Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 1, 2018

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; Jason Wilbur, M.D.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).
Staff
Pam Smith, R.Ph.
Guests
Mark Randleman, D.O., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Brett Faine called the meeting to order at 9:34 a.m. at the State Capitol in Des Moines. The minutes from the June 6, 2018 meeting were reviewed. Mark Graber motioned to accept them, and Jason Kruse seconded. The recommendation letter sent to DHS after the last meeting was also reviewed. Members were asked to complete their annual conflict of interest disclosures. Mark Graber motioned to retain Brett Faine as chairperson and Kellen Ludvigson as vice-chairperson. Jason Wilbur seconded, and all members in attendance were in favor (Kellen Ludvigson arrived late due to a meeting location mix-up, and was not yet present for the vote). There will only be four DUR meetings per year now, scheduled for the first Wednesday every August, November, February, and May.

IME Pharmacy Update

The dispensing fee will be increasing from $10.02 to $10.07, pending CMS approval.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview for fee-for service statistics from May through June 2018, including: total amount paid ($1,716,916), cost per user ($227.83), and number of total prescriptions dispensed (29,922). There were 7,536 unique users, which is 8.4% less than the total for March and April. The top 5 therapeutics classes by paid amount were: Antipsychotics – Atypicals; Anticonvulsants; Anti-Imflammatories, Non-NSAID; Diabetic – Insulin Penfills; and Diabetic – Insulin. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Narcotics – Miscellaneous; and Antiasthmatic – Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The top ten drugs by paid amount were: Vyvanse, Humalog, Invega Sustenna, Novolog Flexpen, Emflaza, Latuda, Genvoya, Advair Diskus, Focalin XR, and Aubagio. The five drugs with the highest prescription count were: hydrocodone/apap, sertraline hcl, gabapentin, lisinopril, and trazodone hcl. Pam Smith also created a report that compared the FFS stats above with those from each MCO below. Its side-by-side

statistics showed that $92,741,300 was spent in total for 239,103 unique users who had 1,303,311 prescriptions. Mark Graber asked that the diagnoses for anticonvulsant medications be researched to see if they were being used for back pain or neuropathic pain, as data shows these medications do not work for chronic back pain.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from May through June 2018, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. The Bi-Monthly Statistics report reflected that expenditures totaled $32,559,345, a 0.1% decrease from March and April. Similar to previous reports, the top 5 therapeutic classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antidiabetics; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Inflammatory. The top five classes by prescription count were: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs. Vyvanse was the costliest medication to the program, followed by Humira Pen, Latuda, Humalog, and Lantus. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and gabapentin.

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from May through June 2018, including: total paid amount ($58,465,039.10), unique users (154,918), and cost per user ($377.39). Utilization by age and gender was reviewed; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, Broadlawns, U of I Ambulatory Care, and 3 Walgreens locations made up the top 5. BriovaRx was the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; and Adrenergics, Aromatic, Non-Catecholamine. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Proton-Pump Inhibitors; Analgesics, Narcotics; and NSAIDs, Cyclooxygenase Inhibitor – Type Analgesics. The costliest drugs to the program were Vyvanse, Humira Pen, Latuda, Humalog, and Lantus, while omeprazole, lisinopril, levothyroxine sodium, atorvastatin calcium, and hydrocodone-acetaminophen had the top 5 prescription counts.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comment from the speaker listed below.

Name	Representing	Drug/Topic
Roya Motarjemi	Merck	Prevymis
Tammy Sova	Biogen	Tecfidera
Erin Conley	Amgen	CGRB Inhibitor Class - Aimovig
Tim Birner	Alkermes	Vivitrol - Addiction

ProDUR Edits

Duplicate Antipsychotics in Adults: Data reported was not consistent between the 3 plans. Data for Amerigroup and United Healthcare was not unique to the drug (i.e. counted same drug if multiple strengths were found in claims). The data will be rerun to remove multiple strengths of same drug and broken out to identify the number of unique providers as well as number of long-acting and short-acting medications. It was suggested letters be sent to the prescribers of members on 3 or more antipsychotics concurrently once the data is updated. Existing quantity limits will also be reviewed, and Pam Smith will look into how Medicare handles duplicate antipsychotics.

CNS Stimulants and Atomoxetine Concurrent Therapy ProDUR Edit: The Commission wants to focus on children on short-acting agents. The Commission requested additional data to look at the number of units of the short-acting agent per day. Data will be brought to the next meeting to further discuss. The quantity limit for short-acting medications will potentially be changed to 1 per day, and allow for a 3-month titration period, should it be needed, before the use of a long-acting agent would be required. Prior authorization criteria language will need to be updated as well, to encourage the use of long-acting agents for members under 21 years of age.

CNS Stimulants and Atomoxetine Age Edit: The minimum FDA approved ages will be followed, and prior authorization criteria needs to be updated to reflect this. No vote was conducted to implement ProDUR age edits as updated PA criteria was requested.

Prior Authorization

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 under the following conditions:

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

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

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.*

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

Janus Kinase Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. *Patient meets the FDA approved age and*
2. *Patient is not using or planning to use tofacitinib in combination with biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and*
3. *Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and*
4. *Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and*
5. *Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and*
6. *Patient is not at an increased risk of gastrointestinal perforation; and*
7. *Is prescribed within the FDA approved dosing for the submitted diagnosis; and*
8. *Patient has a diagnosis of moderate to severe <u>rheumatoid arthritis</u>, and*
    a. *Has a documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The*

combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, leflunomide, or minocycline); and

b. Has a documented trial and inadequate response to two preferred biological DMARDs; or

9. Patient has a diagnosis of active psoriatic arthritis, and

a. Has a documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated), and

b. Has a documented trial and therapy failure with two preferred biological DMARDs; and

c. Will be used in combination with a nonbiologic DMARD; or

10. Patient has a diagnosis of moderately to severely active ulcerative colitis, and

a. Has a documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and

b. Has a documented trial and inadequate response with a preferred biological DMARD; and

c. If requested dose is for 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit.

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

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

Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for CGRP Inhibitors. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of migraine as defined by one of the following:

a. Chronic Migraine

i. ≥ 15 headache days per month for a minimum of 3 months; and

ii. ≥ 8 migraine headache days per month for a minimum of 3 months; or

b. Episodic Migraine

i. 4 to 14 migraine days per month for a minimum of 3 months; and

2. Patient meets the FDA approved age; and

3. Patient has been evaluated for and does not have medication overuse headache; and

4. Patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex,

valproate, topiramate], beta blockers [atenolol, metoprolol, nadalol, propranolol, timolol], antidepressants, [amitriptyline, venlafaxine]); and

5. *The requested dose does not exceed the maximum FDA labeled dose; and*
6. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days).

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

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

Chronic Pain Syndromes: The Commission reviewed the prior authorization criteria as follows:

A prior authorization is required for pregabalin (Lyrica®) and milnacipran (Savella™). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life. Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions:

1. *A diagnosis of fibromyalgia (Lyrica® and Savella™)*
   a. *a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following preferred generic agents: tricyclic antidepressant or SNRI* ***WITH***
   b. *documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.)*
2. *A diagnosis of post-herpetic neuralgia (Lyrica®)*
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. *A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica®)*
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine.
4. *A diagnosis of partial onset seizures, as adjunct therapy (Lyrica®)*
5. *A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica®)*

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

CNS Stimulants and Atomoxetine: The Commission reviewed the prior authorization criteria as follows:

*Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required. Requests will be considered for an FDA approved age for the submitted diagnosis. Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:*

1. *Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more <u>current</u> environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening), and will be limited to one unit dose per day.*
2. *Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).*
3. *Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.*

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

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

Tezacaftor/Ivacaftor (Symdeko): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of cystic fibrosis (CF); and*
3. *Patient is homozygous for the F508del mutation or patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor (listed in the FDA approved labeling) based on in vitro data and/or clinical evidence.*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST/ALT) are provided.*

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

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

Jason Kruse motioned to accept the criteria as amended, and Mark Graber seconded. All members were in favor. As this was the second review of these criteria, the recommendation will be sent to the Department for consideration.

Letermovir (Prevymis): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral letermovir. Requests for intravenous letermovir should be directed to the member's medical benefit. Payment will be considered under the following conditions:

1. *Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and*
2. *Patient or donor is CMV-seropositive R+ (attach documentation); and*
3. *Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provide date patient received HSCT); and*
4. *Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and*
5. *Patient is 18 years of age or older; and*
6. *Dose does not exceed:*
    a. *240mg once daily when co-administered with cyclosporine;*
    b. *480mg once daily; and*
7. *Patient must not be taking the following medications:*
    a. *Pimozide; or*
    b. *Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or*
    c. *Rifampin; or*

   d. *Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and*
8. *Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and*
9. *Therapy duration will not exceed 100 days post-transplantation.*

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

Miscellaneous

DUR Digest: The Commission members conducted the initial review of the draft DUR Digest Volume 31, Number 1. A spacing typo was found and will be corrected.

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

At 11:56, Kellen Ludvigson motioned to move to closed session just to review and approve the minutes from the April closed session, and Mark Graber seconded.

The next meeting will be held at 9:30 a.m. on Wednesday, November 7, 2018, at the State Capitol, Room 116, in Des Moines.