Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes February 1, 2017

Attendees:

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

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:32 a.m. at the Learning Resource Center in West Des Moines. The minutes from the December 7, 2016 meeting were reviewed. Brett Faine motioned to accept them, and Jason Wilbur seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was reviewed.

IME Pharmacy Update/News Relevant to Medicaid

The dispensing fee change from $11.73 to $10.02 effective August 1, 2016, is still pending CMS approval. There could be impacts to the program resulting from the current legislative session, but they are as yet unknown. Pam Smith will be attending the ADURS conference at the end of February and hopes to bring new ideas and suggestions back to the April meeting.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a five-minute overview for fee-for service statistics from November through December 2016, including: total amount paid ($1,536.614), cost per user ($210.75), and number of total prescriptions dispensed (28,626). There were 7,291 unique users, which is 6.8% less than the total for September and October. 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, with the exception of the top one. She is an OB ARNP, but also sees patients at the Meskwaki clinic. Pam Smith also looked further into the prescribers that had a high prescription per member count. There was nothing out of the ordinary on the top 100 prescribing providers by paid amount report. The top 5 therapeutics classes by paid amount were: Antipsychotics – Atypicals; Anticonvulsants; Anti-Inflammatories, Non-NSAID; Diabetic – Insulin; and

Stimulants – Amphetamines – Long Acting. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics - Miscellaneous, Beta-Lactams/Clavulanate Combos, and Antiasthmatic - Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Latuda, methylphenidate hcl er, Humalog, Humira Pen, Lantus, Abilify, Strattera, Enbrel Sureclick, and Lamictal. A letter requesting more information has been sent to the provider of the member taking 16 tablets per day of the 25mg strength of Lamictal; claims have been paying as this member has other primary insurance coverage. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg, Tramadol 50mg, azithromycin 250mg, Ventolin HFA, and fluoxetine 20mg. Mark Graber noted that the Narcotics were dropping in rank; hopefully that trend will continue.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided a three-minute overview for Amerigroup's statistics from November through December 2016, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count (4 of top 5 are Walgreens), top 100 pharmacies by paid amount (top 5 are all specialty pharmacies), top 100 prescribing providers by prescription count (the provider that moved from 155th to 3rd place changed jobs), and top 100 prescribing providers by paid amount (GI specialist #1). Similar to reports from the last 9 months, 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. On the top 100 drugs by paid amount report, Synagis jumped 1110.0% to #14, with $368,480 in expenditures during November and December. Vyvanse was the #1 most expensive medication, followed by methylphenidate er, Humalog, Latuda, and Lantus. The Bi-Monthly Statistics report reflected a fourth quarter/Synagis jump; expenditures totaled $36,257,769, a 13.2% increase from September and October. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Analgesics – Opioid, and Antihypertensives. Hydrocodone-acetaminophen has been the drug with the highest prescription count since April 1, 2016, followed by: omeprazole, amoxicillin, lisinopril, and levothyroxine.

United Healthcare Community Plan: Karrie Hansotia spoke for 2 minutes and provided written summaries that included United's statistics from November through December 2016, including: total paid amount, unique users, and cost per user. She noted that not much changed from the September/October reporting period to the November/December period. There was also a handout showing utilization by age and gender; females age 19-64 had the highest utilization. On the top 20 pharmacies by prescription count report, Broadlawns and 4 Walgreens locations made up the top 5. ARJ Infusion Services was the top pharmacy by paid amount. Lists of the top 20 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulin, Antihemophilic Products, Sympathomimetics, Stimulants – Miscellaneous, and Amphetamines. The top 5 classes by prescription count were: SSRIs, Sympathomimetics, Anticonvulsants – Miscellaneous, Proton Pump Inhibitors, and Opioid Combinations. The most expensive drugs were Novoseven, Vyvanse, Lantus,

and methylphenidate, while hydrocodone/apap, amoxicillin, omeprazole, and Lisinopril had the top 4 prescription counts.

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a two and a half minute overview for AmeriHealth's statistics from November through December 2016, including: total paid amount ($35,419,841.48, not much change from the previous reporting period), unique users (116,378), average cost per user ($304.35), total prescriptions (490,798), utilization by age and gender (age 19-64 category highest for both genders), top 100 pharmacies by prescription count (Walgreens, Broadlawns, and Mercy Family 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 (some prescribers lower down on the list that moved up quickly in the ranks are being researched), and top 100 prescribing providers by paid amount (top 5 similar to last reporting period). The top 4 therapeutics classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; and Anticonvulsants. The top 5 therapeutic classes by prescription count were: Anticonvulsants, SSRIs, Antihistamines – 2nd Generation, Proton-Pump Inhibitors, and Narcotic Analgesic and Non-Salicylate Analgesic. The most expensive drugs were Vyvanse, Abilify, methylphenidate er, and Adynovate, whereas hydrocodone-acetaminophen, omeprazole, amoxicillin, lisinopril, and levothyroxine had the highest prescription counts.

Larry Ambroson asked why there was such a difference in the number of members per MCO plan, so the representatives explained how plans were randomly assigned but still subject to member choice. Pam Smith also noted that the reports had reflected paid claims for Synagis in September & October when claims were not supposed to adjudicate until 11/1/16, and asked the MCOs to investigate those claims. In addition, as all the MCO plans and FFS classified their drug categories a little differently, she wanted to talk with them about that so they could all get a better feel as to true category comparisons.

Public Comment

Name	Representing	Drug/Topic
Pratik Parikh	Sarepta	Exondys 51
Shawn Hansen	Novo Nordisk	Tresiba, Xultify
Tim Starner	University of Iowa	Orkambi

ProDUR Edits

Miscellaneous Quantity Limits: Sandy Pranger from Amerigroup proposed quantity limits for injectable anticoagulants and select GI medications that her company had implemented in other states and run actuarial analysis on the IA Medicaid population, which they estimate would result in $110,000 in savings in 2017, just for Amerigroup.

Drug	Quantity Limit	Drug	Quantity Limit
Fragmin 10,000 u/ mL, 12,500 u/ 0.5 ml, 15,000 u/0.6 mL, 18,000 u/0.72 mL Syringe	20 mL per 30 days	Lovenox 60 mg.0.6 mL Syringe	16.8 mL per 28 days
Fragmin 2,500 u/0.2 ml; 5,000 u/0.2 mL Syringe	4 mL per 30 days	Lovenox 80 mg/0.8 mL Syringe	22.4 mL per 28 days
Fragmin 25,000 units/ mL Vial	76 mL per 30 days	Lovenox 100 mg/1 mL	28 mL per 28 days
Fragmin 7,500 units/0.3 mL Syringe	6 mL per 30 days	Lovenox 120 mg/0.8 mL Syringe	22.4 mL per 28 days
Lovenox 30 mg/0.3 mL Syringe	8.4 mL per 28 days	Lovenox 150 mg/mL Syringe	28 mL per 28 days
Lovenox 40 mg/0.4 mL Syringe	11.2 mL per 28 days	Lovenox 300 mg/3 mL Vial, Syringe	84 mL per 28 days

The Commission requested additional information to determine how many members would be affected by the limits shown in the table above before implementing them. They said BID dosing needed to be allowed. All MCO and FFS representatives will consult with their respective analysts and bring the requested information back to the April meeting. However, the Commission did motion to accept the suggested quantity limits for the GI agents listed in the table below, as they were in line with the max tolerated doses. Kellen Ludvigson made the motion, while Larry Ambroson and Brian Couse seconded simultaneously. All members were in favor. The proposed quantity limits below will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Drug	Quantity Limit	Drug	Quantity Limit
Apriso 0.375 g	4 capsules per day	Giazo 1.1 g	6 tablets per day
Azulfidine 500 mg	8 tablets per day	Lialda 1.2 g	4 tablets per day
Azulfidine EN-tabs 500 mg	8 tablets per day	Pentasa 250 mg	16 capsules per day
Canasa 1000 mg	1 suppository per day	Pentasa 500 mg	8 capsules per day
Delzicol 400 mg	6 capsules per day	Rowasa, SfRowasa 4 g/60 mL	1680 mL per 28 days
Dipentum 250 mg	4 capsules per day	Uceris 9 mg	1 tablet per day
Entocort EC 3 mg	3 capsules per day		

Prior Authorization

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

Prior authorization is required for use of high-dose opioids ≥90 morphine milligram equivalents (MME) per day. 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. *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.*

Jason Wilbur motioned to accept the criteria as modified, and Daniel Gillette seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting. In the future, a POS edit may be needed to block concurrent use of opioids and benzodiazepines. The Commission members inquired if there was still a process to lock in members to pharmacies and prescribers. As the MCO representatives were unsure of the specifics, other than just reporting any issues to Provider Services, they were asked to provide an overview of their Lock In program and contact information for prescribers and pharmacists to recommend members be enrolled in the program at the next meeting.

Insulin, Pre-Filled Pens: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all pre-filled insulin pens. For pre-filled insulin pens where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- *The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and*
- *There is no caregiver available to provide assistance, and*
- *Patient does not reside in a long-term care facility; and*

- *For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).*

For pre-filled insulin pens where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- *Preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and*
- *Non-preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).*
- *Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.*

Brett Faine motioned to accept the criteria as amended, and Kellen Ludvigson seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

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

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

b. *Xultophy persistently below 16 units or over 50 units.*

Larry Ambroson motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

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

1. *Patient is 18 years of age or older and has a diagnosis of chronic hepatitis C; and*
2. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
3. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
4. *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*
5. *Viral load will be submitted by prescriber 12 weeks after completion of therapy; and*
6. *Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:*
   - *Liver biopsy confirming Metavir score ≥ F3; or*
   - *Transient elastography (FibroScan) score ≥ 9.5kPa; or*
   - *FibroSURE (FibroTest) score ≥ 0.58; or*
   - *APRI score > 1.5; 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.*
7. *Patient's prior treatment history is provided (treatment naïve or treatment experienced); and*
8. *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*
9. *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*

10. *For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and*
11. *HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and*
12. *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*
13. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.*
14. *Documentation is provided for patients who are ineligible to receive ribavirin.*
15. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
16. *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.*
17. *Lost or stolen medication replacement requests will not be authorized.*
    The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Jason Wilbur motioned to accept the criteria as amended, and Kellen Ludvigson seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Eteplirsen (Exondys 51): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Exondys 51 (eteplirsen). Payment will be considered for patients when the following criteria are met:

1. *Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing (attach results of genetic testing); and*
2. *Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and*
3. *Patient is currently ambulatory; and*

4. *A baseline 6-Minute Walk Distance (6MWD) is provided and patient is able to achieve a distance of at least 180 meters while walking independently; and*
5. *Patient is currently stable on an oral corticosteroid regimen for at least 6 months; and*
6. *Is dosed based on FDA approved dosing: 30 mg/kg once weekly; and*
7. *Medication is to be administered by a healthcare professional in member's home by home health or in a long-term care facility.*

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

When criteria for coverage are met, an initial authorization will be given for 6 months. Requests for continuation of therapy will be considered at 6 month intervals when the following criteria are met:

1. *Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent); and*
2. *An updated 6MWD is provided documenting patient is able to achieve a distance of at least 180 meters.*

This medication was recently approved through the FDA's accelerated approval program, based on an increase in dystrophin and skeletal muscle observed in some of the patients treated. However, a clinical benefit has not been established, and continued approval may be contingent upon verification of a clinical benefit confirmed in ongoing trials. The first two trials included just 12 patients, and neither provided evidence of a difference in 6-minute walk distance between active treatment and placebo. Study 3 had 13 patients (12 included in results), whose median increase in dystrophin level at 48 weeks was 0.1%. Cost of this medication would vary by weight of the member, but for a 35kg person it would be $67,200/month, or just over $870,000/year. Several members questioned if the state had to pay for this drug as it appeared the state's Medicaid program was essentially paying for research, even if only 4 members in the state would qualify; they felt doing so completely undermines evidence-based medicine. Though other private payers are not covering this medication as they consider it investigational due to lack of established clinical benefit, Medicaid cannot exclude it from coverage. Dr. Smith commented that perhaps even though the trials did not show improvement, patients on this medication might decline at a slower rate. Under the circumstances, Jason Wilbur motioned to accept the criteria as amended, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting. The IME aims to have criteria for this medication be consistent across both the Medical and Pharmacy programs.

Colchicine: The criteria listed below has been recommended to be removed.

Prior authorization is not required for colchicine (Colcrys®) for the treatment of acute gout for three (3) tablets per 60-day period. Prior authorization is required for colchicine (Colcrys®) for the treatment of chronic hyperuricemia/gout

prophylaxis or Familial Mediterranean fever. Payment will be considered under the following conditions:

1. *Chronic hyperuricemia/gout prophylaxis following a trial and therapy failure at a therapeutic dose with allopurinol or probenecid. A quantity limit of sixty (60) tablets per thirty (30) days will be applied, when criteria for coverage are met.*
2. *Familial Mediterranean fever. A maximum quantity of 120 tablets per thirty (30) days will be applied for this diagnosis.*

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

Amerigroup suggested removing these criteria as the majority of prior authorization requests get approved. A ProDUR edit was recommended to limit usage to a quantity of 60 per 30 days, with any quantity greater than that requiring a PA. Jason Wilbur motioned to remove the criteria and implement the ProDUR edit as recommended, and Brian Couse seconded. All members were in favor. The recommendation to remove PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Lumacaftor/Ivacaftor (Orkambi): The Commission reviewed and voted on 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 is 6 years of age or older; 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; and*

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.*

This was the second review for this medication. After further discussion, the Commission made a recommendation to remove requirements requiring a baseline percent predicted forced expiratory volume (ppFEV1), remove exclusion of patients with *Burkholderia cenocepacia, Burkholderia dolosa*, or *Mycobacterium abcessus*, and for PA renewals, remove the requirement to provide documentation of a response to therapy. Brett Faine

motioned to accept the criteria as amended, and Daniel Gillette seconded. All members were in favor. Due to multiple changes to the criteria, the amended PA criteria will be sent to the medical/pharmacy associations again for comment and brought back to the next DUR meeting.

Alpha$_2$ Agonists, Extended-Release: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:

1. *The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
2. *Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
3. *Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant.*

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.

Daclizumab (Zinbryta): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of a relapsing form of multiple sclerosis (MS); and*
2. *Patient is 18 years of age or older; and*
3. *Patient has documentation of previous trials and therapy failures with two or more drugs indicated for the treatment of MS; and*
4. *Patient does not have pre-existing hepatic disease or hepatic impairment (including hepatitis B or C); and*
5. *Baseline transaminases (ALT, AST) and bilirubin levels are obtained; and*
6. *Patient does not have an ALT or AST at least 2 times the upper limit of normal (ULN); and*
7. *Patient does not have a history of autoimmune hepatitis or other autoimmune condition involving the liver, and*
8. *Patient has been screened for TB and treated for TB if positive; and*
9. *Daclizumab will be used as monotherapy; and*
10. *Daclizumab will be dosed as 150 mg once monthly; and*
11. *Prescriber, patient, and pharmacy are enrolled in the Zinbryta REMS program.*
12. *The 72-hour emergency supply rule does not apply to daclizumab.*
13. *Lost or stolen medication replacement requests will not be authorized.*

If criteria for coverage are met, an initial authorization will be given for 12 months. Additional authorizations will be considered when documentation of a positive clinical response to daclizumab therapy is provided.

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

Naloxone Nasal Spray: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for a patient requiring more than 2 doses of Narcan (naloxone) nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. *Documentation is provided indicating why patient needs additional doses of Narcan (naloxone) nasal spray (accidental overdose, intentional overdose, other reason); and*
2. *Narcan (naloxone) nasal spray is to be used solely for the patient it is prescribed for; and*
3. *The patient is receiving an opioid as verified in pharmacy claims; and*
4. *Patient has been reeducated on opioid overdose prevention; and*
5. *Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and*
6. *A treatment plan is included documenting a plan to lower the opioid dose*

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

Buprenorphine Transdermal System & Buccal Film: Current criteria will be removed and medications will be subject to the Long-Acting Opioids criteria as listed below:

Prior authorization is required for all non-preferred long-acting opioids. 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 (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 website at https://pmp.iowa.gov/IAPMPWebCenter/ 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.*

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 Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a long-acting opioid is appropriate for this member.*

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.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 2. They suggested that a link to the opioid dose calculator would be useful on the www.iadur.org and www.iowamedicaidpdl.com sites.

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

At 11:45 am, Larry Ambroson motioned to adjourn the meeting and Jason Wilbur seconded. (No closed session was needed.)

The next meeting will be held at 9:30 a.m. on Wednesday, April 5, 2017, at the Iowa Medicaid Enterprise in Des Moines.