Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 3, 2022

Attendees:

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

Welcome & Introductions

As the Commission was without a chairperson and vice chairperson due to Brett Faine and Kellen Ludvigson's last meeting in May, Pam Smith called the meeting to order at 9:33 a.m. Due to the current federal state of emergency, continually fluctuating numbers of coronavirus cases in various counties, the need for stability and pre-planning for the public, and due to increased workload of our members directly related to the COVID-19 pandemic, the committee finds that it is impossible/impractical to meet in person for the August 3, 2022 meeting and that it must be held electronically. The minutes from the May 4, 2022, meeting were reviewed. Melissa Klotz motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting and a letter from the P&T Committee requesting development of prior authorization criteria for Adbry and Opzelura were also reviewed. Jason Kruse nominated Melissa Klotz for chairperson, and Melissa Klotz then nominated Jason Kruse for chairperson, as well. Jason Kruse agreed to be vice-chairperson, and Melissa Klotz then agreed to be chairperson. Chuck Wadle motioned to make Melissa Klotz chairperson and Jason Kruse vice-chairperson. Jason Wilbur seconded, and all members in attendance were in favor of the motion. Members were also asked to complete their annual conflict of interest disclosures.

IME Pharmacy Update

The final July 2022 cost of dispensing report is available on the reimbursement section of the website. The report showed the mean cost of dispensing as $10.97 per prescription for all pharmacies including specialty, and $10.18 for all non-specialty pharmacies. The current dispensing fee of $10.38 will remain in place until additional state funding is appropriated in the next Iowa legislative session, and a state plan amendment would also have to be submitted to CMS for approval. Any change would be prospective following approval.

Prevalence Report Summaries

Amerigroup*:* Lisa Todd provided an overview for ITC's statistics from March 2022 through May 2022, including: total paid amount ($128,899,388); total prescriptions (1,158,376); and unique users (176,907). 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 and 4 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, Caremark Kansas Specialty Pharmacy, Community Walgreens Pharmacy, Caremark Illinois Specialty Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Trulicity, Vraylar, and Trikafta. Sertraline hcl had the highest prescription count, followed by: omeprazole, trazodone hcl, escitalopram, and fluoxetine.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from March 2022 through May 2022, including: total paid amount ($87,114,575.82); total prescriptions (811,170); and unique users (131,310). 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, 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, Unity Point at Home, Caremark Kansas Specialty Pharmacy, Nucara Specialty, and CVS. The top 5 therapeutic classes by paid amount were: Anti-TNF-alpha-Monoclonal Antibodies; Sympathomimetics; Insulin; Incretin Mimetic Agents (GLP-1 Receptor Agonists); 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, Trulicity, Vraylar, Vyvanse, and Trikafta, while sertraline, omeprazole, trazodone, amoxicillin, and atorvastatin and had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2022 through May 2022, including: total amount paid ($2,357,974), unique users (3,685); cost per user ($639.88), number of total prescriptions dispensed (21,855); and percent generic (88.2%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Muscular Dystrophy Agents; and Antidepressants – Selected SSRIs. 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: Humira Pen, Evrysdi, Biktarvy, Vyvanse, and Enbrel Sureclick. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, sertraline hcl, escitalopram, and omeprazole.

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 $ 218,368,938 was spent in total for 311,902 unique users who had 1,991,401 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira Pen was the most expensive drug for FFS and both MCO plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans, with sertraline in the top spot for both MCOs and third for FFS. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 5,189. 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.

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
Susie Moroney	Novartis	Vijoice
Mariola Vazquez	Leo Pharma	Adbry
James Bauman	Pfizer	Cibinqo & Eucrisa (Atopic Dermatitis)

Written Provider Comments Received: None

Written Manufacturer Comments Received: Humira

Retrospective DUR Data Presentations

High Dose Opioid (> 90 MME) without Opioid Reversal Agent: The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires states have an automated review process in place to identify patients at high risk of opioid overdose without a reversal agent. Current prior authorization criteria for High Dose Opioids, defined as 90 morphine milligram equivalents (MME) per day, requires the prescriber to attest a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose has been provided. As requested at the May meeting, data was pulled to identify members with a claim(s) for an opioid ≥ 90 MME during the month of April 2022, with a look-back at the prior 12, 18 and 24 months to check for naloxone prescriptions in their claim histories, due to the 36-month shelf life. The Commission was also provided a report for the total number of naloxone claims per quarter during the look-back period. The High Dose Opioids PA criteria will be updated to require patients have a paid claim for or documentation of receiving an opioid reversal agent (i.e. documentation from Iowa PMP of dispensation) within a certain time period. Updated criteria will then be brought back for review and approval. Additionally, letters will be sent to prescribers regarding members that do not have an opioid reversal agent in their claims history pointing out the patient's higher risk of opioid overdose due to daily MME, recommending co-prescribing or co-dispensing

of a preferred opioid reversal agent and encouraging the member to have it on-hand for an emergency situation. This may also appear in a future DUR Digest.

Opioid plus Buprenorphine for OUD: The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) requires states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify patients prescribed an opioid after being prescribed one or more drugs used for medication assisted treatment (MAT). Currently, pharmacies receive a ProDUR soft edit regarding the combination. As requested at the May meeting, data was pulled to identify members with concurrent buprenorphine, indicated for the treatment of opioid use disorder (OUD), and an opioid in pharmacy claims, taking days' supply into account due to possible post-operative opioid use. Upon review of the findings, the Commission would like to hold this topic for further future review and take no immediate action. Pam Smith will consult with the MCOs to develop a plan to manage the data and monitor usage, then bring any issues back to the commission if merited.

Retrospective DUR Proposals

LABA without ICS in Asthma: LABAs as monotherapy increase the risk of asthma-related death and should be prescribed only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on an inhaled corticosteroid (ICS). Salmeterol xinafoate inhalation powder (Serevent Diskus) is the only single-ingredient LABA indicated for the treatment of asthma. Pam Smith will run data to identify members with an asthma diagnosis and a claim for Serevent Diskus in their pharmacy claims from May through July 2022 that do not have a claim for an ICS. Results will be brought back to the next meeting.

Concurrent Use of Opioids and Sedatives: Opioids carry an FDA boxed warning of increased risk of respiratory and CNS depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives. Currently, there are no hard POS edits to stop this combination or an automated retrospective claims review process for concurrent use of an opioid and sedative. Questions related to this issue appeared in the FFY21 CMS DUR Survey. Pam Smith will research to find more information regarding increased harm with specific drug combinations, along with a more complete list of sedatives that would be included in the claims data search. Findings will be brought back to the next meeting.

Duplicate Therapy with Opioids – Discussion

Though letters were sent to prescribers a year ago, there has been little impact thus far, with 771 unique members across all plans still showing duplicate therapy for 30 days or more in their claim histories between April and June 2022. Pam Smith will research how other states are addressing this issue and bring additional information for specific options back to a future meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional topic suggestions.

Prospective DUR

Initial Days Supply Limit – Benzodiazepines: At the May meeting, the DUR Commission made a recommendation to implement a 7-day initial limit on all benzodiazepines for new users. The ProDUR point-of-sale (POS) edit would limit to an initial 7 days' supply for a benzodiazepine if the requested benzodiazepine is not found in pharmacy claims in the preceding 90 days. Exceptions to this edit include nasal and rectal diazepam, nasal midazolam and clobazam. Prior authorization would be required for quantities exceeding 7 days and the Commission will develop PA criteria at a future meeting. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

Benzodiazepine Cumulative Quantity Limit: At the May meeting, the DUR Commission made a recommendation to implement a cumulative quantity limit of 4 units per day across the benzodiazepine class for solid oral dosage forms. The limit chart will include a statement, such as "Benzodiazepines are subject to a cumulative quantity limit of 4 units per day, unless otherwise indicated on the chart." No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

Short-Acting Beta Agonist Quantity Limit: At the May meeting, the Commission voted to implement a quantity limit of 2 canisters per 30 days on SABAs, similar to other states, and to send letters to the providers of members with overuse in their claim histories. No further changes were recommended. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

The Commission took a short break and open session resumed at 11:18 a.m.

Prior Authorization

Sedative/Hypnotics, Non-Benzodiazepine: The Commission reviewed the proposed prior authorization criteria as follows:

Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *A diagnosis of insomnia; and*
3. *Medications with a side effect of insomnia are decreased in dose, changed to a short acting product, and/or discontinued; and*
4. *Enforcement of good sleep hygiene is documented; and*

5. *All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses; and*
6. *Will not be used concurrently with a benzodiazepine sedative/hypnotic agent.*
7. *In addition to the above criteria, requests for an orexin receptor antagonist will require documentation of a trial and therapy failure with at least one non-preferred agent prior to consideration of coverage.*
8. *Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.*

The required trials may be overridden when documented evidence is provided that 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 recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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

Prior authorization is required for vericiguat (Verquvo). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and*
3. *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*
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*

c. *Mineralocorticoid receptor antagonist (MRA); and*
d. *Sodium-glucose cotransporter 2 inhibitor (SGLT2i) indicated for the treatment of heart failure (empagliflozin or dapagliflozin); and*

7. *Initial requests for vericiguat (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.

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

Maralixibat (Livmarli): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for maralixibat (Livmarli). 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 for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 mutation or deletion; and*
3. *Patient has cholestasis with moderate to severe pruritus; and*
4. *Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and*
5. *Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:*
    a. *Ursodeoxycholic acid (ursodiol)*
    b. *Cholestyramine*
    c. *Rifampin; and*
6. *Patient's current weight in kilograms (kg) is provided.*

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

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

PIK3CA-Related Overgrowth Spectrum (PROS) Treatments (Vijoice): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for alpelisib (Vijoice). 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 for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by genetic testing demonstrating a PIK3CA mutation; and*
3. *Patient's condition is severe or life-threatening requiring systemic therapy as determined by treating prescriber; and*
4. *Patient has at least one target lesion identified on imaging.*

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by a reduction in sum of measurable lesion volume assessed across 1 to 3 target lesions.

Jason Kruse motioned to accept the criteria, and Melissa Klotz seconded. All members were in favor. Melissa Klotz then motioned to accept the recommended quantity limits listed below. Rhea Hartley seconded, and this decision was unanimous as well. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

- Quantity limits (per 30 days)
  - 50 mg – 30 tablets
  - 125 mg – 30 tablets (must use combination of 50 mg and 200 mg tablet to obtain 250 mg dose)
  - 200 mg – 30 tablets

Mavacamten (Camzyos): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for mavacamten (Camzyos). 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 for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

2. *Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and*
3. *Patient exhibits symptoms of New York Heart Association (NYHA) class II or III symptoms; and*
4. *Is prescribed by or in consultation with a cardiologist; and*
5. *Patient has a left ventricular ejection fraction (LVEF) ≥ 55%; and*
6. *Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation; and*
7. *Documentation of a previous trial and therapy failure, at a maximally tolerated dose, with all of the following:*
    a. *Non-vasodilating beta-blocker (atenolol, metoprolol, bisoprolol, propranolol); and*
    b. *Non-dihydropyridine calcium channel blocker (verapamil, diltiazem); and*
    c. *Combination therapy with disopyramide plus beta-blocker or disopyramide plus a non-dihydropyridine calcium channel blocker.*

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, including a quantity limit of 30 capsules per 30 days across all strengths. Holly Randleman seconded, and all members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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

Prior authorization is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *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*
    d. *Patient has documentation of a previous trial and therapy failure with a*

topical immunomodulator for a minimum of 4 weeks; and

e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
f. *Patient will continue with skin care regimen and regular use of emollients; or*

4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
    d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. *Two (2) or more exacerbations in the previous year or*
        ii. *Require daily oral corticosteroids for at least 3 days; or*
5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
    a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
    b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
        i. *Nasal corticosteroid spray; and*
        ii. *Oral corticosteroid; or*
6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
    a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
    b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
    d. *Documentation of previous trials and therapy failures with all of the following:*
        i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
        ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and*
        iii. *Dietary therapy; and*
7. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months 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.

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

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

Prior authorization is required for viloxazine (Qelbree). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *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*
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 atomoxetine; and*
5. *Dose does not exceed 400 mg per day for pediatric patients (< 18 years of age) and 600 mg per day for adult patients; and*
6. *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.

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

CNS Stimulants and Atomoxetine: The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the

prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. Payment for CNS stimulants and atomoxetine will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

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. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. Use of an amphetamine agent plus a methylphenidate agent will not be considered for a diagnosis of ADHD.

*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.*

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 Wilbur seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Tasimelteon (Hetlioz): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for tasimelteon (Hetlioz®). Requests will be considered when patient has an FDA approved or compendia indication for the requested drug. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

2. *Patient has a documented diagnosis of:*
    a. *Non-24-Hour Sleep-Wake Disorder (Non-24); and*
        i. *Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and*
        ii. *Patient has a documented trial and therapy failure with ramelteon (Rozerem®); or*
    b. *Sleep disturbances in Smith-Magenis Syndrome (SMS); and*
        i. *Documentation of confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is provided (attach results); and*
        ii. *Patient has a documented trial and therapy failure with at least one other medication used for sleep disturbances; and*
3. *Is prescribed by, or in consultation with a physician who specializes in the treatment of sleep disorders; and*
4. *Will not be used concurrently with other sleep medications.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered under the following conditions:

1. *Patient's use of tasimelteon (Hetlioz®) has been continuous without gaps in treatment; and*
2. *Documentation patient has experienced a positive clinical response to therapy with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, significant decreases in daytime sleep, and/or nighttime sleep quality.*

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 (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 for the requested drug when the following conditions are met:

1. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and*
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); 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 (tofacitinib, upadacitinib); 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 (tofacitinib, upadacitinib); 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 (tofacitinib); 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; OR*
e. *Ankylosing spondylitis (tofacitinib, upadacitinib); with*
   i. *A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and*
   ii. *A documented trial and inadequate response with at least one preferred TNF inhibitor; OR*
f. *Atopic dermatitis; with*
   i. *Documentation patient has failed to respond to good skin care and regular use of emollients; and*
   ii. *A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
   iii. *A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
   iv. *For mild to moderate atopic dermatitis (ruxolitinib)*

a. *A documented trial and therapy failure with crisaborole; and*
b. *Affected area is less than 20% of body surface area (BSA); and*
c. *Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or*

v. *For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):*
   a. *A documented trial and therapy failure with cyclosporine or azathioprine; and*
   b. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.*

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.

Drug	Proposed Quantity Limit per 30 Days (unless otherwise noted)
Cibinqo 50 mg, 100 mg, 100 mg tablet	30
Olumiant 1 mg, 2 mg tablet	30
Opzelura 1.5% cream	240 g (4 tubes)
Rinvoq 15 mg, 30 mg tablet	30
Rinvoq 45 mg tablet	28 per 28 days
Xeljanz 5 mg, 10 mg tablet	60
Xeljanz XR 11 mg, 22 mg tablet	30

Tralokinumab-ldrm (Adbry): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for tralokinumab-ldrm (Adbry). 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 for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of moderate to severe atopic dermatitis; 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 at least 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 preferred 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.*

If criteria for coverage are met, initial authorization 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 and documentation patient will continue with skin care regimen and regular use of emollients.

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.

Crisaborole (Eucrisa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for Eucrisa (crisaborole). Payment will be considered when patient has an FDA approved or compendia indication for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of mild to moderate atopic dermatitis; and*
3. *Patient has failed to respond to good skin care and regular use of emollients; and*
4. *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*
5. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
6. *Patient will continue with skin care regimen and regular use of emollients.*
7. *Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.*

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.

Extended-Release Formulations: The Commission reviewed the prior authorization criteria as follows:

Payment for a non-preferred extended release formulation will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Previous trial and therapy failure with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
3. *Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.*

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-Preferred Drug: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be considered for an FDA approved or compendia indicated diagnosis only for cases in which there is documentation of previous trial and therapy failure with the preferred agent(s), unless evidence is provided that use of these agents would be medically contraindicated. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations.

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 Hidradenitis Suppurativa: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals FDA approved or compendia indicated for the treatment of Hidradenitis Suppurativa (HS). Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred biologic agent. Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and*

2. *Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.*

Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and*
3. *Patient has at least three (3) abscesses or inflammatory nodules; and*
4. *Patient has documentation of adequate trials and therapy failures with the following:*
    a. *Daily treatment with topical clindamycin;*
    b. *Oral clindamycin plus rifampin;*
    c. *Maintenance therapy with a preferred tetracycline*

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

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 currently recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration. However, Jason Kruse would like more information on the study that was referenced in the public comment presented. Pam Smith will reach out to the manufacturer and provide this to the commission once received.

Ophthalmic Agents for Presbyopia: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for ophthalmic agents indicated for presbyopia. Requests will be considered when patient has an FDA approved or compendia indication for the requested drug. Payment for a non-preferred agent will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a documented diagnosis of presbyopia; and*
3. *Patient is aged 40 to 55 years old at start of therapy; and*
4. *Is prescribed by or in consultation with an ophthalmologist or optometrist; and*
5. *Patient has documentation of a therapeutic failure with corrective lenses (eyeglasses or contact lenses), unless contraindicated or clinically significant intolerance.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered under the following conditions:

1. *Patient has a documented improvement in presbyopia defined as the patient gained 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA); and*

Patient is not experiencing adverse effects from the drug.

No further changes were currently 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 DUR Digest Volume 34, Number 2.

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

At 12:25, Jason Kruse motioned to adjourn, and Melissa Klotz and John Ellis both seconded. All in attendance agreed.

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