Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes December 7, 2016

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, 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 9:33 a.m. at the Learning Resource Center in West Des Moines. The minutes from the October 5, 2016 meeting were reviewed. Jason Wilbur motioned to accept them, and Kellen Ludvigson seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was also reviewed, along with the SFY16 Annual DUR Report and a recommendation from the P&T Committee for development of prior authorization criteria for Zinbryta.

IME Pharmacy Update/News Relevant to Medicaid

CMS released the final covered outpatient pharmacy rule that required the states to make changes to their State Plan Amendments effective April 1, 2017. Associated companion rules from the state rules process were released at the end of November 2016, specifying reimbursement methodology, which is already at the required Actual Acquisition Cost (AAC) for Iowa. However, the rules also apply to 340B entities, Federal supply schedule, and nominal price. The rules just make the existing reimbursement methodology official. The only thing that will actually be changing is that Indian Health Services has requested that their pharmacy be reimbursed based on the daily encounter rate set by the Federal government; 100% of funding for this will come from Federal funding. The dispensing fee change from $11.73 to $10.02 effective August 1, 2016, is still pending CMS approval. Monthly Iowa Health Link meetings are being held, and all public comments are welcome; one was held on the day of this meeting, December 7, 2016, at the Des Moines Central Library. Pam Smith summarized the updated Medicare/Medicaid drug spending dashboard released by CMS. The MCO representatives each provided a written summary of their recent prior authorization and claim statistics similar to those provided in the fee-for-service prevalence report summary below.

Prevalence Report Summary

Fee-for service statistics from September through October 2016 were discussed, including: cost per user ($192.72), number of total prescriptions dispensed (an increase of 0.3% compared to the previous reporting period), average cost per prescription ($52.57), and generic utilization (86.8%). The total paid amount increased by 2.8% from the previous reporting period. There were 7,738 unique users, which is 0.9% more than the total for July and August. Lists of the top 20 therapeutic classes were provided. The highest prescription count continues to come from the SSRI category, with Miscellaneous Narcotics in second place. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, methylphenidate hcl er, Humalog, Sprycel, Humira Pen, Lantus, Strattera, Latuda, Abilify, and Focalin XR. Pam Smith did make note of the fact that changes to these statistics do not necessarily represent real upward or downward trends, due to the transient nature of the fee-for-service member population as it now stands post MCO transition.

Public Comment

Name	Representing	Drug/Topic
Anthony Pudlo	Iowa Pharmacy Association	Naloxone
Alan Roloff	Biogen	Tecfidera
Nancy Bell	Pfizer	Opiates and Chronic Pain PA
Kerri Hoernemann	Novartis	Entresto
Jan Foote	Blank Children's Hospital	Lupron Depot Ped
Peter Zoob	Vertex	Orkambi

Focus Studies

Hepatitis C Agents: A form will be developed to be faxed to providers 90 days after a member begins therapy, to track progress now that the CPOP program is no longer in operation. A question will be added to this form to ask about hospitalizations, and SVR will be tracked. Information can then be compared to historical studies, or information collected by other states.

ProDUR Edits

EpiPen: As requested at the last meeting, claims from April through October 2016 were checked for frequent fills, unique users, and number of fills. Letters will be sent to the providers of members with three or more fills, to inquire as to the reasoning or circumstances behind multiple fills. The MCOs also agreed to do this, and will bring information regarding responses back to the April 2017 meeting. No Point of Sale (POS) edit will be implemented at this time.

Codeine – Age Edit: An age edit will be implemented in the POS system preventing claims from paying for members less than 18 years of age, and the 72-hour emergency override option will be removed. Daniel Gillette made this motion, Brett Faine seconded, and Jason Wilbur offered a third. All members were in favor.

Prior Authorization

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. *Baseline percent predicted forced expiratory volume (ppFEV1) is provided and is greater than or equal to (≥) 40; and*
6. *Prescriber is a CF specialist or pulmonologist; and*
7. *Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus.*

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. *Response to therapy is documented by prescriber (e.g., improved ppFEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
3. *Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.*

Daniel Gillette motioned to accept the criteria as amended, and Larry Ambroson 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.

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.

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.

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.

Brett Faine motioned to accept the criteria as listed above, and Brian Couse and Larry Ambroson both seconded simultaneously. 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, palliative care, 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; and
3. The opioid is prescribed by a pain specialist or in consultation with a pain specialist, or oncologist for the treatment of cancer related pain; and
4. 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
5. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and
6. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
7. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
8. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
9. Chart notes from a recent pain management visit is included documenting the following:
    a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
    b. Treatment goals; and
10. Patient has been informed of the risks of high-dose opioid therapy; and
11. 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
12. 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
13. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and

14. The requested dosing interval does not exceed the maximum FDA-approved dosing interval; and
15. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
16. Patient has been educated on opioid overdose prevention; and
17. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and
18. Patient will not be using opioids and benzodiazepines concurrently.

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 3 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.

Multiple updates were recommended to the above criteria. Pam Smith will revise the criteria as suggested and bring it back to the next meeting for discussion and vote if criteria is sufficient.

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*

Jason Wilbur motioned to accept the criteria as amended, and Brian Couse 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.

Buprenorphine Transdermal System & Buccal Film: Current criteria specific to buprenorphine transdermal system and buccal film will be removed and medications now subject to the current 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.

Larry Ambroson motioned to accept the criteria as amended, and Brian Couse 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.

Omalizumab (Xolair): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

<u>Moderate to Severe Persistent Asthma</u>

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Patient is 6 years of age or older; and*
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
    b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
5. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
    b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and*
6. *History of positive skin or RAST test to a perennial aeroallergen; and*
7. *Prescriber is an allergist, immunologist, or pulmonologist; and*
8. *Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and*
9. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.*
10. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of Xolair®.*

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high

dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

Chronic Idiopathic Urticaria

1. *Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and*
2. *Patient is 12 years of age or older; and*
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. *Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
5. *Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and*
6. *Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
7. *Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.

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.

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

Prior authorization is required for oral constipation agents. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; 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).*
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® or Linzess™)*

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® or Linzess™)*
    i. *Patient is female (Amitiza® only); and*
    ii. *Patient has abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two (2) or more of the following:*
        1. *Improvement with defecation;*
        2. *Onset associated with a change in stool frequency; and/or*
        3. *Onset associated with a change in stool form.*

c. *A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™ or Relistor®)*
    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.*
    iii. *Patient has documentation of an adequate trial and therapy failure with Amitiza®, if prior authorization request is for a different oral constipation agent.*

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.

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

Multiple Sclerosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis; and*
3. *Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.*

For patients initiating therapy with fingolimod (Gilenya™), a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. *Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class lll/IV heart failure.*
2. *Patient does not have a history or presence of Mobitz Type ll 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.*
3. *Patient does not have a baseline QTc interval ≥ 500ms.*
4. *Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.*

For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:

1. *Patient does not have severe hepatic impairment.*
2. *A negative pregnancy test for females of childbearing age.*
3. *Use of a reliable form of contraception for females of childbearing age.*
4. *Patient is not taking leflunomide.*

For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:

1. *Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.*
2. *Upon renewal, documentation of an updated CBC.*

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.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 2. This was the first review and will be brought back to the next meeting for a second review prior to posting to the website.

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

At 11:35, Daniel Gillette motioned to adjourn the meeting and Larry Ambroson 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, February 1, 2017, at the Learning Resource Center in West Des Moines.