Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes October 7, 2015

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Kellen Ludvigson, Pharm.D.; Jason Wilbur, M.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; and Melissa Biddle, IME.

Welcome & Introductions

Mark Graber called the meeting to order at 9:35 a.m. at the Learning Resource Center in West Des Moines. The minutes from the August 5, 2015 meeting were reviewed. Brian Couse motioned to accept them, and Kellen Ludvigson seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed, along with the letter from the P&T Committee requesting that the DUR Commission develop prior authorization criteria for Cholbam.

IME Updates

On August 17, 2015, four managed care organizations (MCOs) were selected from the 11 bids submitted in response to the Medicaid Modernization managed care Request for Proposal (RFP): Amerigroup Iowa, Inc.; AmeriHealth Caritas Iowa, Inc.; UnitedHealthcare Plan of the River Valley, Inc.; and WellCare of Iowa, Inc. Contracts will be signed soon. An Iowa Health Link Tool Kit is available for providers on the Medicaid Modernization web site. Provider training sessions are also scheduled, with implementation still slated for January 1, 2016. Providers can enroll with any or all of the MCOs and should contact the MCOs about enrollment; Informational Letter 1539 contains their contact information.

Prevalence Report Summary

Statistics from July though August 2015 were discussed, including: cost per user ($356.41), number of total prescriptions dispensed (an increase of 1.0% compared to the previous reporting period), average cost per prescription ($69.39), and generic utilization (85.3%). The total paid amount increased by 2.5% from the previous reporting period. There were 193,048 unique users, which is 1.5% less than the total for May and June 2015. 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 on the top therapeutic classes by paid amount report, currently in fifth place with $2,818,490 in expenditures, an increase of 9.8% 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, Humalog, Focalin XR, Advate, Strattera, and Spiriva Handihaler.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $1,107.65 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Matt Lewis	Amgen	PCSK9 Inhibitors, Repatha
Rick Melbye	Sanofi	Praluent
Tyrone McBayne	Baxalta	Glassia and Aralast
Shelley Baugh	Celgene	Otezla

Pam Smith also clarified the Oncology Agents prior authorization criteria, as there had been multiple written public comments received regarding the criteria implementation. The criteria will only apply to outpatient services, including home health, and does not include steps through other preferred agents. It is merely clinical criteria, based on the medication labels, and all medications subject to PA use the same PA form. The IME Pharmacy department is required to process all requests within 24 hours once received.

Focus Studies

Short-Acting Opioid Overutilization (Four or More Doses per Day): This was a follow-up discussion. Three-hundred sixty-seven (367) of the 1,990 members identified changed therapy, for an annualized cost savings of $93,607.04 (state and federal, pre-rebate) as a result of the 6,352 surveys sent out to prescribers and pharmacies. A total of 2,343 (36.89%) surveys were returned.

Duplicate Inhaled Corticosteroids: Letters will be sent to the providers of the members identified as using concurrent inhaled corticosteroids pointing out the use of more than one inhaled corticosteroid is not supported in guidelines and can increase the risk of adverse drug events and asking if one could be discontinued.

Duplicate Long-Acting Beta-2 Agonists: Letters will be sent to the providers of the members identified as using concurrent LABAs pointing out the use of more than one LABA is not supported in guidelines and can increase the risk of adverse drug events and asking if one could be discontinued. Only twelve members were identified as having 60 days or more of therapy with two or more LABAs.

Public Comment

Name	Representing	Drug/Topic
Peter Zoob	Vertex	Orkambi

Prior Authorization

Annual Review of Prior Authorization Criteria: Changes were suggested for the following categories, to be discussed at upcoming meetings:

PA Category	Recommended Changes
Anti-Acne	Will be updated once acne guidelines are updated.
Antiemetic-5HT3 Receptor Agonists/Substance P Neurokinin Agents	Increase the quantity limit on ondansetron.
Apixaban (Eliquis)	Update to CHA_2DS_2 – Vasc score
Biologic Immunomodulators	Will be updated once guidelines are updated.
Daibigatran (Pradaxa)	Update to CHA_2DS_2 – Vasc score
Erythropoisis Stimulating Agents	CHF thresholds
Ketorolac	Verify not taking oral agents. Total combined duration should not exceed 5 days.
Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products	Remove prior authorization requirement and add a quantity limit of 90 per 30 days.
Pulmonary Arterial Hypertension Agents	Review to establish more specific criteria.
Rivaroxaban (Xarelto)	Update to CHA_2DS_2 – Vasc score
Repository Corticotropin Injection (Acthar HP)	Sabril has also been approved for infantile spasms and is more cost effective, possibly require trial.
Thrombopoietin Receptor Agents	Review, possibly change ribavirin therapy requirement.
Topical Retinoids	Will be updated once acne guidelines are updated.
Roflumilast (Daliresp)	Require both a beta-agonist and anticholinergic prior to oral.
Zontivity	Possibly require trials of other anti-platelet agents first.

Growth Hormone: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for therapy with growth hormones. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones:

1. *Standard deviation of 2.0 or more below mean height for chronological age.*
2. *No intracranial lesion or tumor diagnosed by MRI.*
3. *Growth rate below five centimeters per year.*
4. *Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter. Stimuli testing will not be required for the following diagnoses: Turners Syndrome, chronic renal failure, and HIV/AIDS.*
5. *Annual bone age testing is required for the diagnosis of Growth Hormone Deficiency. A bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required.*

6. *Epiphyses open.*

Prior authorization will be granted for 12-month periods per patient as needed.

The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA).

If the request is for Zorbtive® [somatropin (rDNA origin) for injection] approval will be granted for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome.

The Commission members voted, by a show of hands, 4 to 3 in favor of excluding coverage for treatment of SGA as is not medically necessary or is considered cosmetic. Brian Couse then motioned to accept the criteria as amended, and Daniel Gillette and Jason Wilbur both seconded. Mark Graber was opposed, but the motion passed. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

PCSK9 Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for PCSK9 Inhibitors. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older (or, for Homozygous Familial Hypercholesterolemia patient is 13 years of age or older); AND*
2. *Documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); AND*
3. *Is to be prescribed as an adjunct to a low fat diet; AND*
4. *A baseline lipid profile is provided; AND*
5. *Documented abstinence from tobacco for the previous 90 days is provided; AND*
6. *Is prescribed by a lipidologist or cardiologist.*
7. *The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors.*
8. *Prescriber and dispensing pharmacy has educated the patient on proper storage and administration. Improperly stored medications will not be replaced.*
9. *Lost or stolen medication replacement requests will not be authorized.*
10. *Is prescribed for one of the following diagnoses:*

<u>Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)</u>

1. *Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND*
    a. *Presence of tendon xanthomas; OR*
    b. *In first or second degree relative, one of the following:*
        i. *Documented tendon xanthomas; or*
        ii. *MI at age ≤60 years; or*
        iii. *Total cholesterol > 290mg/dL; OR*
    c. *Confirmation of diagnosis by gene or receptor testing (attach results); AND*

2. *Unable to reach goal LDL-C with a maximally tolerated dose of <u>two</u> or more statins (at least one of which must be either atorvastatin or rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily PLUS at least one other concurrently administered lipid lowering agent.*

<u>Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)</u>

1. *History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; AND*
2. *Unable to reach goal LDL-C with a maximally tolerated dose of <u>two</u> or more statins (at least one of which must be either atorvastatin or rosuvastatin) PLUS ezetimibe (Zetia) 10mg daily.*

<u>Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) – Repatha (evolocumab) only</u>

1. *Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; OR*
2. *Confirmation of diagnosis by gene or receptor testing (attach results); AND*
3. *Unable to reach goal LDL-C with maximally tolerated dose of atorvastatin or rosuvastatin (or other preferred high-dose statin if patient cannot take atorvastatin or rosuvastatin) PLUS ezetimibe (Zetia) 10mg daily PLUS at least one other concurrently administered lipid lowering agent.*

Initial and Renewal Authorizations
<u>HeFH or ASCVD</u>

- *Initial*
    - *Praluent 75mg or Repatha 140mg every 2 weeks for 8 weeks (4 doses).*
- *Renewal*
    - *Lipid profile required at week 8, week 24, and every 6 months thereafter; and*
    - *Patient continues therapy with a maximally tolerated statin dose and remains at goal; and*

  <u>Praluent</u>
    - *If LDL-C at goal, continue therapy at 75mg every 2 weeks for 24 weeks.*
    - *If LDL-C not at goal, dose increase to 150mg every 2 weeks for 8 weeks (4 doses) and repeat LDL-C in 8 weeks.*
        - *If repeat LDL-C not at goal, discontinue Praluent.*
        - *If repeat LDL-C at goal, continue therapy at 150mg every 2 weeks for 24 weeks; or*

  <u>Repatha</u>
    - *If LDL-C at goal, continue therapy at 140mg every 2 weeks for 24 weeks.*
    - *If LDL-C not at goal, discontinue Repatha.*

<u>HoFH (Repatha only)</u>

- *Initial*
    - *Repatha 420mg (3x140mg autoinjectors) every month for 3 months.*
- *Renewal*
    - *Lipid profile required after 3 months (third dose) and every 6 months thereafter; and*
    - *Continued therapy with a maximally tolerated statin dose.*
        - *If LDL-C at goal, continue therapy at 420mg every month for six months.*
        - *If LDL-C not at goal, discontinue Repatha.*

Quantity Limits
Praluent/Repatha for HeFH or ASCVD

- *A quantity limit of one syringe/pen/autoinjector per fill will apply (requires refill every 14 days).*

Repatha for HoFH only

- *A quantity limit of one three-pack per month*

Pam Smith will revise the criteria, incorporating suggested changes, and bring it back to the next meeting for further review. The baseline and current numbers need to be clarified, with current regimen provided, and goal defined, with member counseled about weight loss and smoking cessation.

Cholic Acid (Cholbam): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for cholic acid (Cholbam). Payment will be considered under the following conditions:

1. *Is prescribed by a hepatologist or pediatric gastroenterologist; and*
2. *Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including:*
    - *3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3β-HSD),*
    - *aldo-keto reductase 1D1 (AKR1D1),*
    - *alpha-methylacyl-CoA racemase deficiency (AMACR deficiency),*
    - *sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]),*
    - *cytochrome P450 7A1 (CYP7A1),*
    - *25-hydroxylation pathway (Smith-Lemli-Opitz); OR*
3. *Is prescribed as an adjunctive treatment of a peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infantile refsum disease (IRD); and*

4. *Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and*
5. *Baseline liver function tests are taken prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR) and provided with request; and*
6. *Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and*
7. *Patient is at least 3 weeks old.*

When criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two the following criteria:

- *Body weight has increased by 10% or is stable at ≥50th percentile,*
- *Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,*
- *Total bilirubin level reduced to ≤1mg/dL.*

Kellen Ludvigson motioned to accept the criteria, and Jason Wilbur and Larry Ambroson seconded simultaneously. The decision was unanimous. Dr. Graber suggested also checking to see if the member is on an enzyme inducer, and Pam Smith said that could be checked internally by IME staff. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Binge Eating Disorder Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for Vyvanse for the treatment of Binge Eating Disorder (BED). Prior to requesting PA, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website at https://pmp.iowa.gov/IAPMPWebCenter/. Payment will be considered under the following conditions:

1. *Patient is 18 to 55 years of age; and*
2. *Patient meets the DSM-5 criteria for BED; and*
3. *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number must be reported); and*
4. *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*
5. *Prescription is written by a psychiatrist or psychiatric nurse practitioner;*
6. *Patient has a BMI of 25 to 45; and*
7. *Patient does not have a personal history of cardiovascular disease; and*
8. *Patient has no history of substance abuse; and*
9. *Is not being prescribed for the treatment of obesity or weight loss; and*
10. *Doses above 70mg per day will not be considered.*

Initial requests will be approved for 12 weeks when criteria for coverage are met. Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

Jason Wilbur motioned to accept the criteria, and Kellen Ludvigson 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 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.

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

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.*

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

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.*

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 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.

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. 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.

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. 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.

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

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.*

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 28, Number 1. No changes were recommended and the DUR Digest will be posted to the DUR website.

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

A unanimous roll call vote was made at 11:48 to adjourn the meeting and move to closed session (motion by Daniel Gillette, second by Brian Couse).

The next meeting will be held at 9:30 a.m. on Wednesday, December 2, 2015, at the Learning Resource Center in West Des Moines.