counseling 1) to Quitline Iowa program for Medicaid Fee-for service members or 2) through the Managed Care Organization program for managed care members.*
2. *Confirmation of enrollment in the counseling program is required for approval. Continuation therapy is available only with documentation of ongoing participation in the counseling program.*
3. *Approvals will only be granted for patients eighteen years of age and older.*
4. *The maximum allowed duration of therapy is twelve weeks total combined therapy within a twelve-month period.*

5. *Patients may receive nicotine replacement patches in combination with one of the oral nicotine replacement products (gum or lozenges). A maximum quantity of 14 nicotine replacement patches and 110 pieces of nicotine gum or 144 nicotine lozenges may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at one unit per day of nicotine replacement patches and 330 pieces of nicotine gum or 288 nicotine lozenges.*
6. *Requests for non-preferred nicotine replacement products will be considered after documentation of previous trials and intolerance with a preferred oral and preferred topical nicotine replacement product. A maximum quantity of 168 nicotine inhalers or 40ml nicotine nasal spray may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at 336 nicotine inhalers or 80ml of nicotine nasal spray.*
7. *The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.*

AmeriHealth requested that the patient counseling requirement be reviewed and potentially removed from these criteria, as it is not included in their PA criteria in other states that they manage. While they understand that statistics show higher success rates when counseling is used in conjunction with medication, they believe this requirement may be preventing some members from attempting to quit smoking. Currently, the FFS program requires counseling through Quitline, and the MCOs must all meet the counseling requirement, though not necessarily through Quitline. Jason Kruse commented that unreliable phone numbers could also be an issue, as he has had patients who are refused access to these medications as they were unable to be contacted for counseling. Jason Wilbur agreed that presented a challenge with this patient population, and noted that prescribers were responsible for completing multiple forms the way the current PA process was set up. He thinks that counseling could be removed as a mandatory requirement. Mark Graber added that data suggested that success rates were higher for 24 weeks versus 12, and recommended that those in counseling (or those who appeared to be more motivated) could be approved for 24 weeks of therapy. Melissa Klotz commented that increasing the allowance to 24 weeks could also help members who require more than one quit attempt. Jennifer Schonhorst from AmeriHealth also suggested that this could be managed through quantity limits set at 24 weeks for both nicotine replacement and smoking cessation therapy, which would mean the prior authorization requirements could be removed completely. The other MCO representatives and Commission members seemed open to this approach, as well. Kellen Ludvigson added that there wasn't really abuse potential, so allowing easier access to help more members quit is a good thing, as long as it was possible from a budgeting standpoint. Pam Smith will bring the criteria back to the next meeting for further discussion and specific quantity limits should a formal recommendation be made to remove PA criteria.

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 ≥ 200 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 allow only apply the criteria to those taking 200 MME or more (and allow no grandfathering), and then gradually lower that amount over time. All providers will receive an educational letter prior to implementation, and those identified as having affected members will receive a separate letter listing the members. Pam Smith will also attempt to gather more information about how other states are approaching this issue. Brett Faine motioned to accept the criteria as amended, and Kellen Ludvigson seconded. All members were in favor.

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.

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

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.*

At the last meeting, the Commission voted to modify the PA criteria to include those with a Metavir score of F2 or greater, based on the following reasoning: 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. 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.

As he was not at the last meeting, Jason Kruse asked for an explanation as to the reason for not including people with F1, and for including the criteria found under #7 and #12. Pam Smith responded that it had been a fiscal decision due to the cost of the newer medications, initially limiting use to F3 and F4, which also matched the AASLD guidelines at the time. Jason Kruse would like to lower the criteria recommendation to F1 and leave the ultimate decision to DHS. Mark Graber suggested that it be left at F2 for now, and then re-evaluated for fiscal impact in six months. Pam Smith reminded everyone that exception to policy submission was always an option. Jason Kruse motioned to lower the criteria to include F1. Brett Faine agreed with lowering, but the other members felt this could overwhelm the budget. Mark Graber referenced a letter which claimed that 75% of patients likely hadn't yet been diagnosed; these members could have a big impact on the budget. He also reiterated that those with F1 were less likely to progress, though Jason Kruse replied that there was still risk of transmission and psychological concerns. Mark Graber is worried that if they get screened but only have F1 they won't return for follow-up. Jason Kruse also asked as to the reasoning for requiring a specialist to prescribe; this was the Commission consensus at the last meeting. As no actual criteria changes were made, no motion was necessary, and this will now go on to the Department for consideration.

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

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.

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. *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.

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

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.

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 first review of the draft DUR Digest Volume 30, Number 1. There were no recommended changes.

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

At 12:11, Brett Faine motioned to adjourn the meeting and Jason Wilbur seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, October 4, 2017, at the Fred Maytag II Scout Center in Des Moines.