Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes February 6, 2019

Attendees:

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

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Pam Smith ran the meeting as both the chairperson and vice-chairperson were connecting via phone due to inclement weather. She called the meeting to order at 9:35 a.m. at the Iowa Medicaid Enterprise in Des Moines. The minutes from the November 7, 2018 meeting were reviewed. Mark Graber motioned to accept them, and Jason Kruse seconded. Chuck Wadle abstained as he had been absent, but all others were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Pharmacy Update

There was nothing notable to report.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview of fee-for-service statistics from September through November 2018, including: total amount paid ($2,790,494), cost per user ($264.65), and number of total prescriptions dispensed (46,357). There were 10,544 unique users, which is 5.4% more than the total for June through August. The top 5 therapeutics classes by paid amount were: Antiretroviral Combinations; Antipsychotics – Atypicals; Anticonvulsants; Stimulants – Amphetamines – Long Acting; and Antiasthmatic – Adrenergic Combos. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Narcotics – Miscellaneous; 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, Epclusa, Concerta, Genvoya, Latuda, Biktarvy, Emflaza, Humalog, ProAir HFA, and Symbicort. The five drugs with the highest prescription count were: hydrocodone/apap, amoxicillin, sertraline hcl, gabapentin, and trazodone hcl. Pam Smith also created a report that compared the FFS stats above with those from each MCO below. Its side-by-side statistics showed that $142,344,043 was spent in total for 284,282 unique users who had 2,000,116 prescriptions.

MCO Prevalence Report Summary and Updates

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from September through November 2018, including: total paid amount ($88,606,728.93), unique users (180,845), and cost per user ($489.96). 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 five. 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; Beta-Adrenergic Agents, Inhaled, Short Acting; and Antihyperlipidemic – HMG COA Reductase Inhibitors. The most expensive drugs were Vyvanse, Concerta, Humira Pen, Latuda, and Humalog, while omeprazole, lisinopril, levothyroxine sodium, atorvastatin calcium, and sertraline hcl had the top 5 prescription counts.

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from September through November 2018, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. The Bi-Monthly Statistics report reflected that expenditures totaled $50,946,820, a 5.0% increase from the total for June through August. 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 Analgesics – Anti-Imflammatory. 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 gabapentin.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comment from Flora Schmidt, Executive Director for the Iowa Behavioral Health Association, concerning prior authorization (PA) requirements for Medication-Assisted Treatment (MAT) medications. She summarized the emails sent in by clinicians from several of the MAT providers they represent (which are posted on the www.iowamedicaidpdl.com site), expressing their wishes and reasoning to request removal of the PA criteria to allow for immediate access to MAT medications often needed urgently. Charles Wadle, DUR Commission member, then provided some additional counter-points, admitting that his own practice had some issues when the PA was initially put in place. He suggested on-site induction as an option to allow for PA processing time,

and acceptance of walk-in patients for those truly in need of immediate medical attention. He reminded her that the PA criteria was being reviewed at this meeting, with many requirements set to be removed (see revised criteria below), and that issues with the way individual MCO companies handled the PAs should be taken up with those MCOs directly. He thought the providers might also be missing things necessary for approved prior authorization, as his office had at first. He also reiterated that requiring prior authorization for this was not a decision based on cost. This is a drug to treat an epidemic that was not addressed appropriately, and that's why there is an epidemic. We don't need to create another epidemic with another opioid just because it's a good opioid to treat other opioids. Caution is necessary as it does get diverted, does get misused, and overzealous prescribing of it does lend to street value and street exchange. He believes there's still value in the PA, but it will be tweaked.

H.R. 6 SUPPORT for Patients and Communities Act

H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act is legislation intended to address the opioid epidemic, including treatment, prevention, recovery, and enforcement. This legislation contains several provisions related to Medicaid. Section 1004 is specific to DUR. The full bill can be found here: https://www.govtrack.us/congress/bills/115/hr6/text. Section 1004, Medicaid Drug Review and Utilization, identifies new requirements for DUR, to be effective October 1, 2019, including: claims review limitations, program to monitor antipsychotic medications by children, fraud and abuse identification, reports, and exceptions. The Commission reviewed the required changes. For opioids, it was suggested a 7-day initial fill limit be implemented, with PA in conjunction with existing MME requirements needed after that. The MME limit is set to drop to 150 in March and eventually to 90. Kellen suggested opioid naïve POS edits that he had seen other payers use, that would allow the claim to pay if the member was already established. Pam Smith will do some additional research and bring this back to a future meeting.

ProDUR Edits

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, 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. Jason Kruse made the motion to put the edit in place, and Melissa Klotz seconded. The decision was unanimous.

Concurrent Use of Opioids and Antipsychotics: Due to requirements in the SUPPORT for Patients and Communities Act, 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. Jason Kruse made the motion to put the edit in place, and Melissa Klotz seconded. The decision was unanimous.

Duplicate Antipsychotics in Adults: A ProDUR edit to limit members 18 years of age and older to two chemically distinct antipsychotics will be implemented. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

CNS Stimulants and Atomoxetine Concurrent Therapy ProDUR Edit: For members under 21 years of age, the DUR Commission recommended to allow one unit of a short-acting stimulant with a long-acting stimulant by implementing a quantity limit on all short-acting stimulants to one unit per day (i.e., 30 units per 30 days). The intent is to require the use of long-acting stimulants, while allowing for one dose of a short-acting stimulant if needed. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

CNS Stimulants and Atomoxetine Age Edit: The minimum FDA approved ages will be followed, and prior authorization criteria updated to reflect this. No further changes were recommended. As this was the second review, 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 11:19.

Prior Authorization

Sodium Oxybate (Xyrem): 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.

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

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.*

Chuck Wadle motioned to accept the criteria as amended, and Jason Kruse seconded. All members were in favor. Additionally, it was recommended to add extra lines to the PA form to provide more writing space for strength and dosage instructions, as well as lines for induction and maintenance doses. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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.

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

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.

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

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

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

1. *Patient meets the FDA approved age; and*
2. *Has a diagnosis of cystic fibrosis; and*

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

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

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

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.

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

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

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

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

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

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.

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

Prior authorization is required for hematopoietics/chronic ITP agents. Request must adhere to all FDA approved labeling. Payment for a non-preferred hematopoietic/chronic ITP agent will be considered following documentation of a

recent trial and therapy failure with a preferred hematopoietic/chronic ITP agent when applicable, unless such a trial would be medically contraindicated. Payment will be considered under the following conditions:

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

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.

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

Prior authorization is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

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

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

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

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.

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

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

1. *Patient meets the FDA approved age; and*
2. *Patient must have documentation of adequate trials and therapy failures with both of the following:*
    a. *Stimulant laxative (senna) plus saline laxative (milk of magnesia); and*
    b. *Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); and*
3. *Patient does not have a known or suspected mechanical gastrointestinal obstruction; and*
4. *Patient has one of the following diagnoses:*
    a. *A diagnosis of chronic idiopathic constipation (Amitiza®, Linzess™, Trulance®)*
        i. *Patient has less than 3 spontaneous bowel movements (SBMs) per week; and*
        ii. *Patient has two or more of the following symptoms within the last 3 months:*
            1. *Straining during at least 25% of bowel movements;*
            2. *Lumpy or hard stools for at least 25% of bowel movements; and*
            3. *Sensation of incomplete evacuation for at least 25% of bowel movements; and*
        iii. *Documentation the patient is not currently taking constipation causing therapies*
    b. *A diagnosis of irritable bowel syndrome with constipation (Amitiza®, Linzess™, Trulance®)*
        i. *Patient is female (Amitiza® only); and*

ii. Patient has recurrent abdominal pain on average at least 1 day per week in the last 3 months associated with two (2) or more of the following:
1. *Related to defecation;*
2. *Associated with a change in stool frequency; and/or*
3. *Associated with a change in stool form*

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

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

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.

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

Prior authorization is required for Noctiva (desmopressin acetate). Payment will be considered for patients when the following criteria are met:
1. *Patient is 50 years of age or older; and*
2. *Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine production occurring at night; and*
3. *Patient wakens at least 2 times at night to void; and*
4. *Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and*
5. *Patient is not taking a diuretic in the evening; and*
6. *Patient does not have any of the following contraindications:*
   a) *Current or previous history of hyponatremia; and*
   b) *Primary nocturnal enuresis; and*
   c) *Polydipsia; and*
   d) *Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and*
   e) *Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and*

f) Estimated glomerular filtration rate < 50 mL/min/1.73 m^2; and
g) Illnesses that can cause fluid or electrolyte imbalance; and
h) New York Heart Association (NYHA) Class II-IV congestive heart failure; and
i) Uncontrolled hypertension.

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

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

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 initial review of the draft DUR Digest Volume 31, Number 2. They asked that statistics on the last page be combined to include those from both MCOs and FFS when possible.

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

At 12:10, Jason Kruse motioned to adjourn, and Chuck Wadle seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, May 1, 2019, at the Department for the Blind in Des Moines.