Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes June 6, 2018

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; Susan Parker, Pharm.D.; and Sandy Pranger, R.Ph. (Amerigroup).
Staff
Pam Smith, R.Ph.
Guests
Mark Randleman, D.O., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Brett Faine called the meeting to order at 9:31 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 4, 2018 meeting were reviewed. Jason Kruse motioned to accept them, and Mark Graber seconded. Chuck Wadle abstained as he had not been present at the April meeting, but all other members were in favor. The recommendation letter sent to DHS after the last meeting, and a letter from the P&T Committee requesting development of PA criteria for Prevymis, were also reviewed.

IME Pharmacy Update

Pam Smith welcomed Dr. Wadle to the Commission.

Fee-for-Service Prevalence Report Summary

Pam Smith provided an overview for fee-for service statistics from March through April 2018, including: total amount paid ($1,835,350), cost per user ($221.79), and number of total prescriptions dispensed (31,710). There were 8,275 unique users, which is 40.6% less than the total for January and February due to the approximately 10,000 members who were temporarily assigned FFS benefits after they lost AmeriHealth coverage November 30th transitioning back to managed care. There were many large ranking changes on the top 100 pharmacies and prescribers reports, also due to the reassigned population. The top 5 therapeutics classes by paid amount were: Antipsychotics – Atypicals; Anticonvulsants; Stimulants – Amphetamines – Long Acting; Antiretroviral Combinations; and Antiasthmatic – Adrenergic Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Narcotics – Miscellaneous; and Beta-Lactams/Clavulanate Combinations. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, methylphenidate hcl er, Genvoya, Invega Sustenna, Advair Diskus; Latuda, Humalog, Focalin XR, Adynovate, and Gilenya. The five drugs with the highest prescription count were: hydrocodone/apap, amoxicillin, sertraline hcl, trazodone hcl, and gabapentin. 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 $92,221,672 was spent in total for 240,618 unique users who had 1,250,382 prescriptions. Kellen Ludvigson asked about test strip reimbursement, but Susan Parker replied that should be deferred to a later meeting, as it's a medical supply issue and the relevant staff member was not present to answer.

MCO Prevalence Report Summary and Updates

United Healthcare Community Plan: Karrie Hansotia spoke and provided written summaries that included United's statistics from March through April 2018, including: total paid amount ($59,378,039.07), unique users (159,868), and cost per user ($371.42). 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. Hy-Vee Pharmacy Solutions was the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; Adrenergics, Aromatic, Non-Catecholamine; and Anti-Inflammatory Tumor Necrosis Factor Inhibitor. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Proton-Pump Inhibitors; Analgesics, Narcotics; and NSAIDs, Cyclooxygenase Inhibitor – Type Analgesics. The most expensive drugs were Vyvanse, Latuda, Humira Pen, methylphenidate er, and Humalog, while omeprazole, lisinopril, amoxicillin, levothyroxine sodium, and atorvastatin calcium had the top 5 prescription counts.

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from March through April 2018, 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 $31,008,283, an 8.5% decrease from January and February. 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-Imflammatory. 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, Latuda, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, levothyroxine sodium, atorvastatin calcium, and amoxicillin.

Public Comment

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

Name	Representing	Drug/Topic
Nancy Bell	Pfizer	Janus Kinase Inhibitors

ProDUR Edits

Duplicate Antipsychotics: The Commission requested data be pulled to determine the impact. Pam Smith will work with the MCOs to pull data and create potential criteria. United Healthcare and Amerigroup both say they're already sending out letters for duplicate antipsychotics. Pam Smith asked that the MCOs provide outcomes data from more than 120 days ago.

Prior Authorization

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 indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. 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. Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life. Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. 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 post-herpetic 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 (duloxetine and Lyrica®)*
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine.
4. *A diagnosis of partial onset seizures, as adjunct therapy (Lyrica®)*
5. *A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica®)*

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

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. 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 extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required. Requests will be considered for an FDA approved age for the submitted diagnosis. 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. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:*

1. *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 improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening), and will be limited to one unit dose per day.*
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.*

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

Kellen Ludvigson motioned to accept the criteria as amended, and Melissa Klotz seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion. Potential age edits will be reviewed at a future meeting as well as data for duplicate therapy (combination of short- and long-acting stimulants) in children.

Tezacaftor/Ivacaftor (Symdeko): The Commission reviewed the prior authorization criteria as follows:

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

1. *Patient is 12 years of age or older; and*
2. *Patient has a diagnosis of cystic fibrosis (CF); and*
3. *Patient is homozygous for the F508del mutation or patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor (listed in the FDA approved labeling) based on in vitro data and/or clinical evidence.*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST/ALT) are provided.*

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

1. *Adherence to tezacaftor/ivacaftor therapy is confirmed; and*
2. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

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

Letermovir (Prevymis): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral letermovir. Requests for intravenous letermovir should be directed to the members medical benefit. Payment will be considered under the following conditions:

1. *Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and*
2. *Patient or donor is CMV-seropositive R+ (attach documentation); and*
3. *Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provide date patient received HSCT); and*
4. *Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and*
5. *Patient is 18 years of age or older; and*
6. *Dose does not exceed:*
    a. *240mg once daily when co-administered with cyclosporine;*
    b. *480mg once daily; and*
7. *Patient must not be taking the following medications:*
    a. *Pimozide; or*
    b. *Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or*
    c. *Rifampin; or*
    d. *Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and*
8. *Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and*

9. *Therapy duration will not exceed 100 days post-transplantation.*

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

Vesicular Monoamine Transporter (VMAT) 2 Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:

<u>Tardive Dyskinesia</u> (Ingrezza or Austedo)

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:*
    a. *Involuntary athetoid or choreiform movements*
    b. *Documentation or claims history of current or former chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)*
    c. *Symptoms lasting longer than 4-8 weeks; and*
3. *Prescribed by or in consultation with a neurologist or psychiatrist; and*
4. *Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and*
5. *Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and*
6. *For Ingrezza:*
    a. *Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and*
    b. *Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and*
    c. *Is prescribed within the FDA approved dosing; or*
7. *For Austedo:*
    a. *Patient is not suicidal, or does not have untreated/inadequately treated depression;*
    b. *Patient does not have hepatic impairment;*
    c. *Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and*

d. *Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and*
e. *Is prescribed within the FDA approved dosing.*

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to meet the criteria for initial approval; and*
2. *Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS).*

Chorea associated with Huntington's disease (Austedo or tetrabenazine)

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of Huntington's disease with chorea symptoms; and*
3. *Prescribed by or in consultation with a neurologist or psychiatrist; and*
4. *Is prescribed within the FDA approved dosing; and*
5. *Patient is not suicidal, or does not have untreated or inadequately treated depression; and*
6. *Patient does not have hepatic impairment; and*
7. *Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and*
8. *For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and*
9. *In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following:*
    a. *Austedo - 36mg per day (18mg single dose) or*
    b. *Tetrabenazine – 50mg per day (25mg single dose)*

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to meet the criteria for initial approval; and*
2. *Documentation of improvement in chorea symptoms is provided.*

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

Hepatitis C Treatments: 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 has a diagnosis of chronic hepatitis C and*
2. *Patient's age and/or weight is within the FDA labeled age and/or weight; and*
3. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
4. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
5. *Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and*
6. *Viral load will be submitted by prescriber 12 weeks after completion of therapy; and*
7. *Patient's prior treatment history is provided (treatment naïve or treatment experienced); and*
8. *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*
9. *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*
10. *For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and*
11. *HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and*
12. *For patients on a regimen containing ribavirin, the following must be documented on the PA form:*
    a) *Patient is not a pregnant female or 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*
13. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.*
14. *Documentation is provided for patients who are ineligible to receive ribavirin.*
15. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
16. *Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.*
17. *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 length of therapy for the particular treatment.*

18. *Lost or stolen medication replacement requests will not be authorized.*
19. *The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.*

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

Janus Kinase Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. *Patient meets the FDA approved age and*
2. *Patient is not using or planning to use tofacitinib in combination with biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and*
3. *Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and*
4. *Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and*
5. *Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and*
6. *Patient is not at an increased risk of gastrointestinal perforation; and*
7. *Patient does not have an active, serious infection, including localized infections; and*
8. *Medication will not be given concurrently with live vaccines; and*
9. *Follows FDA approved dosing based on indication; and*
10. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis with*
        i. *A documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide; and*
        ii. *A documented trial and inadequate response to two preferred biological DMARDs; OR*
    b. *Psoriatic arthritis with*
        i. *A documented trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
        ii. *Documented trial and therapy failure with two preferred biological agents used for psoriatic arthritis.*

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

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

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

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

1. *Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and*
2. *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*
3. *Patient has a diagnosis of rheumatoid arthritis (RA):*
   A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxycholoroquine, sulfasalazine, or leflunomide.
   Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions; or
4. *Patient has a diagnosis of moderate to severe psoriatic arthritis:*
   A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
5. *Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis:*
   A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

In addition to the above:
Requests for TNF Inhibitors:

1. *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*
2. *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:

1. *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.

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

Apremilast (Otezla): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for apremilast (Otezla®). Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); or*
3. *Patient has a diagnosis of moderate to severe plaque psoriasis; and*
4. *Patient does not have severe renal impairment (CrCl < 30 mL/min).*

<u>Psoriatic Arthritis</u>

1. *Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
2. *Patient has documentation of trials and therapy failures with two preferred biological agents indicated for psoriatic arthritis.*

<u>Plaque Psoriasis</u>

1. *Patient has documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; and*
2. *Patient has documentation of trials and therapy failures with two preferred biological agents indicated for plaque psoriasis.*

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

Methotrexate Injection: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for non-preferred methotrexate injection. Payment will be considered under the following conditions:

1. *Diagnosis of severe, active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA) and ALL of the following:*
   a. *Prescribed by a rheumatologist; and*
   b. *Patient has a documented trial and intolerance with oral methotrexate; and*
   c. *Patient has a documented trial and therapy failure or intolerance with at least one other non-biologic DMARD (hydroxychloroquine, leflunomide, or sulfasalazine); and*
   d. *Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and*

there is no caregiver available to provide assistance; and

e. *Patient does not reside in a long-term care facility.*

2. *Diagnosis of severe, recalcitrant, disabling psoriasis and ALL of the following:*
   a. *Patient is 18 years of age or older; and*
   b. *Prescribed by a dermatologist; and*
   c. *Patient has documentation of an inadequate response to all other standard therapies (oral methotrexate, topical corticosteroids, vitamin D analogues, cyclosporine, systemic retinoids, tazarotene, and phototherapy).*
   d. *Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and*
   e. *Patient does not reside in a long-term care facility.*

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

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

Miscellaneous

DUR Digest: The Commission members conducted the second review of the draft DUR Digest Volume 30, Number 3.

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

At 11:16, Kellen Ludvigson motioned to move to closed session for the review of historical member profiles, and Mark Graber seconded.

The next meeting will be held at 9:30 a.m. on Wednesday, August 1, 2018, at the State Capitol, Room 116, in Des Moines.