Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes December 6, 2017

Attendees:

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

Staff
Pam Smith, R.Ph.

Guests
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 9:30 a.m. at the Learning Resource Center in West Des Moines. The minutes from the October 4, 2017 meeting were reviewed. Jason Wilbur motioned to accept them, and Jason Kruse seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting and the letter from the P&T Committee requesting development of PA criteria for Austedo and Ingrezza as well as reevaluation of the current criteria for Entresto were also reviewed.

IME Pharmacy Update

Effective December 1, 2017, approximately 10,000 members previously enrolled with AmeriHealth Caritas will receive coverage through the fee-for-service program until Amerigroup is ready to accept additional members. Michael Randol has been appointed the new Iowa Medicaid Director. Pam Smith thanked Mark Graber and Laurie Anderson for their many years of service in the chairperson and vice-chairperson positions.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a six-minute overview for fee-for service statistics from September through October 2017, including: total amount paid ($1,396,795), cost per user ($204.72), and number of total prescriptions dispensed (24,072). There were 6,823 unique users, which is 1.8% more than the total for July and August. 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; Hepatitis C Agents; and Anti-Inflammatories,

Non-NSAID. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics – Miscellaneous; Antiasthmatic – Beta – Adrenergics; and Antipsychotics – Atypicals. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Harvoni, Vyvanse, Ravicti, Latuda, methylphenidate hcl er, Genvoya, Humalog, Onfi, Lantus, and Afinitor. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg, Tramadol 50mg, Ventolin HFA, ProAir HFA, 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 $90,477,715 was spent in total for 234,719 unique users who had 1,270,838 prescriptions.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided a four-minute overview for Amerigroup's statistics from September through October 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. The Bi-Monthly Statistics report reflected that expenditures totaled $32,270,553, a 0.6% increase from July and August. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antidiabetics; Antiasthmatic and Bronchodilator Agents; Antipsychotics/Antimanic Agents; and Analgesics – Anti-Inflammatory. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs. Vyvanse was the most expensive medication, followed by Humira Pen, methylphenidate er, Humalog, and Latuda. Hydrocodone-acetaminophen has been the drug with the highest prescription count since April 1, 2016, followed by: omeprazole, Ventolin HFA, fluticasone, and gabapentin.

United Healthcare Community Plan: Karrie Hansotia spoke for four minutes and provided written summaries that included United's statistics from September through October 2017, including: total paid amount ($24,105,338.49), unique users (68,312), and cost per user ($352.87). She noted that not much changed from the July/August reporting period to the September/October period. There was also a handout showing utilization by age and gender; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, Broadlawns and 4 Walgreens locations made up the top 5. Nucara Specialty Pharmacy 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; Adrenergics, Aromatic, Non-Catecholamine; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; and Anticonvulsants. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Analgesics, Narcotics; Proton-Pump Inhibitors; and NSAIDs, Cyclooxygenase Inhibitor-Type Analgesics. The most expensive drugs were Vyvanse, Humalog, Latuda, Humira Pen, and, methylphenidate er, while omeprazole, hydrocodone/apap, lisinopril, levothyroxine sodium, and amoxicillin had the top 5 prescription counts.

AmeriHealth Caritas Iowa: The DUR Commission members were provided a copy of the report for September/October 2017.

Public Comment

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

Name	Representing	Drug/Topic
Nathan Price	University of Iowa	Hepatitis C Agents PA criteria
Steven Lash	Genentech	Hemlibra
Robert Gerdes	Genentech	Hemlibra
Tom Peddicord	Novartis	Entresto
Peter Zoob	Vertex	Ivacaftor
Nancy Bell	Pfizer	Smoking Cessation PA criteria and Topical Immunmodulators

Based on public comment, a request was made to review the PA criteria for Hepatitis C agents at a future meeting, specifically around the fibrosis score in general and in pediatric patients.

Prior Authorization

Buprenorphine/Naloxone: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids or tramadol will be prohibited. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of opioid dependence and meets the FDA approved age: AND*
2. *Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND*
3. *Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND*
4. *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances; and*
5. *A projected treatment plan is provided, including:*
    - *Anticipated induction/stabilization dose,*

- *Anticipated maintenance dose,*
- *Expected frequency of office visits, and*
- *Expected frequency of counseling/psychosocial therapy visits; AND*

6. *A treatment plan is provided for patients taking buprenorphine in combination with a benzodiazepine or central nervous system (CNS) depressants, including:*
   - *Documentation patient has been educated on the serous risks of combined use;*
   - *A plan to taper the benzodiazepine or CNS depressant to discontinuation, if possible;*
   - *Consideration of alternate anxiety or insomnia treatment options when the benzodiazepine or CNS depressant is used for anxiety or*
   - *Other prescribers involved in the care of the patient are aware of the patient's use of buprenorphine; AND*
7. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
8. *Requests for single ingredient buprenorphine will only be considered for pregnant patients.*

Requests for renewal must include:

1. *An updated treatment plan documenting the following:*
   a. *Consideration of a medical taper to the lowest effective dose based on a self-assessment scale, and*
   b. *Assessment of concomitant benzodiazepine or CNS depressant use (if applicable) as outlined above, AND*
2. *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request, AND*
3. *Documentation of a current, negative drug screen, AND*
4. *Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits, AND*
5. *Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.*

Jason Wilbur motioned to accept the criteria as amended. Mark Graber and Jason Kruse both seconded, and the motion passed with no objections. The recommendation will be sent to the medical/pharmacy groups for comment and will be brought back to the next meeting for further discussion.

Smoking Cessation Therapy, Oral & Nicotine Replacement Therapy: Given the discussions at previous meetings, the DUR Commission made a recommendation to remove clinical prior authorization criteria for Smoking Cessation Therapy and Nicotine

Replacement Therapy. With removal of the prior authorization, the DUR Commission also recommended a quantity limit of 24 weeks of total treatment within a 12-month period for tobacco cessation medications. Jason Kruse made the motion to remove criteria and implement the quantity limit. Jason Wilbur and Melissa Klotz both seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy groups for comment and will be brought back to the next meeting for further discussion.

Angiotensin Receptor Blocker before ACE Inhibitor: The DUR Commission made a recommendation (motion by Mark Graber, second by Jason Kruse) to remove the Angiotensin Receptor Blocker before ACE Inhibitor clinical prior authorization criteria. The motion passed unanimously. The recommendation will be sent to the medical/pharmacy groups for comment and will be brought back to the next meeting for further discussion.

Immunomodulators, Topical: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for topical immunomodulators. Payment for pimecrolimus (Elidel®) or tacrolimus (Protopic®) 0.03% will be considered for non-immunocompromised patients two years of age and older and tacrolimus (Protopic®) 0.1% for patients 16 years of age and older when there is an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroids, except on face or groin. If criteria for coverage are met, requests will be approved for one tube per 90 days to ensure appropriate short-term and intermittent utilization of the medication. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 60 grams or 100 grams for all other areas. The required trials may be overridden when documented evidence is provided that 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 will be brought back to the next meeting for further discussion.

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

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

1. *Patient is 2 years of age or older; and*
2. *Patient has a diagnosis of cystic fibrosis; and*
3. *Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST/ALT)*

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

1. *Adherence to ivacaftor therapy is confirmed; and*

2. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

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

Lidocaine Patch: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for topical lidocaine patches. Payment will be considered only for cases in which there is a diagnosis of pain associated with post-herpetic neuralgia. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

Jason Wilbur 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 will be brought back to the next meeting for further discussion.

Topical Acne and Rosacea Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

1. *Documentation of diagnosis.*
2. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid..*
3. *Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid).*
4. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent.*
5. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products.*
6. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis.*
7. *Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.*
8. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

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

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

Biologicals for Ankylosing Spondylitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for ankylosing spondylitis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for ankylosing spondylitis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions.

- *Patient has documentation of an inadequate responses to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least three months in duration; and*
- *Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate; and*
- *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
- *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*

In addition to the above:
Requests for TNF Inhibitors:

- *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
- *Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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.

Biologicals for Arthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions

- *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
- *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
- *Patient has a diagnosis of rheumatoid arthritis (RA):*
  A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, leflunomide, or minocycline). Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions; or
- *Patient has a diagnosis of moderate to severe psoriatic arthritis:*
  A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
- *Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis:*
  A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

  In addition to the above:
  Requests for TNF Inhibitors:
- *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
- *Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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.

Biologicals for Inflammatory Bowel Disease: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for inflammatory bowel disease. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.

Payment will be considered under the following conditions:

- *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
- *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
- *Patient has a diagnosis of Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapy including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; or*
- *Patient has a diagnosis of Ulcerative Colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine; and*

In addition to the above:

Requests for TNF Inhibitors:

- *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
- *Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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.

Biologicals for Plaque Psoriasis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for biologicals used for plaque psoriasis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

- *Patient has documentation of an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine; and*
- *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
- *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*

In addition to the above:
Requests for TNF Inhibitors:

- *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
- *Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

- *Medication will not be given concurrently with live vaccines.*

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.

Tramadol or Codeine in Members < 18: The Commission reviewed the prior authorization criteria as follows:

An age edit override for codeine or tramadol is required for patients under 18 years of age. Payment will be considered under the following conditions:

1. *Member is 12 years of age or older; and*
2. *Medication is not being prescribed to treat pain after surgery following tonsil and/or adenoid procedure for members 12 to18 years of age; and*
3. *If member is between 12 and 18 years of age, member is not obese (BMI greater than 30kg/m2), does not have obstructive sleep apnea, or severe lung disease.*

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

Sacubitril/Valsartan (Entresto): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for valsartan/sacubitril (Entresto™). Requests above the manufacturer recommended dose will not be considered. Payment 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 NYHA Functional Class II, III, or IV heart failure; and*
3. *Patient has a left ventricular ejection fraction (LVEF) ≤40%; and*
4. *Patient is currently tolerating treatment with an ACE inhibitor or angiotensin II receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality*
5. *Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); and*
6. *Will not be used in combination with an ACE inhibitor or ARB; and*
7. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
8. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
9. *Patient is not pregnant; and*
10. *Patient does not have severe hepatic impairment (Child Pugh Class C); and*
11. *Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).*

The required trial(s) may be overridden when documented evidence is provided that the use of these agent(s) 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.

Miscellaneous

DUR Digest: The Commission members conducted the initial review of the draft DUR Digest Volume 30, Number 2.

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

At 11:14, Mark Graber motioned to adjourn the meeting and Jason Kruse 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 7, 2018, at the Learning Resource Center in West Des Moines.