Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes June 3, 2015

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Gregory Barclay, M.D.; Jason Wilbur, M.D.: Kellen Ludvigson, Pharm.D.; Brett Faine, Pharm.D.; Brian Couse, M.D.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; Megan Smith, Pharm.D., IME; Tina Valentino, Pharm.D., IME; and Melissa Biddle, IME.

Welcome & Introductions

Mark Graber called the meeting to order at 9:34 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 1, 2015 meeting were reviewed. Jason Wilbur motioned to accept them, and Gregory Barclay seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed, along with a recommendation from the P&T Committee requesting that the DUR Commission develop prior authorization criteria for Esbriet, Ofev, Lynparza, and Savaysa. The results of an OIG study conducted for second-generation antipsychotic use among Medicaid-enrolled children were also provided, available at http://oig.hhs.gov/oei/reports/oei-07-12-00320.asp.

IME Updates

There have been some changes to the wellness exam portion of the Iowa Health and Wellness Plan (IHAWP). Eleven (11) 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 7, 2015, with implementation still slated for January 1, 2016. Mikki Stier, formerly the Vice President of Government and External Relations at Broadlawns Medical Center, is the new Iowa Medicaid Director. CMS just released a 201-page document with proposed changes for managed care guidelines as relating to Medicaid; comments can be submitted online and must be received no later than July 27, 2015. Megan Smith has resigned her position as Clinical Pharmacy Manager, and this will be her last meeting. Tina Valentino provided a quarterly report on the new Complex Pharmaceutical Oversight Program (CPOP), which brought $287,747 in direct cost avoidance savings (State and Federal dollars extrapolated to the end of the state fiscal year) from 12 interventions in its first quarter of operation. There have already been an additional 30 interventions in the second quarter. Members on Hepatitis C treatments are being closely monitored by CPOP, and

there are currently 55 of them, with 14 having completed therapy since January. Pam Smith presented Dr. Barclay with a letter and certificate signed by the Medicaid Director in thanks for his four years service, and this will be his last meeting.

Prevalence Report Summary

Statistics from March through April 2015 were discussed, including: cost per user ($331.81), number of total prescriptions dispensed (an increase of 10.0% compared to the previous reporting period), average cost per prescription ($66.90), and generic utilization (84.8%). The total paid amount increased by 13.3% from the previous reporting period. There were 211,678 unique users, which is 4.4% more than the total for January and February. 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 eleventh place with $1,781,823 in expenditures, an increase of 108.7% from the previous reporting period. The top 100 drugs were also reviewed. The ten most expensive medications were: Abilify, methylphenidate hcl er, Vyvanse, Lantus, Focalin XR, Advate, Strattera, Harvoni, Advair Diskus, and Spiriva Handihaler. Kellen Ludvigson asked about the top drugs for a non-Medicaid population, and Pam Smith will look for information prior to the next meeting.

Case Studies

Pam Smith presented four case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $4,925.40 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Elizabeth Potente	Avanir	Nuedexta
Paul McCray	University of Iowa Pediatrics, Pulmonary Division	ivacaftor

Mental Health Advisory Group Update

ProDUR Edits on Antipsychotics in Children: At their May 8, 2015 meeting, the MHAG re-reviewed the recommendations originally made in 2012 and recently approved for implementation by DHS. Pam Smith shared the concerns of the MHAG, which included: 1.)Dr. Augspurger wanted his objection noted again that chlorpromazine is FDA approved to be dosed down to six months of age and haloperidol is FDA approved to be dosed down to three years of age, which are outside of the proposed ProDUR age edits. The DUR Commission was made aware of his objection, but decided to proceed with the edits as initially recommended as they felt it is important to track members that young on antipsychotics. 2.) The MHAG is concerned the ProDUR edits will delay discharge of admitted patients due to PA requirements. Everyone was reminded there is a 24 hour turnaround time for PA once received and pharmacies have

the option to process a three day emergency supply. The DUR recommended proceeding with the original recommendations. An age edit will be applied on risperidone for members less than five years of age and an age edit on all other antipsychotics for members less than six years of age. Additionally, edits will be put into place to prevent duplicate therapy for members less than 18 years of age initially, with the same edit to be applied to members 18 and older in the second phase of implementation, at a time to be determined at a later date.

Proposed ProDUR Edits on CNS Stimulants: After discussion and feedback from the Iowa Psychiatric Society at the April DUR meeting, the DUR Commission decided to refer this topic to the Mental Health Advisory Group (MHAG) again prior to implementation. The MHAG met in May and felt that the quantity limit for Concerta 54mg should remain at 60 for 30 days as literature exists to support dosing at 108mg per day, and there are children weighing 80-90 kilograms that require a higher dose. The DUR Commission agreed unanimously with this change (motion by Kellen Ludvigson, second by Brian Couse.) Current recommendations are as follows:

Drug	Proposed Quantity Limit Per 30 Days	Current Quantity Limit Per 30 Days
Adderall 12.5mg tablet	90	120
Adderall 20mg tablet	90	120
Concerta 18mg tablet	30	60
Concerta 27mg tablet	30	60
Concerta 54mg tablet	60	60
Focalin IR tablet (all strengths)	60	None
Focalin XR 5mg	30	60
Focalin XR 10mg	30	60
Focalin XR 15mg	30	90
Focalin XR 20mg	30	60
Focalin XR 25mg	30	60
Focalin XR 30mg	30	60
Ritalin IR (all strengths)	90	None

Focus Studies

Prasugrel Contraindications: This was a follow-up discussion. Two of the six members identified changed therapy, for an annualized cost savings of $1,194.92 (state and federal, pre-rebate) as a result of the 14 surveys sent out to prescribers and pharmacies. Six (42.86%) of those surveys were returned.

Eszopiclone Dose: This was a follow-up discussion. Thirty-one of the 52 members identified changed therapy, for an annualized cost savings of $48,667.64 (state and federal, pre-rebate) as a result of the 105 surveys sent out

to prescribers and pharmacies. Thirty-seven (35.24%) of those surveys were returned.

Second Generation Antipsychotics with Anticholinergics: One letter will be sent, asking if the member has experienced EPS, pointing out being on more than one Second Generation Antipsychotic (SGA) increases the risk of EPS. Providers will be asked the following: if the SGA could be discontinued (if multiple SGAs) or the dose decreased; and/or if the anticholinergic could be discontinued if patient has not experience EPS in the past. Dr. Graber asked that members on multiple anticholinergics also be evaluated in the future.

Metoclopramide Utilization Greater than 12 Weeks: Gastroparesis and chemotherapy regimens will be removed from the results. Data will be rerun and brought back to the Commission at the next meeting prior to further action.

Public Comment

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	Chronic Pain PA Criteria
Ketul Patel	Vertex	Kalydeco

Prior Authorization

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

Jublia (efinaconazole) and Kerydin (tavaborole) will be considered for up to 48-weeks treatment in patients 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 trial and therapy failure or intolerance to oral terbinafine; and*
4. *Patient has documentation of a trial and therapy failure or intolerance to ciclopirox 8% topical solution.*

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

The Commission would like to add language clarifying that this must be used for medical purposes, such as pain, diabetes, or other certain comorbidities, rather than aesthetics, and only allow 1 course of treatment with recurrence not covered. Pam Smith will revise the wording and bring it back to the next 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.

Agents will be separated by potency on the PDL as requested. Jason Wilbur motioned to accept the criteria, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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. *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*
3. *Prescriber is a CF specialist or pulmonologist; and*
4. *Baseline liver function tests (AST/ALT) and FEV1, if age appropriate, are provided; and*
5. *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 ivacaftor therapy is confirmed; and*
2. *Response to therapy is documented by prescriber (e.g., improved FEV1 from baseline, weight increased from baseline, decreased exacerbations and/or improved quality of life or rationale for continued care); and*
3. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment an annually thereafter.*

Jason Wilbur motioned to accept the criteria as modified, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Olaparib (Lynparza): This topic was put aside as it will be included on the Oncology Agents PA form that is currently in progress.

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 ALT, AST, and bilirubin are assessed periodically during therapy.*

Brett Faine motioned to accept the criteria as modified, and Kellen Ludvigson 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.

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 apixaban or rivaroxaban, where applicable.*

<u>Atrial Fibrillation</u>

1. *Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with*
2. *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*
3. *Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥1; and*
4. *Patient does not have a creatinine clearance (CrCl) > 95 mL/min.*
5. *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*

<u>Treatment of Deep Vein Thrombosis or Pulmonary Embolism</u>

1. *Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with*
2. *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); with*

3. *Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).*
4. *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.

Brett Faine motioned to accept the criteria as modified, 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. The P&T Committee will also be reviewing the NOACs at a future meeting, so there may be additional recommended changes in the up coming months.

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

Prior authorization is required for oral oncology agents. FDA approved labeling will be followed. The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, authorizations will be given at three (3) month intervals. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued.

Brian Couse motioned to accept the criteria, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Hepatitis C Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older and has a diagnosis of chronic hepatitis C; and*
2. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
3. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
4. *Viral load will be submitted by prescriber 12 weeks after completion of*

therapy; and

5. *Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:*
    - *Liver biopsy confirming a Metavir score ≥ F3; or*
    - *Transient elastography (FibroScan) score ≥ 9.5kPa; or*
    - *FibroSURE (FibroTest) score ≥ 0.58; or*
    - *APRI score > 1.5; or*
    - *Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or*
    - *Physical findings or clinical evidence consistent with cirrhosis; or*
    - *Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.*
6. *Patient's prior treatment history is provided (treatment naïve or treatment experienced); and*
7. *If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and*
8. *Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and*
9. *Patient does not have severe renal impairment (creatinine clearance <30ml/min) or end stage renal disease requiring hemodialysis; and*
10. *HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and*
11. *For patients on a regimen containing ribavirin, the following must be documented on the PA form:*
    a) *Patient is not a pregnant female or a male with a pregnant female partner; and*
    b) *Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and*
    c) *Monthly pregnancy tests will be performed during treatment; and*
12. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.*
13. *Documentation is provided for patients who are ineligible to receive interferon or ribavirin.*
14. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
15. *If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on established length of therapy for the particular treatment (defined below).*
16. *Lost or stolen medication replacement requests will not be authorized.*

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

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

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. 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 at https://pmp.iowa.gov/IAPMPWebCenter/. Payment for CNS stimulants and Atomoxetine will be considered under the following conditions:

1. *Attention Deficit Disorder (ADD) or 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 current environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms the patient continues to require medication to treat the symptoms of ADD/ADHD will be required for renewals or patients newly eligible that are established on medication to treat ADD/ADHD.*
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.*
4. *Binge Eating Disorder (Vyvanse only)*
   - *Patient is 18 to 55 years of age; and*
   - *Patient meets the DSM-5 criteria for Binge Eating Disorder; and*
   - *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and*
   - *Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and*
   - *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with topiramate and fluvoxamine*
   - *Prescription is written by a psychiatrist or psychiatric nurse practitioner; and*
   - *Patient has a BMI of 25 to 45; and*

- *Patient does not have a personal history of cardiovascular disease; and*
- *Patient has no history of substance abuse; and*
- *Is not being prescribed for the treatment of obesity or weight loss; and*
- *Doses above 70mg per day will not be considered.*
- *Initial requests will be approved for 12 weeks.*
- *Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.*

DSM-5 Criteria

i. *Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and*
ii. *The binge eating episodes are marked by at least three of the following:*
    1. *Eating more rapidly than normal*
    2. *Eating until feeling uncomfortably full*
    3. *Eating large amounts of food when not feeling physically hungry*
    4. *Eating alone because of embarrassment by the amount of food consumed*
    5. *Feeling disgusted with oneself, depressed, or guilty after overeating; and*
iii. *Episodes occur at least 1 day a week for at least 3 months; and*
iv. *No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and*
v. *Does not occur solely during the course of bulimia nervosa or anorexia nervosa.*

Moderate to Severe BED

Based on the number of binge eating episodes per week:

Moderate - 4 to 7
Severe – 8 to 13
Extreme – 14 or more

*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 immediate release and extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.*

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.

Dextromethorphan/Quinidine (Nuedexta): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Nuedexta®. Payment will be considered under the following conditions:

1. *Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to a neurological condition.*
2. *A trial and therapy failure at a therapeutic dose with amitriptyline or an SSRI; and*
3. *Patient has documentation of a current EKG (within the past 3 months) without QT prolongation.*
4. *Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire.*
5. *Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.*

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.

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 indication(s) and other conditions as listed in the compendia. 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. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization. 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 **postherpetic 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*** *(Lyrica®)*

   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, duloxetine or topical lidocaine.

4. *A diagnosis of* ***partial onset seizures****, as adjunct therapy (Lyrica®)*

Requests for doses above the manufacturer recommended dose will not be considered.

As this was the second review of these criteria, no motion was necessary. However, the Commission wanted to remove the SSRI trial for a fibromyalgia diagnosis. Brett Faine motioned to accept this modification, and Brian Couse seconded. All members were in favor. The recommendation will be sent to the Department for consideration.

Sedative/Hypnotics – Non-Benzodiazepines: The Commission reviewed the prior authorization criteria as follows:

Preferred agents are available without prior authorization (PA). Requests for doses above the manufacturer recommended dose will not be considered. Prior authorization is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when the following criteria are met:

1. *A diagnosis of insomnia; and*
2. *Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued; and*
3. *Enforcement of good sleep hygiene is documented; and*
4. *All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.*
5. *In addition to the above criteria, requests for suvorexant (Belsomra) will require documentation of a trial and therapy failure with at least one non-preferred agent, other than suvorexant, prior to consideration of coverage.*
6. *Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.*

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.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 27, Number 3. This was the second review of the DUR Digest and will be posted to the website.

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

A unanimous roll call vote was made at 11:42 to adjourn the meeting and move to closed session (motion by Jason Wilbur).

The next meeting will be held at 9:30 a.m. on Wednesday, August 5, 2015, at the Learning Resource Center in West Des Moines.