Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes April 5, 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 9:35 a.m. at the Iowa Medicaid Enterprise in Des Moines. The minutes from the February 1, 2017 meeting were reviewed. Jason Wilbur motioned to accept them, and Kellen Ludvigson and Brett Faine both seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was also reviewed.

MCO Lock-In Programs

At the February meeting, 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 bring that information, specifically the most direct contact options, back to the next meeting. Details are described below.

Amerigroup: Members are assigned to the program if they have 2 providers, 2 pharmacies, 5 controlled substances, and 3 opioids within 45 days. Amerigroup averages about 150 members per month, or 1800 per year, that qualify. Referrals are accepted from anyone, by calling the Provider Services toll-free number. Members, pharmacies, and prescribers will all receive letters before the lock-in goes into effect. Members do have the right to appeal within 10 days if they want to change their lock-in pharmacy.

United Healthcare Community Plan: Members on controlled substances are assigned to the program if they have 9 or more pharmacies per quarter, or 3 or more prescribers as well as 3 or more pharmacies per quarter. Once started, they are locked in for 2 years, at which point their information is reviewed to see if they need to be renewed for another lock-in period or can be released from the program. Members receive notification letters before the lock-in goes into effect, and are provided a 30-day appeal window. Referrals are accepted by calling Provider Services.

AmeriHealth Caritas Iowa: Program approval has been given, but it has not yet been launched, though tentatively scheduled to go into effect this summer. Members are assigned to the program if 21 years or older with 2 or more prescribers per month, 2 or more qualifying medications per month, or duplicating medications filled. Members can voluntarily restrict themselves if they choose. Referrals are accepted by calling Provider Services, which will transfer the call to a lock-in coordinator. Members, pharmacies, and prescribers will all receive letters before the lock-in goes into effect, and the member is provided a 30-day appeal window. The physician has the right to refuse lock-in assignment, and the pharmacy should, as well. Once started, members are locked in for 2 years, at which point their information is reviewed to see if they need to be renewed for another lock-in period or can be released from the program. Members who lose and gain back eligibility do remain locked in.

Synagis Claims

At the February meeting, Pam Smith noted that the prevalence reports had reflected paid claims for Synagis in the September and October reporting period when claims were not supposed to be allowed to adjudicate until November 1, 2016, and asked that the MCOs could investigate those claims. Each MCO representative explained their findings; most of the claims came from specialty pharmacies who requested overrides to account for shipping to home health care agencies and were not filled early enough to allow for an additional dose beyond the approved 5 within the RSV season. However, given that RSV season usually peaks much later in the season in Iowa (IDPH did not show prevalence until November 20th) and the start date of November 1st was earlier that originally scheduled, Pam Smith and Susan Parker still felt the early overrides weren't necessary.

IME Pharmacy Update/News Relevant to Medicaid

The dispensing fee change from $11.73 to $10.02 effective August 1, 2016, has been approved by CMS. An informational letter will go out shortly. Pam Smith reviewed some of the topics that were discussed at the ADURS conference she attended in February.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a four-minute overview for fee-for service statistics from January through February 2017, including: total amount paid ($1,741,916), cost per user ($214.31), and number of total prescriptions dispensed (31,081). There were 8,128 unique users, which is 11.4% more than the total for November and December. There were no large changes on the top 100 pharmacies by prescription count report, given the small FFS population. All ranking changes on the top 100 pharmacies by paid amount report were understandable given the number of members, prescriptions, and drugs dispensed. On the top 100 prescribing providers by prescription count report, the prescribing practices of the top 5 prescribers were all in line with their specialties. Pam Smith also looked further into the prescribers that had a high prescription per member count. There was nothing out of the ordinary on the top 100 prescribing providers by paid amount report. The top 5 therapeutics classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Stimulants – Amphetamines – Long Acting; Anti-Inflammatories, Non-NSAID; and Diabetic – Insulin. 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 Antipsychotics - Atypicals. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Synagis, Tamiflu, methylphenidate hcl er, Humalog, Latuda, Humira Pen, Onfi, Strattera, and Advair Diskus. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg, tramadol 50mg, amoxicillin 400/5ml, azithromycin 250mg, and fluoxetine 20mg. Pam Smith also created a report that compared the FFS stats above with those from each MCO below. Its side-by-side statistics showed that $98,736,859 was spent in total for 261,785 unique users who had 1,333,399 prescriptions.

MCO Prevalence Report Summary and Updates

United Healthcare Community Plan: Karrie Hansotia spoke for 3 minutes and provided an overview of United's statistics from January through February 2017, including: total paid amount, unique users, and cost per user. She noted that not much changed from the November/December reporting period to the January/February period. The report showed utilization by age and gender; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, Broadlawns and 4 Walgreens locations made up the top 5. ARJ Infusion Services was the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulins; Adrenergics, Aromatic, Non-Catecholamine; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; and Antihemophilic Products. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Analgesics, Narcotics; Penicillins; and NSAIDs, Cyclooxygenase Inhibitor-Type Analgesics. The most expensive drugs were Vyvanse, Novoseven, methylphenidate er, Humira Pen, and Humalog, while amoxicillin, hydrocodone/apap, omeprazole, lisinopril, and azithromycin had the top 5 prescription counts.

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a six-minute overview for AmeriHealth's statistics from January through February 2017, including: total paid amount ($35,053,806, not much change from the previous reporting period), unique users (96,878), average cost per user ($361.83), total prescriptions (499,389), utilization by age and gender (age 19-64 category highest for both genders), top 100 pharmacies by prescription count (Walgreens, Mercy Family, and Broadlawns had the highest counts), top 100 pharmacies by paid amount (predominantly specialty pharmacies at the top of the list), top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount (top 4 similar to last reporting period). The top 5 therapeutics classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Anticonvulsants; Adrenergics, Aromatic, Non-Catecholamine; and Tx for Attention Deficit-Hyperactivity (ADHD)/Narcolepsy. The top 5 therapeutic classes by prescription count were: Anticonvulsants; SSRIs; Penicillins; Proton-Pump Inhibitors; and Beta-Adrenergic Agents, Inhaled, Short Acting. The most expensive drugs were Vyvanse, methylphenidate er, Humalog, Latuda, and Tamiflu, whereas hydrocodone-acetaminophen, loratadine, amoxicillin, cetirizine, and omeprazole had the highest prescription counts.

Amerigroup: Sandy Pranger provided a four-minute overview for Amerigroup's statistics from January through February 2017, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, Antidiabetics, Antiasthmatic and Bronchodilator Agents, Antipsychotics/Antimanic Agents, and Antivirals. Vyvanse was the most expensive medication, followed by methylphenidate er, Humalog, Latuda, and Humira Pen. The bi-monthly statistics report reflected that expenditures totaled $36,927,972, a 2.0% increase from November and December. The top five classes by prescription count were: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Analgesics – Opioid. Hydrocodone-acetaminophen has been the drug with the highest prescription count since April 1, 2016, followed by: amoxicillin, escitalopram, omeprazole, and fluoxetine. Sandy Pranger is checking with report analysts to confirm that reversed claims are not included in the reports; this may account for the discrepancy in totals as compared to reports from the other MCOs.

Oral Public Comment

Name	Representing	Drug/Topic
Lisa Borland	Sarepta	Exondys 51
Charles Tyler	Marathon Pharmaceuticals	Emflaza
Jason Luek	Novo Nordisk	Xultophy

The Commission also reviewed written public comment as part of their meeting materials. The following written comments were reviewed:

- The Iowa Pharmacy Association (IPA) provided comments on: High Dose Opioids; Insulin-Prefilled Pens; GLP-1 Agonist/Basal Insulin Combinations; Hepatitis C Treatments; Eteplirsen (Exondys 51); removal of Colchicine PA criteria; and Lumacaftor/Ivacaftor (Orkambi).
- A letter from the University of Iowa Stead Family Children's Hospital regarding proposed Exondys 51 PA criteria.
- A letter from the Cystic Fibrosis Foundation supporting the revisions to the PA criteria for lumacaftor/ivacaftor.

ProDUR Edits

Injectable Anticoagulant Quantity Limits: At the February meeting, Sandy Pranger from Amerigroup proposed quantity limits that her company had implemented in other states and run actuarial analysis on for the IA Medicaid population, which they think 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 wanted to see how many members would be affected by the limits shown in the table above before implementing them (with an allowance for BID dosing), so all the MCO and FFS representatives consulted with their respective analysts and brought back the requested information as follows: AmeriGroup with 57 members, United Healthcare with 71, AmeriHealth with 50 or more per month (also found incorrect quantities billed resulting in overpayment), and FFS with 13 members. Kellen Ludvigson motioned to recommended placing quantity limits on the above agents, after doubling them to allow for BID dosing. Daniel Gillette and Jason Wilbur both seconded, and all members were in agreement. The recommended quantity limits will be sent out for public comment and brought back to the next meeting.

Miscellaneous Quantity Limits: New quantity limits for the oral agents listed in the table below will be implemented. No motion was necessary as this was the second review. The recommendation will be sent to the Department for consideration.

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		

EpiPen: As requested at the December meeting, letters were sent to the providers of members with three or more fills from April through October 2016, to inquire as to the reasoning or circumstances behind multiple fills. Amerigroup had 37 claims and contacted all prescribers; many were unaware members were receiving that much. United Healthcare had 26 claims and were able to reach out to 23 prescribers, though 21

of the prescribers had no plans to contact the members. AmeriHealth had 19 claims and mailed out surveys; 8 surveys were returned with auto-filling listed as the issue in at least 3 instances. No Point of Sale (POS) quantity limit or edit will be implemented at this time but claims should continue to be monitored. Kellen Ludvigson also suggested calling pharmacies to try to prevent auto-filling, as the MCOs had targeted prescribers.

Prior Authorization

Deflazacort (Emflaza):

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

1. *Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and*
2. *Patient is within the FDA labeled age; and*
3. *Patient experienced onset of weakness before 5 years of age; and*
4. *Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and*
5. *Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (> X% of baseline bodyweight) with prednisone at a therapeutic dose; and*
6. *Is dosed based on FDA approved dosing.*

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

The Commission felt BMI or percentile on a growth chart might be a better reflection of weight gain as opposed to a certain (as yet undetermined) percentage of baseline bodyweight. The topic was tabled to allow Pam Smith to seek input from a specialist that treats DMD.

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

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

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

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

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

Brett Faine 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.

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

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

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of hyperuricemia associated with gout; and*
3. *Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least 3 months; and*
4. *Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and*
5. *Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and*
6. *Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor.*
    a. *If taking allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min); and*
7. *Patient does not have a contraindication to therapy including any of the following:*
    a. *Severe renal impairment (eCrCl <30 mL/min),*
    b. *End stage renal disease,*
    c. *Kidney transplant recipient,*
    d. *On dialysis,*
    e. *Tumor lysis syndrome, or*
    f. *Lesch-Nyhan syndrome.*

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

1. *Patient continues to take medication in combination with a xanthine oxidase inhibitor.*

a. *If allopurinol, dose should be ≥300 mg per day (or ≥200 mg per day in patients with an eCrCl < 60 mL/min)*

2. *Patient has an eCrCl > 45 mL/min; and*
3. *Patient does not have a contraindication to therapy including any of the following:*
   a. *Severe renal impairment (eCrCl <30 mL/min),*
   b. *End stage renal disease,*
   c. *Kidney transplant recipient,*
   d. *On dialysis,*
   e. *Tumor lysis syndrome, or*
   f. *Lesch-Nyhan syndrome.*
4. *Documentation of a positive clinical response to lesinurad.*

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

Brian Couse 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.

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

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

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

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

1. *Patient's current weight is provided; and*
2. *Patient continues on a Phe restricted diet; and*

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

Daniel Gillette 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.

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.*

Given the additional burden this will create for the MCOs, the Commission agreed to initially only apply the criteria for new starts, and let existing users continue on their existing regimens for now, potentially addressing them in a future DUR focus study. They

also suggested letters and calls to providers and members along with the customary informational letter. Pam Smith and the MCO representatives will look into how many members and providers will be impacted and bring those numbers back to the next meeting. Laurie Pestel asked if data could be examined to identify those taking benzodiazepines concurrently. Additionally, it was suggested that bullets 14-18 be copied to the refill criteria section. Pam Smith will revise the criteria and bring it back to 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 <u>is</u> 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 <u>is not</u> 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.*

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

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

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

1. *A diagnosis of type 2 diabetes mellitus; and*

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

As this was the second review of these criteria, no motion was necessary. Midway through the discussion, a request was made to revisit the High Dose Opioids criteria. Since the DUR Commission did not have the opportunity to further discuss the proposed criteria, this item will be brought back to the June 2017 DUR meeting to allow Commissioners the opportunity for further discussion, if needed, prior to making the recommendation to the Department.

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.*
18. *The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.*

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 is also interested in potentially adjusting the criteria to include members with a Metavir score of 2 or greater fibrosis now that many members in the more advanced

stages have received treatment. Criteria will be brought back to a future meeting to discuss changes.

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.*

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

Colchicine: The criteria listed below is 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.

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

Lumacaftor/Ivacaftor (Orkambi): 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 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.*

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 3. It will be brought back to the next meeting for a second review.

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

Articles of Interest:

First- and Second-Generation Antipsychotics in Children and Young Adults: Systematic Review Update; found at https://www.effectivehealthcare.ahrq.gov/ehc/products/615/2437/antipsychotics-children-update-report-170316.pdf

Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; found at

http://www.nejm.org/doi/full/10.1056/NEJMoa1615664#t=article

After reviewing the articles provided, the Commission decided to check back on claims data in six months to see if the new age edits already implemented had an effect on antipsychotic use in children and young adults. As evolocumab has shown no effect on mortality in patients with cardiovascular disease, they did not want to change that criteria at this time, either.

At 12:22, Brett Faine motioned to adjourn the meeting and Daniel Gillette seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, June 7, 2017, at the Learning Resource Center in West Des Moines.