

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes May 1, 2019

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. Chuck Wadle, D.O.; 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

Chairperson Brett Faine called the meeting to order at 9:31 a.m. at the Iowa Department for the Blind in Des Moines. The minutes from the February 6, 2019 meeting were reviewed. Mark Graber motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting and the recommendation letter from the P&T Committee regarding development of criteria for Epidiolex were also reviewed. Following up from previous meetings, Pam Smith announced that the prior authorization requirement would be removed for smoking cessation and nicotine replacement products, and that prior authorization for Nucala and Exondys 51 would no longer be available through the pharmacy benefit and needs to go through the Medical benefit.

IME Pharmacy Update

There is a legislative bill in process that would require removal of the clinical prior authorization for the preferred Medical Assisted Treatment (MAT) medications if signed by the governor. Prior authorization would still be allowed for the non-preferred products, but at least one preferred agent must be available without PA in the following categories: methadone, buprenorphine, naloxone, buprenorphine and naloxone combination, and naltrexone. Rules would have to be put in place within six months of initiating the process. DHS did try to make some technical corrections to the bill as naloxone is not used for treatment of substance abuse disorder, but they were not initiated. Thus DHS will have to work with the lawyers to figure out how to put everything into rules and correct the problematic areas if the bill goes through as written. Pam Smith provided a letter and certificate of appreciation to Laurie Anderson for her twelve years of service to the DUR Commission as this was her last meeting. There is now an opening for a pharmacist.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from December 2018 through February 2019, including: total amount paid (\$2,760,948), cost per user

(\$270.71), and number of total prescriptions dispensed (44,919). There were 10,199 unique users, which is 3.1% less than the total for September through November. The top 5 therapeutics classes by paid amount were: Anticonvulsants; Antiretroviral Combinations; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; and Stimulants – Amphetamines – Long Acting. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Beta-Lactams/Clavulanate Combos; and Narcotics – Miscellaneous. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Concerta, Tamiflu, Synagis, Latuda, Humalog, Invega Systema, Biktarvy, Advair Diskus, and Aubagio. The five drugs with the highest prescription count were: amoxicillin, sertraline hcl, hydrocodone/apap, trazodone hcl, and gabapentin. 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 \$143,597,344 was spent in total for 283,629 unique users who had 1,969,165 prescriptions.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from December 2018 through February 2019, 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 \$51,015,412, a 0.7% increase from the total for September through November. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant; Antidiabetics; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Inflammatory. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Humira Pen, Concerta, Latuda, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and sertraline hcl.

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from December 2018 through February 2019, including: total paid amount (\$89,820,984.49), unique users (180,074), and cost per user (\$489.80). 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, Broadlawn, 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 Beta-Adrenergic Agents, Inhaled, Short Acting. The most expensive drugs were Vyvanse, Concerta, Latuda, Humalog, and Humira Pen, while omeprazole, lisinopril, amoxicillin, levothyroxine sodium, and atorvastatin calcium had the top 5 prescription counts.

Public Comment

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

Name	Representing	Drug/Topic
Jennifer Triemstra	Greenwich Biosciences	Epidiolex
Kevin Duhrkopf	Sanofi Genzyme	Dupixent

ProDUR Edits

Initial Seven Day Opioid Supply Limit: The Commission discussed and recommended a POS hard edit, that could be overridden at the POS by the pharmacist with DUR codes, be implemented with a 60-day look-back on member claims. Kellen Ludvigson made the motion, and Jason Kruse seconded. The decision was unanimous.

Concurrent Use of Opioids and Benzodiazepines: Due to requirements in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, at the February meeting the DUR Commission made the recommendation to implement a soft edit that would identify members with concurrent use of an opioid and benzodiazepine in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the point of sale (POS). Claims would not be blocked. 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.

Concurrent Use of Opioids and Antipsychotics: Due to requirements in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, at the February meeting the DUR Commission made the recommendation to implement a soft edit that would identify members with concurrent use of an opioid and antipsychotic in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the POS. Claims would not be blocked. 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.

The Commission took a short break and open session resumed at 10:45.

Prior Authorization

Benzodiazepines: The Commission reviewed the prior authorization criteria as follows:
Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of

previous trial and therapy failure with two preferred products. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determine if the use of a benzodiazepine is appropriate for this member.

Prior authorization will be approved for up to 12 months for documented:

- 1. Generalized anxiety disorder.*
- 2. Panic attack with or without agoraphobia.*
- 3. Seizure.*
- 4. Non-progressive motor disorder.*
- 5. Dystonia.*

Prior authorization requests will be approved for up to a three-month period for all other diagnoses related to the use of benzodiazepines.

For patients taking concurrent opioids, the prescriber must document the following:

- 1. The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
- 2. Documentation as to why concurrent use is medically necessary is provided; and*
- 3. A plan to taper the opioid or benzodiazepine is provided, if appropriate.*

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

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

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

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

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

5. *Patient has a diagnosis of advanced prostate cancer.*

Therapy will be limited as follows:

1. *Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.*
2. *Uterine leiomyomata – 3 month approval.*
3. *Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).*

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

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

Prior authorization is required for Dupixent (dupilumab). Payment will be considered under the following conditions:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
 - a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
 - b. *Patient has failed to respond to good skin care and regular use of emollients; and*
 - c. *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*
 - d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
 - e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
 - f. *Patient will continue with skin care regimen and regular use of emollients; or*
3. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
 - a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
 - b. *Has a pretreatment forced expiratory volume in 1 second (FEV₁) \leq 80% predicted; and*
 - c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in*

- combination with a controller medication (e.g. long acting beta₂ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
- d. Patient must have one of the following, in addition to the regular maintenance medications defined above:*
 - i. Two (2) or more exacerbations in the previous year or*
 - ii. Require daily oral corticosteroids for at least 3 days; and*
- 4. Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization 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 Melissa Klotz seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Cannabidiol (Epidiolex): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for cannabidiol (Epidiolex). Payment will be considered under the following conditions:

- 1. Patient meets the FDA approved age; and*
- 2. Baseline serum transaminases (ALT and AST) and total bilirubin levels have been obtained prior to initiating therapy (attach results); and*
- 3. A diagnosis of Lenox-Gastaut syndrome with documentation of an adequate trial and inadequate response with at least two concomitant antiepileptic drugs (AEDs) from the following:*
 - a. Valproic acid,*
 - b. Lamotrigine,*
 - c. Topiramate,*
 - d. Felbamate,*
 - e. Rufinamide,*
 - f. Clobazam, or*
- 4. A diagnosis of Dravet syndrome with documentation of an adequate trial and inadequate response with at least two concomitant AEDs from the following:*
 - a. Clobazam,*
 - b. Valproic acid,*
 - c. Levetiracetam,*
 - d. Topiramate, and*

5. *Is prescribed by or in consultation with a neurologist; and*
6. *The total daily dose does not exceed 20mg/kg/day.*

If criteria for coverage are met, initial requests will be approved for 3 months. Additional prior authorization requests will be considered when the following criteria are met:

1. *Documentation of clinical response to therapy (i.e. reduction in the frequency of seizures); and*
2. *The total daily dose does not exceed 20mg/kg/day.*

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

Mark Graber motioned to accept the recommended criteria, and Jason Kruse seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Growth Hormones: The Commission reviewed the prior authorization criteria as follows: *Prior authorization (PA) is required for therapy with growth hormones. Requests will only be considered for FDA approved dosing. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA). Payment will be considered under the following conditions:*

Children with Growth Hormone Deficiency

1. *Standard deviation of 2.0 or more below mean height for chronological age; and*
2. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
3. *Growth rate below five centimeters per year; and*
4. *Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter; and*
5. *Annual bone age testing is required. A Bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required; and*
6. *Epiphyses open.*

Pediatric Chronic Kidney Disease

1. *Is prescribed by or in consultation with a nephrologist; and*
2. *Standard deviation of 2.0 or more below mean height for chronological age; and*
3. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
4. *Growth rate below five centimeters per year; and*
5. *Bone age of 14-15 years or less in females and 15-16 years or less in*

- males; and
6. Epiphyses open.

Turner's Syndrome

1. Chromosomal abnormality showing Turners syndrome; and
2. Prescribed by or in consultation with an endocrinologist; and
3. Standard deviation of 2.0 or more below mean height for chronological age; and
4. No expanding intracranial lesion or tumor diagnosed by MRI; and
5. Growth rate below five centimeters per year; and
6. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
7. Epiphyses open.

Prader Willi Syndrome

1. Diagnosis is confirmed by appropriate genetic testing (attach results); and
2. Prescribed by or in consultation with an endocrinologist; and
3. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
4. Epiphyses open.

Noonan Syndrome

1. Diagnosis is confirmed by the appropriate genetic testing (attach results); and
2. Prescribed by or in consultation with an endocrinologist; and
3. Standard deviation of 2.0 or more below mean height for chronological age; and
4. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
5. Epiphyses open.

SHOX (Short Stature Homeobox)

1. Diagnosis is confirmed by the appropriate genetic testing (attach results); and
2. Prescribed by or in consultation with an endocrinologist; and
3. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
4. Epiphyses open.

Adults with Growth Hormone Deficiency

1. Patients who were growth hormone deficient during childhood (childhood onset) and who have a continued deficiency; or
2. Patients who have growth hormone deficiency (adult onset) as a result of pituitary or hypothalamic disease (e.g., panhypopituitarism, pituitary adenoma, trauma, cranial irradiation, pituitary surgery); and
3. Failure of at least one growth hormone stimulation test as an adult with a

peak growth hormone value of ≤ 5 mcg/L after stimulation.

Adults with AIDS Wasting/Cachexia

- 1. Greater than 10% of baseline weight loss over 12 months that cannot be explained by a concurrent illness other than HIV infection; and*
- 2. Patient is currently being treated with antiviral agents; and*
- 3. Patient has documentation of a previous trial and therapy failure with an appetite stimulant (i.e. dronabinol or megestrol).*

Short Bowel Syndrome

*If the request is for **Zorbtive**[®] [somatropin (rDNA origin) for injection] approval will be granted in patients receiving specialized nutritional support. Zorbtive[®] therapy should be used in conjunction with optimal management of Short Bowel Syndrome. PA will be considered for a maximum of 4 weeks.*

If the criteria for coverage is met, initial requests will be given for 12-months, unless otherwise stated above. Additional prior authorizations will be considered upon documentation of clinical response to therapy and patient continues to meet the criteria for the submitted diagnosis.

Jason Kruse motioned to accept the recommended criteria, and Jason Wilbur seconded. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Sodium Oxybate (Zyrem): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sodium oxybate (Xyrem[®]). Payment will be considered under the following conditions:

- 1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; or*
- 2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant; and*
- 3. Patient meets the FDA approved age; and*
- 4. Is prescribed within the FDA approved dosing; and*
- 5. Patient and provider are enrolled in the Xyrem[®] REMS Program; and*
- 6. Patient has been instructed to not drink alcohol when using Xyrem[®]; and*
- 7. Patient has been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence; and*
- 8. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered; and-*

9. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website prior to requesting prior authorization.*

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.

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

Prior authorization is required for transmucosal buprenorphine or buprenorphine/naloxone. Requests will be considered for FDA approved dosing, including induction and maintenance dose. Requests for doses above 24mg per day 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. After the initial 3 month prior authorization, renewal requests for doses ≤ 16mg per day may be considered for 12 month renewals as long as the member meets all other prior authorization criteria. 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 or buprenorphine depot injection 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 meets the FDA approved age; AND*
- 2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number (provide X DEA number); AND*
- 3. Documentation the Iowa Prescription Monitoring Program (PMP) website has been reviewed for the patient's use of controlled substances; AND*
- 4. Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant or depot injection.*
- 5. Requests for single ingredient buprenorphine will only be considered for pregnant patients.*

Requests for renewal must include:

- 1. Documentation the Iowa PMP website has been reviewed for the patient's use of controlled substances since the last prior authorization request, AND*
- 2. Patient does not have documentation of concomitant use of an opioid or tramadol with the requested buprenorphine product, as seen in paid pharmacy claims, AND*

3. *Patient is not using transmucosal buprenorphine with buprenorphine implant or depot injection.*

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.

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

Prior authorization is required for all non-preferred short acting opioids. Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions:

1. *Patient has pain severe enough to require opioid treatment; and*
2. *Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two non-opioid pharmacologic therapies (e.g. acetaminophen or NSAIDs); and*
4. *Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and*
5. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
6. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids; and*
7. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
 - a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
 - b. *Documentation as to why concurrent use is medically necessary is provided; and*
 - c. *A plan to taper the benzodiazepine is provided, if appropriate.*

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

1. *Patient has experienced improvement in pain control and level of functioning; and*

2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website and has determined continued use of a short-acting opioid is appropriate for this member; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
 - a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
 - b. *Documentation as to why concurrent use is medically necessary is provided; and*
 - c. *A plan to taper the benzodiazepine is provided, if appropriate.*

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

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.

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

Prior authorization is required for all non-preferred long-acting opioids. Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and*
2. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two nonopioid pharmacologic therapies (e.g. acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and*
4. *There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and*
5. *A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and*
6. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
7. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical*

dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.

8. *Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered; and*
9. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
 - a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
 - b. *Documentation as to why concurrent use is medically necessary is provided; and*
 - c. *A plan to taper the benzodiazepine is provided, if appropriate.*

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

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website and has determined continued use of a long-acting opioid is appropriate for this member; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
 - a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
 - b. *Documentation as to why concurrent use is medically necessary is provided; and*
 - c. *A plan to taper the benzodiazepine is provided, if appropriate.*

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 2. The DUR Digest will be posted to the DUR website.

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

At 11:29, Chuck Wadle motioned to adjourn, and Jason Kruse seconded. All in attendance agreed. **The next meeting will be held at 9:30 a.m. on Wednesday, August 7, 2019, at a location to be determined.**