Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 5, 2015

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Kellen Ludvigson, Pharm.D.; Brett Faine, Pharm.D.; Brian Couse, M.D.; Daniel Gillette, M.D.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; Gina Tiernan, Pharm.D., IME; Tina Valentino, Pharm.D., IME; and Melissa Biddle, IME.

Welcome & Introductions

Mark Graber called the meeting to order at 9:37 a.m. at the Learning Resource Center in West Des Moines. The minutes from the June 3, 2015 meeting were reviewed. Brian Couse motioned to accept them, and Brett Faine seconded. All members were in favor. Members were asked to update their conflict of interest disclosure forms, and the Commission then proceeded to chairperson and vice-chairperson elections. Mark Graber nominated Brett Faine, who respectfully declined and then nominated Mark Graber to remain as chairperson. This was met with unanimous approval from the other members. Kellen Ludvigson then nominated Laurie Pestel to remain as vice-chairperson, and Larry Ambroson seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed, along with a summary of the Annual Federal Report for federal fiscal year ending 2014. Overall, the program produced $138,853.65 in savings from patient-focused review, and $482,262.85 from problem-focused studies, for a net savings of $351,116.50 after administrative costs.

IME Updates

Almost 134,000 members are now enrolled in the Iowa Health and Wellness Plan. Eleven bids were submitted in response to the Medicaid Modernization managed care Request for Proposal (RFP). Awards are expected to be announced on or around August 17, 2015, with implementation still slated for January 1, 2016. This is the first meeting for new Commission member, Dr. Daniel Gillette. Pam Smith provided a quarterly report on the new Complex Pharmaceutical Oversight Program (CPOP), which brought $476,274 in direct cost avoidance savings (State and Federal dollars extrapolated to the end of the state fiscal year) from 38 interventions in its second quarter of operation. Additionally, Gina Tiernan is now Clinical Pharmacy Manager at the IME, and this is her first meeting.

Prevalence Report Summary

Statistics from May though June 2015 were discussed, including: cost per user ($343.09), number of total prescriptions dispensed (a decrease of 5.0% compared to the previous reporting period), average cost per prescription ($68.42), and generic utilization (85.2%). The total paid amount decreased by 2.8% from the previous reporting period. There were 197,276 unique users, which is 6.2% less than the total for March and April. Lists of the top 20 therapeutic classes were provided. SSRIs had the highest prescription count, and Anticonvulsants came in second. The Hepatitis C category is quickly rising up the top therapeutic classes by paid amount report, currently in seventh place with $2,567,268 in expenditures, an increase of 45.7% from the previous reporting period. The top 100 drugs were also reviewed. The ten most expensive medications were: Abilify, Vyvanse, methylphenidate hcl er, Harvoni, Lantus, Focalin XR, Advate, Novoseven RT, Strattera, and Spiriva Handihaler. Pam Smith also reviewed the top drugs for other insurance carriers, as had been requested at the previous meeting.

Case Studies

Pam Smith presented 4 case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of $8,333.50 pre-rebate (state and federal).

Public Comment #1

Name	Representing	Drug/Topic
Lee Ding	Genentech	Esbriet
Nancy Bell	Pfizer	NOACs (DOACs)
Tyrone McBayne	Baxalta	Glassia and Aralast
Larry Lanier	National Patient Advocate Foundation	Prior Authorizations
Kori Hack	Novartis	Cosentyx
Jennifer Stofel	Janssen	Stelara
Peter Zoob	Vertex	Orkambi
Betty Johnston	National Patient Advocate Foundation (volunteer)	Prior Authorizations

Focus Studies

Short-Acting Opioid Overutilization: This was a follow-up discussion. Nine of the 33 members identified changed therapy, for an annualized cost savings of $1,876.16 (state and federal, pre-rebate) as a result of the 109 surveys sent out to prescribers and pharmacies. A total of 38 (34.86%) of those surveys were returned.

Metoclopramide Utilization: Gastroparesis and chemotherapy regimens were removed from the results as requested at the June meeting, which left 103 members identified as taking oral metoclopramide for greater than 90 days

without a medical reason, when therapy should not exceed 12 weeks. Letters will be sent to the providers of these 103 members to ask if the medication can be discontinued.

Modafinil Utilization: Letters will be sent to the providers of the members under 21 years of age taking modafinil for ADHD to ask if the patient has had adequate trials and therapy failures with methylphenidate and/or amphetamine agents prior to the use of modafinil, and if not, if the patient would be a candidate to use a different preferred stimulant. In the future, the quantity limit on the 400mg dose may also be lowered.

Duplicate Antidepressants: Letters will be sent to the providers of the members taking 4 or more antidepressents concurrently, as well those of members taking 2 or more medications from the same drug class and those taking both an SSRI and SNRI. Pam Smith will pull doses on the TCAs, and serotonergic drugs, and pull up the old data from the previous study to compare.

Public Comment #2

Name	Representing	Drug/Topic
Doug Struyk	American Cancer Society Cancer Action Network	Oncology PA Criteria

Prior Authorization

Topical Antifungals for Onychomycosis: The Commission reviewed the prior authorization criteria as follows:

Jublia® (efinaconazole) and Kerydin® (tavaborole) will be considered when the following criteria are met:

1. *Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and*
2. *Patient is 18 years of age or older; and*
3. *Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and*
4. *Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and*
5. *Patient is diabetic or immunosuppressed/immunocompromised.*

If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered.

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

Kellen Ludvigson 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.

Alpha-1 Proteinase Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Alpha$_1$-Proteinase Inhibitor enzymes. Payment for a non-preferred Alpha$_1$-Proteinase Inhibitor enzyme will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of congenital alpha$_1$-antitrypsin (AAT) deficiency; with a pretreatment serum concentration of AAT less than 11µM/L or*
    - *80mg/dl if measured by radial immunodiffusion, or*
    - *50mg/dl if measured by nephelometry; and*
2. *Patient has a high-risk AAT deficiency phenotype (PiZZ, PiZ (null), or PI (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11µM/L, such as PiSZ or PiMZ); and*
3. *Patient has documented progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV$_1$); and*
4. *Patient is 18 years of age or older; and*
5. *Patient is currently a non-smoker; and*
6. *Patient is currently on optimal supportive therapy for obstructive lung disease (inhaled bronchodilators, inhaled steroids); and*
7. *Medication will be administered in the member's home by home health or in a long-term care facility.*

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. *Evidence of clinical efficacy, as documented by:*
    a) *An elevation of AAT levels (above protective threshold i.e., > 11µM/L); and*
    b) *A reduction in rate of deterioration of lung function as measured by a decrease in the FEV$_1$ rate of decline; and*
2. *Patient continues to be a non-smoker; and*
3. *Patient continues supportive therapy for obstructive lung disease.*

Brett Faine 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.

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 12 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 ($ppFEV_1$) 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 $ppFEV_1$ 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.*

Brett Faine motioned to accept the criteria, 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.

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

Prior authorization is required for biologicals used for ankylosing spondylitis. 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.

Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
2. *Have 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*

3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment while patients with active TB will only be considered upon completion of TB treatment.*

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

Brett Faine motioned to accept the criteria as modified (for all three Biologicals categories), and Larry Ambroson seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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. 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. Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
2. *Have 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*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

- *Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies including*

aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate.

- *Ulcerative colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine.*

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

Brett Faine motioned to accept the criteria as modified (for all three Biologicals categories), and Larry Ambroson seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

Prior authorization is required for biologicals used for plaque psoriasis. Payment for non-preferred biologicals for plaque psoriasis will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
2. *Have 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*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment while patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered following an inadequate response to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Brett Faine motioned to accept the criteria as modified (for all three Biologicals categories), and Larry Ambroson seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Topical Corticosteroids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical

corticosteroid agents within the same potency class or a higher potency class in the past 12 months. 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.

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:

8. *Patient is 2 years of age or older; and*
9. *Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and R117H as detected by a FDA-cleared CF mutation test; and*
10. *Prescriber is a CF specialist or pulmonologist; and*
11. *Baseline liver function tests (AST/ALT) and FEV1, if age appropriate, are provided; and*
12. *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:

4. *Adherence to ivacaftor therapy is confirmed; and*
5. *Response to therapy is documented by prescriber (e.g., improved FEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
6. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment an 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.

Idiopathic Pulmonary Fibrosis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for pirfenidone (Esbriet®) and nintedanib (Ofev®). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient is 40 years of age or older; and*
2. *Is prescribed by a pulmonologist; and*
3. *Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):*

a) *Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or*
b) *A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and*

4. *Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and*
5. *Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and*
6. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; and*
7. *Patient does not have hepatic impairment as defined below:*
   a) *Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or*
   b) *Pifenidone - Patient does not have severe hepatic impairment (Child Pugh C); and*
8. *Patient does not have renal impairment as defined below:*
   a) *Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or*
   b) *Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and*
9. *Patient is a nonsmoker or has been abstinent from smoking for at least six weeks.*

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

a) *Adherence to pirfenidone (Esbriet®) and nintedanib (Ofev®) is confirmed; and*
b) *Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC); and*
c) *Documentation is provided that the patient has remained tobacco-free; and*
d) *Patient is tolerating treatment; and*
e) *ALT, AST, and bilirubin are assessed periodically during therapy.*

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

Edoxaban (Savaysa): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient does not have a mechanical heart valve; and*

2. *Patient does not have moderate to severe mitral stenosis; and*
3. *Patient does not have active pathological bleeding; and*
4. *A recent creatinine clearance (CrCl) is provided and is within specified range listed below; and*
5. *Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C).*
6. *Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial): and*
7. *Patient has documentation of a previous trial and therapy failure with apixaban or rivaroxaban, where applicable.*

Atrial Fibrillation

1. *Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with*
2. *Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥1; and*
3. *Patient does not have a creatinine clearance (CrCl) > 95 mL/min.*
4. *Requests will be considered for the following dosing:*
    a) *60mg once daily in patients with a CrCl of > 50 mL/min to ≤ 95 mL/min; or*
    b) *30mg once daily in patients with a CrCl of 15 to 50 mL/min*

Treatment of Deep Vein Thrombosis or Pulmonary Embolism

1. *Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with*
2. *Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).*
3. *Requests will be considered for the following dosing:*
    a. *60mg once daily; or*
    b. *30mg once daily in patients with any of the following:*
        i. *CrCl 15 mL/min to 50 mL/min*
        ii. *Body weight ≤60 kg*

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. The P&T Committee will also be reviewing the NOACs at their November meeting, and there may be additional recommended changes after their review.

Select Oncology Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.

After a lengthy discussion, Kellen Ludvigson motioned to accept the criteria as amended, and Daniel Gillette seconded. The decision was unanimous. Due to changes in the recommended criteria, the PA criteria will be sent to the medical/pharmacy associations for their comment and brought back to the next DUR meeting.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 27, Number 3. Dr. Gillette will review his introductory paragraph and let Pam Smith know of any requested changes.

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

A unanimous roll call vote was made at 12:26 to adjourn the meeting and move to closed session (motion by Kellen Ludvigson, second by Daniel Gillette).

The next meeting will be held at 9:30 a.m. on Wednesday, October 7, 2015, at the Learning Resource Center in West Des Moines.