Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 3, 2021

Attendees:

Commission Members
Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Melissa Klotz, Pharm.D.; and Susan Parker, Pharm.D.; Lisa Todd, R.Ph. Amerigroup.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; Emily Rogers, Pharm.D. Iowa Total Care; and

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:31 a.m. This meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the August 4, 2021, meeting were reviewed. Chuck Wadle motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

IME Pharmacy Update

Informational Letter 2282 notified providers that effective November 1, 2021, the dispensing fee will be increased to $10.38. This is Brett Faine's last year on the DUR Commission, after which he will have served three 4-year terms. That will leave a pharmacist position open, in addition to the physician position recently left by Mark Graber. DHS is accepting referrals and applicants.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2021 through August 2021, including: total amount paid ($2,306,502), unique users (3,757); cost per user ($613.92), number of total prescriptions dispensed (22,467); and percent generic (89.5%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; Muscular Dystrophy Agents; and Antiretroviral Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta-Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Evrysdi, Vyvanse, Humira Pen, Sabril, and Invega Sustenna. The five drugs with the highest prescription counts were: sertraline hcl, trazodone hcl, clonidine hcl, albuterol, and escitalopram.

***Amerigroup**:* Lisa Todd provided an overview for Amerigroup's statistics from June 2021 through August 2021, including: total paid amount ($102,362,297); unique users (159,946); total prescriptions (1,014,236); generic prescriptions (912,117 totaling $18,609,656); brand prescriptions (102,119 totaling $83,752,641). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty, CVS Specialty, Caremark Illinois Specialty, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Imflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Latuda, and Invega Sustenna. Omeprazole had the highest prescription count, followed by: sertraline hcl, albuterol, trazodone hcl, and atorvastatin.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from June 2021 through August 2021, including: total paid amount ($79,344,428.95); total prescriptions (786,401); and unique users (120,462). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns Outpatient Pharmacy, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Nucara Specialty, CVS, Unity Point at Home, and Community (a Walgreens Pharmacy). The top 5 therapeutic classes by paid amount were: Insulin; Anti-TNF-alpha-Monoclonal Antibodies; Sympathomimetics; Antiretrovirals; and Antipsychotics – Misc. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and NSAIDs. The most expensive drugs were Humira Pen, Vyvanse, Trikafta, Vraylar, and Invega Sustenna, while albuterol, omeprazole, sertraline, atorvastatin, and trazodone had the top 5 prescription counts.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $184,013,228 was spent in total for 284,165 unique users who had 1,823,104 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for the MCO plans. Humira was in third place for FFS, but Everysdi and Vyvanse had the top 2 spots. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,222. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

The three representatives from FFS and both MCOs also presented findings from claims queries for ivermectin, as there has been recent usage of that medication for off-label COVID-19 treatment. However, the Commission does not think the current quantities of members and prescriptions involved merit additional action at this point. Pam Smith and the MCOs will continue to monitor claims stats for any future issues.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page and summarized below, they heard oral public comment from the speakers shown below.

Name	Representing	Drug/Topic
Scott Anderson	Regeneron	Praluent
Nishil Patel	Amgen	Otezla, Repatha
Sean Byrne	Gilead Sciences	Hepatitis C medications
Joseph Dang	Novartis	Kesimpta

Written Provider Comments Received:
CGRP monoclonal antibodies, Otezla, Medication adherence measures, Hep C DAAs

Written Manufacturer Comments Received: Ajovy

Retrospective DUR Data Presentations

Concurrent Opioids and Benzodiazepines: This topic is included in the SUPPORT Act and required for CMS reporting, optional this year, but mandatory in 2 years. After discussion at two prior meetings, the Commission thought a hard POS edit preventing concurrent use and development of PA criteria would be the best course of action. Data was then run to see the top providers and number of claims involved. A duration limit could also be applied across the benzodiapezine class, regardless of utilization. Pam Smith suggested that since there was such a large number of members, and it's difficult to change therapy once someone is established, that new starts be targeted. If there were fewer new starts, over time the utilization would decrease. Chuck Wadle asked if there was any data proving the consequences of the risks of concurrent therapy, as he had not personally encountered issues in his practice over the years, and that obviously the biggest issue was if they misuse, overuse, or overdose. Jason Wilbur replied that he did think there was data showing an increased mortality risk for patients that were chronically on opioids and benzodiazepines together, but agreed that individual risk/benefit anyleses often found that the medication benefits outweighed the risks. However, as an organization and a society, he thought that given the known mortality risk, we should try to limit concurrent use. He also agreed that it would be far easier to prevent future use rather than trying to get 6000 people to discontinue use. The Commission would like information as to what other states are doing, prior to implementation of any edits or criteria. Pam Smith will bring the findings back to the next meeting.

Duplicate PPIs: Data was run to identy members with two or more chemically distinct PPIs with 60 or more days of overlap. Iowa Total Care had no claims, while Amerigroup had

1519 and FFS 7. Emily Rogers believes this is because ITC already has an edit in place, though all plans are meant to be using the same criteria to be consistent. DHS and Pam Smith will get more information on this potential edit and bring that back to the next meeting. No letters will be sent until a decision is made on the ProDUR edit.

Chronic Use of Controlled Sedative/Hypnotic Agents: Data identifying members with claims for a controlled sedative/hypnotic agent for more than 90 days in a 120-day period was examined and discussed. The Commission wondered if other treatment options would be available if sedative/hypnotics were more controlled with a POS edit or PA criteria. Pam Smith will research if the state or MCO plans provide cognitive behavioral therapy for sleep disorders and bring additional information to the next meeting. They did not feel letters would be beneficial at this point, as most physicians are likely already aware of the chronic use.

Montelukast without Asthma Diagnosis: At the August meeting, the Commission reviewed data for members on montelukast without an asthma diagnosis in the previous 12 months medical claims.Given the higher than anticipated utilization of montelukast without an asthma diagnosis, it was recommended to further look at these members and review claims for an inhaled corticosteroid (ICS), and identifying those without an ICS. The COmmisison reviewed the updated data and recommended to send letters to the prescribers of members not also on an ICS, pointing out the *Boxed Warning* due to the risk of serious neuropsychiatric events, asking if patient had an inadequate response or intolerance to alternative therapies, and if therapy with montelukast outweighs the potential risks.

Retrospective DUR Proposals

Concurrent use of GLP-1 RA and DPP-4 Inhibitors: Pam Smith will pull data to identify members with concurrent use of a GLP-1 RA and DPP-4i with 60 or more days of overlap, and bring findings back to the next meeting for discussion. Updated recommendations from the American Diabetes Association indicate combined use of these is not recommended. Use of both agents concurrently does not offer additional significant lowering of A1C and adds to the patient's pill burden and increased medical costs.

High Dose Glucocorticoid without Bisphosphonate: Pam Smith will pull data to identify adults receiving the equivalent daily dosage of prednisone 7.5 mg without an oral bisphosphonate for 90 or more days, and bring findings back to the next meeting. As glucocorticoid therapy is associated with a risk of bone loss, and can also increase fracture risk, letters will likely be sent to providers and a DUR digest article created for this topic.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional topic suggestions.

Prospective DUR

Oral Benzodiazepine Quantity Limits: Data was run to identify the number of unique patients receiving 60 or more units. After review of the data, the Commission would like to focus on members receiving quantities of 120 or more per 30 days over a 6-month span, as that is the highest risk population, specifically focusing on clonazepam, alprazolam, lorazepam, and diazepam, though Dr. Wadle previously suggested limits on all bendodiazepines to prevent possible drift to other agents when these four were further restricted. They also questioned why anyone would need to take these medications four times per day. Pam Smith will re-run the data with the updated parameters, and this will be discussed again at a future meeting.

The Commission took a short break and open session resumed at 11:34 a.m.

Prior Authorization

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

PA Category	Recommended Changes
Antidepressants	Check for upcoming generic releases
Anti-Diabetics, Non-Insulin Agents	Discuss DPP-4 trials due to reduced demonstrated benefit in cardiovascular disease compared to GLP-1 Inhibitors
Anti-Fungal- Oral/Injectable	Adjust criteria to align with recommended treatment duration for onychomycosis of the toes
Biologicals for Hidradenitis Suppurativa	Look at criteria for topical agent trials, especially those listed on the Anti-Acne PA form. Dr. Kruse has had issues getting PA requests approved for this diagnosis.
Cholic Acid (Cholbam)	Allow consultation with a specialist
CNS Stimulants and Atomoxetine	Allow consultation with a specialist under BED criteria, and potentially remove criteria for atomoxetine if PA not due to cost
Crisaborole (Eucrisa)	Discuss reducing to 1 topical corticosteroid trial prior to immunomodulator trial
Deferasirox (Exjade)	Correct to FDA-approved age
Linezolid (Zyvox)	Possibly remove prior authorization, or amend criteria to make it easier to obtain, PICC line issues
Methotrexate Injection	Allow consultation with a specialist

Select Preventative Migraine Treatments: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for select preventative migraine agents. Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent. Payment will be considered under the following conditions:

1. *Patient has one of the following diagnoses:*
   a. *Chronic Migraine, defined as:*
      i. *≥ 15 headache days per month for a minimum of 3 months; and*
      ii. *≥ 8 migraine headache days per month for a minimum of 3 months; or*
   b. *Episodic Migraine, defined as:*
      i. *4 to 14 migraine days per month for a minimum of 3 months; or*
   c. *Episodic Cluster Headache, defined as:*
      i. *Occurring with a frequency between one attack every other day and 8 attacks per day; and*
      ii. *With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and*
      iii. *Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and*
2. *Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings, and precautions; and*
3. *The requested agent will not be used in combination with another CGRP inhibitor for the preventative treatment of migraine; and*
4. *Patient has been evaluated for and does not have medication overuse headache; and*
5. *For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e., anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or*
6. *For Episodic Cluster Headache, patient has documentation of*
   a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine,*

lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and

b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*

7. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

Initial requests will be approved for 3 months. Additional PAs will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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

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

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

Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). 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. *Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and*
7. *If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and*
8. *Patient has been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as the SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools and*

the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C); and

9. *Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drugs and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling; and*
10. *HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and*
11. *FDA approved pediatric formulations of HCV DAAs and DAA approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines including for indication and age; 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 DAA; and*
14. *Documentation is provided for patients who are ineligible to receive ribavirin; and*
15. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved; and*
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 DAAs.*

Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:

1. *Patient must meet all criteria for treatment approval above; and*
2. *Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and*

3. *The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and*
4. *Patient has not been previously treated with and failed the requested DAA therapy; and*
5. *Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.*

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

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

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis when the following conditions are met:

1. *Patient meets the FDA approved age for indication; and*
2. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, 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, at a maximally tolerated dose, with methotrexate; and*
        ii. *A documented trial and inadequate response to one preferred TNF inhibitor; OR*
    b. *Psoriatic arthritis; with*
        i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*

ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR

c. Moderately to severely active ulcerative colitis; with

i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and

ii. A documented trial and inadequate response with a preferred TNF inhibitor; and

iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR

d. Polyarticular Course Juvenile Idiopathic Arthritis; with

i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and

ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

iii. A documented trial and inadequate response with a preferred TNF inhibitor.

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

Chuck Wadle motioned to accept the criteria as amended, and Jason Kruse and Kellen Ludvigson both seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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

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

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and*
2. *Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); with*
    a. *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; or*
3. *Patient has a diagnosis of moderate to severe plaque psoriasis; with*
    a. *Documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; or*
4. *Patient has a diagnosis of Behçet disease; with*
    a. *Documentation of active oral ulcers associated with Behçet disease; and*
    b. *Documentation of a previous trial and inadequate response, at a*

therapeutic dose, to colchicine.

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

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

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

Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling, including age, indication, dosing, and contraindications. 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); with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (hydroxycholoroquine, sulfasalazine, or leflunomide may be used if methotrexate is contraindicated) or*
4. *Patient has a diagnosis of moderate to severe psoriatic arthritis; with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
5. *Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis; with*
    a. *Documentation of a trial and inadequate response to intraarticular glucocorticoid injections and methotrexate at a maximally tolerated dose (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 lV 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.

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

Triheptanoin (Dojolvi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for triheptanoin (Dojolvi). Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings, and precautions; and*
2. *Patient has a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD), with supporting documentation of gene mutation(s) associated with LC-FAOD (LC-FAODs include: CPT I, CACT, CPT II, VLCAD, TFP, LCHAD); and*
3. *Patient will not be using another medium chain triglyceride (MCT) product; and*
4. *Documentation of patient's daily caloric intake (DCI) is provided; and*
5. *Patient's target daily dosage is provided as a percentage of the patient's total daily prescribed DCI, not to exceed 35%; and*
6. *Is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic disease specialist.*

If the criteria for coverage are met, initial requests will be approved for four months. Additional authorizations will be considered upon documentation of a positive clinical response to therapy.

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

Baclofen Oral Solution (Ozobax): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for baclofen oral solution (Ozobax). Payment for a non-preferred agent will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and*
2. *Patient meets the FDA approved age; and*
3. *Documentation of a patient-specific, clinically significant reason (beyond convenience) why the member cannot use baclofen oral tablets, even when*

tablets are crushed and sprinkled on soft food or liquid. Presence of a nasogastric (NG) tube/J-tube alone are not reasons for approval; and

4. *Request does not exceed the maximum dosage of 80mg daily.*

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

Topical Acne and Rosacea Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered under the following conditions:

1. *Documentation of diagnosis; and*
2. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and*
3. *Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and*
4. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and*
5. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and*
6. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and*
7. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

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.

Omalizumab (Xolair) Prefilled Syringe: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe. Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit. Payment for omalizumab (Xolair)

prefilled syringe will be considered for FDA approved and compendia indications under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and*
3. *The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and*
4. *Dose follows the FDA approved dosing for indication; and*
5. *Prescriber is an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist; and*
6. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and*
7. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

<u>Moderate to Severe Persistent Asthma</u>

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
    b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
    b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and*
4. *History of positive skin or RAST test to a perennial aeroallergen; and*
5. *Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

Chronic Idiopathic Urticaria

1. *Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and*
2. *Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
3. *Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and*
4. *Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
5. *Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.

Nasal Polyps

1. *Patient has a diagnosis of nasal polyps; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 1500 IU/mL; and*
3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; and*
4. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
5. *Will be used concurrently with a nasal corticosteroid; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

If criteria for coverage are met, the initial authorization will be given for 24 weeks to assess the need for continued therapy. Requests for continuation of therapy

will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.

The required trials may be overridden when documented evidence is provided that 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.

Vericiguat (Verquvo): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for vericiguat (Verquvo). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and*
2. *Patient meets one of the following:*
    a. *Recent hospitalization for heart failure (within the last 6 months); or*
    b. *Recent need for outpatient intravenous diuretics (within the last 3 months); and*
3. *Patient is within the FDA labeled age for indication; and*
4. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and*
5. *Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and*
6. *Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:*
    a. *Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and*
    b. *Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and*
7. *Is dosed based on FDA approved dosing; and*
8. *Initial requests for Verquvo 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.*

The required trials may be overridden when documented evidence is provided that 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.

Viloxazine (Qelbree): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for viloxazine (Qelbree). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and*
2. *Patient is between 6 and 17 years of age; and*
3. *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) and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and*
5. *Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and*
6. *Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and*
7. *Is dosed based on FDA approved dosing, and dose does not exceed 400 mg per day; and*
8. *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.*

The required trials may be overridden when documented evidence is provided that 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.

Non-Biologic Agents for Ulcerative Colitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for select non-biologicals for ulcerative colitis (UC). Payment for non-preferred select non-biologics for UC may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of moderately to severely active ulcerative colitis (UC) and*
2. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and*
3. *A documented trial and inadequate response to two preferred conventional therapies (immunomodulators) including aminosalicylates and azathioprine/6-mercaptopurine; and*

4. *A documented trial and inadequate response with a preferred biological DMARD; and*
5. *Will not be taken concomitantly with immunomodulators or biologic therapies.*

The required trials may be overridden when documented evidence is provided that 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.

Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for oral gonadotropin-releasing hormone (GnRH) antagonists. Payment for non-preferred oral GnRH antagonists may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent. Payment will be considered for patients when the following is met:

1. *Pregnancy has been ruled out; and*
2. *Patient does not have osteoporosis; and*
3. *Request adheres to all FDA approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
4. *Requests for elagolix (Orilissa) will be considered under the following conditions:*
    a. *Patient has a diagnosis of moderate to severe pain associated with endometriosis; and*
    b. *Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and*
    c. *Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.*
    d. *Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.*
    e. *Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose; or*
5. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) or relugolix, estradiol, norethindrone acetate (Myfembree) will be considered under the following conditions:*
    a. *Patient is premenopausal; and*
    b. *Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and*

c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*
e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
f. *Requests will be considered for a maximum of 24 months treatment.*

The required trials may be overridden when documented evidence is provided that 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 initial review of DUR Digest Volume 34, Number 1.

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

At 1:03, Kellen Ludvigson motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for February 2, 2022, location to be determined.