Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes October 4, 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.; Daniel Gillette, M.D.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:34 a.m. at the Fred Maytag II Scout Center in Des Moines. The minutes from the August 2, 2017 meeting were reviewed. Jason Wilbur motioned to accept them, and Brett Faine seconded. The decision was unanimous. Mark Graber nominated Brett Faine to take over as chairperson, and Jason Wilbur seconded. All members were in favor. Mark Graber then nominated Kellen Ludvigson as vice-chairperson, and Laurie Anderson seconded. This decision was also unanimous. The recommendation letter sent to DHS after the August DUR meeting and the letter from the P&T Committee requesting development of PA criteria for Dupixent were also reviewed.

Biologics and Genetically Targeted Drugs

The DUR Commission was provided a copy of Informational Letter No. 1919-MC-FFS-D outlining the process on the Drugs for Rare Diseases under the Outpatient Pharmacy Benefit.

Step Therapy Protocol for Prescription Drugs

The DUR Commission reviewed the comments/concerns regarding the review of HF 233, in the context of the HF 635 review request and current DHS process for step therapy overrides within the Medicaid Pharmacy benefit.

The DUR Commission focused on Section 1, subsection 3b as it was the most applicable to the Commission. Below are the documented comments/concerns of the DUR Commission:

- The development of Medicaid Pharmacy prior authorization (PA) criteria is currently a transparent process conducted in open public meetings with several opportunities for written and oral public comments.
- Item 3(b) (1-3) Circumstances to allow Step Therapy Exceptions - The current Medicaid Pharmacy PA process generally covers the circumstances described in

this section as allowed by Medicaid regulations and allows for exceptions to step therapy requirements using clinical judgment with proper medical documentation from the prescriber.

- Item 3(b)(2) Prescription drug is expected to be ineffective - It is unclear how patient adherence could be evaluated ahead of time. Predicted non-compliance should not be an exception and members should be required to try preferred medications first. While prescribers attempt to simplify patient regimens, it should not be the primary driving force for selecting a prescription drug. After much discussion, the Commission felt this entire section should be stricken as it creates a loophole for everyone and completely undermines the concept of the Preferred Drug List (POL) and PA criteria.

Overall, the DUR Commission felt there is no need to change the current PDL and PA process to accommodate a step therapy protocol. There are current processes in place to allow for the types of step therapy exceptions detailed in HF 223 consistent with Medicaid regulations and implementing this protocol would undermine the concept of the PDL and PA criteria. Jason Wilbur motioned to accept the DUR response as written, and Brett Faine and Jason Kruse both seconded. All members were in favor.

IME Pharmacy Update

There was nothing in addition to those already mentioned above.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a twelve-minute overview for fee-for service (FFS) statistics from July through August 2017, including: total amount paid ($1,586,733), cost per user ($238.25), and number of total prescriptions dispensed (25,679). There were 6,660 unique users, which is 0.5% more than the total for May and June. 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 (≥10 prescriptions per member). This was mainly due to members in long-term care (LTC) facilities where a 7 or 14 day supply was being dispensed. It was noted that 7 and 14 day fills (which allow for multiple dispensing fees per month) might be becoming an issue, and the Commission discussed implementing something to discourage them in the future. 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: Hepatitis C Agents; Anticonvulsants; Antipsychotics – Atypicals; Diabetic – Insulin; 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, Antipsychotics – Atypicals, and Antihypertensives - Central. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Epclusa, Vyvanse, Latuda, Humalog, methylphenidate hcl er, Genvoya, Harvoni, Lantus, Strattera, and Novoeight. The five drugs with the highest prescription count were:

hydrocodone/apap 5-325mg, Tramadol 50mg, fluoxetine 20mg, trazodone 50mg, and omeprazole 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 $92,239,848 was spent in total for 231,289 unique users who had 1,269,846 prescriptions across all four programs.

MCO Prevalence Report Summary and Updates

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a six-and-a-half-minute overview for AmeriHealth's statistics from July through August 2017, including: total paid amount ($34,150,963.73 - not much change from the previous reporting period), unique users (87,170), average cost per user ($391.77), total prescriptions (484,026), utilization by age and gender (age 19-64 category highest for both genders), top 100 pharmacies by prescription count (Walgreens, Mercy Family, and Broadlawns had the highest counts), top 100 pharmacies by paid amount (predominantly specialty pharmacies at the top of the list), top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount (top 2 similar to last reporting period). The top 5 therapeutics classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Anticonvulsants; Adrenergics, Aromatic, Non-Catecholamine; and Ani-Inflammatory Tumor Necrosis Factor Inhibitor. The top 5 therapeutic classes by prescription count were: Anticonvulsants; SSRIs; Proton-Pump Inhibitors; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; and Antihistamines – Second Generation. The most expensive drugs were Vyvanse, Latuda, Humalog, methylphenidate er, and Humira Pen, whereas omeprazole, hydrocodone-acetaminophen, lisinopril, levothyroxine sodium, and sertraline had the highest prescription counts.

Amerigroup: Sandy Pranger provided a six-minute overview for Amerigroup's statistics from July through August 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 $32,255,678, a 2.2% decrease from May and June. 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: escitalopram, omeprazole, and gabapentin.

United Healthcare Community Plan: Karrie Hansotia spoke for five minutes and provided written summaries that included United's statistics from July through August 2017, including: total paid amount ($24,246,473.40), unique users (64,868), and cost per user ($373.78). She noted that not much changed from the May/June reporting period to the July/August 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. The University of Iowa Ambulatory Care 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; Anti-Inflammatory Tumor Necrosis Factor Inhibitor; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Adrenergics, Aromatic, Non-Catecholamine; and Hep C Virus – NS5B Polymerase & NS5A Inhibitor Combo. 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, Humira Pen, Harvoni, Humalog, and Latuda, while omeprazole, hydrocodone/apap, lisinopril, levothyroxine sodium, and atorvastatin had the top 5 prescription counts.

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
Michael West	Celgene	Otezla
Janet Ritter	Sanofi Genzyme	Dupixent/Atopic Dermatitis
Jim Baumann	Pfizer	Chantix and Smoking Cessation
Erin Conley	Amgen	Enbrel
Tom Peddicord	Novartis	Cosentyx and Entresto
Anthony Pudlo and Shannon Rudolph	Iowa Pharmacy Association	Adherence Rates & Pen Needle Coverage

ProDUR Edits

Tramadol Age Edit: Due to the recent changes to the label of tramadol containing medications, the DUR Commission has made a recommendation to implement an age edit on all tramadol containing medications. As this was the second review of this age edit, no motion was necessary. The recommendation will be sent to the Department for consideration.

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
Alpha$_2$ Agonists, Extended - Release	#3 - Clarify language to show that the intent of the trials is for 1 preferred amphetamine and 1 preferred methylphenidate or dexmethylphenidate product
Alpha$_1$ – Proteinase Inhibitor Enzymes	Change #6 to say “Patient is currently on optimal supportive therapy for COPD”. Renewal criteria #1a – change “and” to “or”.

Angiotensin Receptor Blocker Before ACE Inhibitor	Remove criteria completely
Apremilast (Otezla)	Remove #4 requiring it be prescribed by rheumatologist or dermatologist
Buprenorphine/Naloxone	Review cumulative 30 days per 12 months allowance
Chronic Pain Syndromes	Discuss relaxing requirement to decrease concurrent opioids
CNS Stimulants and Atomoxetine	Review ratings scale requirements as none are validated in adults. Review adult use criteria in general, especially short vs. long-acting, as use has increased
Growth Hormone	Specify reauthorization criteria
Idiopathic Pulmonary Fibrosis	Review #4 of renewal criteria to require reassessment of kidney function
Immunomodulators – Topical	Change trial with two preferred topical corticosteroids down to one preferred
Ivacaftor (Kalydeco)	Reword due to new CFTR gene mutations
Janus Kinase Inhibitors	Remove minocycline as a trial option?
Lidocaine Patch (Lidoderm)	Consider broadening criteria to allow more usage to compensate for lessening opioid use, maybe 1 trial vs. 2 or possibly remove trials for post-herpetic neuralgia diagnosis
Methotrexate Injection	Remove minocycline as a trial option?
Topical Acne and Rosacea Products	change wording to diagnosis of acne with regards to benzoyl peroxide trial

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. *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*
5. *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 other treatment options when the benzodiazepine or CNS depressant is used for anxiety or insomnia; and*
   - *Other prescribers involved in the care of the patient are aware of the patient's use of buprenorphine; AND*
6. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
7. *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 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.*

PA criteria were being updated regarding the age requirement. Given the recent FDA Drug Safety Communication cautioning against withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants, no vote was taken. Pam

Smith will revise the criteria to addressing the current requirement limiting patients to 30 days of benzodiazepines over a 12 month period and bring it to the next meeting for review.

Smoking Cessation Therapy, Oral & Nicotine Replacement Therapy: The Commission reviewed the prior authorization criteria as follows:

Smoking Cessation Therapy – Oral

Prior Authorization is required for varenicline (Chantix®) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:

1. *Diagnosis of nicotine dependence and referral for counseling 1) to Quitline Iowa program for Medicaid Fee-for service members or 2) through the Managed Care Organization program for managed care members.*
2. *Confirmation of enrollment and ongoing participation in the counseling program is required for approval and continued coverage.*
3. *Approvals will only be granted for patients eighteen years of age and older.*
4. *The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period.*
5. *Requests for varenicline to be used in combination with bupropion SR that is FDA indicated for smoking cessation or nicotine replacement therapy will not be approved.*
6. *The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation*

Nicotine Replacement Therapy

Prior Authorization is required for over-the-counter nicotine replacement patches, gum, or lozenges, and prescription nicotine nasal spray or inhaler. Requests for authorization must include:

1. *Diagnosis of nicotine dependence and referral for counseling 1) to Quitline Iowa program for Medicaid Fee-for service members or 2) through the Managed Care Organization program for managed care members.*
2. *Confirmation of enrollment in the counseling program is required for approval. Continuation therapy is available only with documentation of ongoing participation in the counseling program.*
3. *Approvals will only be granted for patients eighteen years of age and older.*
4. *The maximum allowed duration of therapy is twelve weeks total combined therapy within a twelve-month period.*
5. *Patients may receive nicotine replacement patches in combination with one of the oral nicotine replacement products (gum or lozenges). A maximum quantity of 14*

nicotine replacement patches and 110 pieces of nicotine gum or 144 nicotine lozenges may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at one unit per day of nicotine replacement patches and 330 pieces of nicotine gum or 288 nicotine lozenges.

6. *Requests for non-preferred nicotine replacement products will be considered after documentation of previous trials and intolerance with a preferred oral and preferred topical nicotine replacement product. A maximum quantity of 168 nicotine inhalers or 40ml nicotine nasal spray may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at 336 nicotine inhalers or 80ml of nicotine nasal spray.*
7. *The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation.*

At the August meeting, AmeriHealth requested that the patient counseling requirement be reviewed and potentially removed from these criteria, as it is not included in their PA criteria in other states that they manage. While they understand that statistics show higher success rates when counseling is used in conjunction with medication, they believe this requirement may be preventing some members from attempting to quit smoking. Currently, prior authorization criteria requires counseling, of which the MCOs must follow, though not necessarily through the FFS vendor, Quitline Iowa. Mark Graber asked for an approximation of costs if all PA criteria were removed, and Susan Parker replied that the MCOs needed to provide information for an impact analysis. Amerigroup projected an 80% increase in Chantix use resulting in current expenditures of $50,000-$60,000 per month possibly doubling. United Healthcare estimated a 30% increase, which would come out to an additional $180,000 annually. AmeriHealth Caritas projected a smaller 13.23% increase, for a $101,150.28 increase. Karrie Hansotia added that there seemed to be a problem with providers keeping track of which members were enrolled due to 4 different plan options with the MCOs and FFS, and the MCOs aren't able to easily get counseling verification. Jason Kruse commented that unreliable phone numbers could also be an issue, as he has had patients who are refused access to these medications as they were unable to be contacted for counseling. Pam Smith wondered what would happen if costs increase even more than projected, given the current budget shortfall. When the Commission members noted that these expenditures were nothing when compared to those for Hep C medications, Susan Parker reminded them that those medications could cure Hep C whereas these were reliant on member lifestyle choices. She believes that someone who is really ready to stop smoking would be willing to comply with the counseling requirement. Jason Wilbur commented that the counseling option would still be available, but could be removed as a mandatory requirement. Jason Kruse suggested removing PA criteria just for nicotine replacement products and leaving criteria for Chantix initially to determine fiscal impact, or, if PA criteria stayed in place, removing the second bullet point requiring confirmation of enrollment and ongoing participation in the counseling program. In other states, the MCOs manage these products solely through quantity limits. Mark Graber added that data suggested that success rates were higher for 24 weeks versus 12, so that criteria should be changed as well. Jason Wilbur

noted that it made sense to manage through quantity limits then, if removing the counseling requirement. Pam Smith replied that managing through quantity limits would likely result in fewer patients being offered a referral to a counseling program, whereas the PA would prompt the prescriber to think about that. Mark Graber added that given the low cost of bupropion, it and the nicotine products could be handled with quantity limits, while leaving a separate PA requirement for Chantix. Given the aforementioned budget crisis, Pam Smith suggested leaving the PA in place but increasing the allowance to 24 weeks, then checking fiscal impact from that change before going further, in incremental steps. This would leave the counseling requirement in place. She understands it can be a barrier, but is appropriate and does help members to succeed. Jason Kruse reiterated that phone access was a big impediment to treatment for his patients. Susan Parker reminded them that members did have the option of setting up a time to call Quitline, rather than waiting for a call. Mark Graber then suggested doing away with the counseling requirement unless quantity limits are exceeded; providers could attest that the member is in counseling on the PA form. Jason Kruse suggested that this category be referred to the P&T Committee for financial review; however, development of PA criteria is still the responsibility of the DUR Commission. Ultimately, the Commission voted to remove the PA criteria entirely, to improve access to these medications, reduce administrative burden to prescribers, pharmacies and the MCOs, and hopefully lessen future pharmacy and medical expenditures for resulting diseases such as COPD and myocardial infarctions. Jason Kruse made the motion, Melissa Klotz seconded, and it passed 4 to 3, with Mark Graber, Laurie Anderson, and Kellen Ludvigson opposed (Daniel Gillette was absent for the vote). They did not technically finalize or vote on any accompanying quantity limits.

PA criteria for the following Biologicals were reviewed and voted on together:

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 IV 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

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 a 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*

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 IV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

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

For the following indications:

- *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 (hydroxycholoroquine, 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.
- *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).
- *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).

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

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. Patients initiating therapy with a biological agent must:
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*

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 IV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

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

For the following indications:

- *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.*
- *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.

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. Patients initiating therapy with a biological agent must:
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

The Biologicals categories were reviewed and voted on together since changes were only made to break out TNF Inhibitors and Interleukins. Brett Faine made the motion to accept the criteria as proposed, and Kellen Ludvigson and Jason Kruse both seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy groups for comment and will be brought back to the next meeting for further discussion.

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.*

Jason Wilbur made the motion to accept the criteria as amended, and Brett Faine 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.

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.

Jason Kruse made the motion to accept the criteria as amended, and Brett Faine 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.

Dupilumab (Dupixent): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
2. *Patient is within the FDA labeled age; and*
3. *Is prescribed by or in consultation with a dermatologist; and*
4. *Patient has failed to respond to good skin care and regular use of emollients; and*
5. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
6. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
7. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
8. *Patient will continue with skin care regimen and regular use of emollients; and*
9. *Dose does not exceed an initial one-time dose of 600mg and maintenance dose of 300mg thereafter given every other week.*

If criteria for coverage are met, initial authorizations will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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 conducted the second review of the draft DUR Digest Volume 30, Number 1. There were no recommended changes. The DUR Digest will be posted to the website.

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

At 12:24, Jason Kruse motioned to adjourn the meeting and Mark Graber 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, December 6, 2017, at the Learning Resource Center in West Des Moines.