Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 6, 2024

Attendees:

Commission Members Present
Voting: Jason Kruse, D.O.; Holly Randleman, Pharm.D.; Caitlin Reinking, Pharm.D.; Chuck Wadle, D.O.; Bryon Schaeffer, MD, FAAFP; Rhea Hartley, M.D. Non-Voting: Abby Cate, Pharm.D., Iowa Department of Health and Human Services; and Emily Rogers, Pharm.D., Iowa Total Care.

Commission Members Absent
Voting: Melissa Klotz, Pharm.D.; and Jennifer Johnson, Pharm.D.

Staff in Attendance
Pam Smith, R.Ph.

Guests in Attendance
Erin Halverson, R.Ph., Iowa Medicaid; Gina Kuebler, R.Ph., Iowa Medicaid; Melissa Biddle, Iowa Medicaid; Darian Forcier, Iowa Department of Health and Human Services; Candace Jordan, Pharm.D., Molina Healthcare; and Jordan Thoman, Pharm.D., Wellpoint Iowa.

Welcome & Introductions

Vice-Chairperson Jason Kruse called the virtual meeting to order at 9:30 a.m. The minutes from the August 7, 2024, meeting were reviewed. Rhea Hartley motioned to accept them, and Chuck Wadle seconded. All members were in favor. The recommendation letter sent to DHHS after the last DUR meeting was also reviewed.

Iowa Medicaid Pharmacy Update

Elizabeth Matney resigned as Medicaid Director effective November 1st. While a nationwide search is conducted, HHS Director Kelly Garcia is currently overseeing the Medicaid division, with the help of the two Deputy Medicaid Directors. A cost of dispensing survey was sent out to providers in May, with responses due back August 14, 2024. Results are being reviewed by HHS leadership, with the intent that the dispensing fee increase be added into the HHS budget request for the next legislative session. Once finalized, the report will be published on the state's rate setting vendor Myers & Stauffer's web page and provided to the committee. Dr. Bryon Schaeffer was welcomed as a new commission member, and another new member, Jennifer Johnson, Pharm.D., was unable to attend this meeting, but will be at the next meeting in February. At the last legislative session, Iowa Code Chapter 21 was modified to require that governmental bodies provide hybrid or virtual meeting options for the members of the governmental body to participate in official meetings. Due to this change, DUR meetings going forward will either be 100% virtual or hybrid, pending availability of a meeting space that allows for a hybrid setup. Guests in attendance will be allowed to attend and provide public

comment virtually, as well. The MCOs will have a larger role in DUR initiatives going forward, taking turns providing pitch ideas to HHS and the DUR Coordinator for each meeting, and presenting their retrospective study suggestions to the commission if approved. The DUR contact email has been updated to pba_iadur@optum.com as shown on the agenda, and anything sent to the old address is no longer forwarding. HHS and Medicaid staff addresses have also changed to a firstname.lastname@hhs.iowa.gov format rather than the previous name@dhs.state.ia.us, though those are set to forward for six months. The DUR website is still down following the Change Healthcare cyber-attack, but is anticipated to be back up within the next few months, and should keep the same address www.iadur.org.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from June 2024 through August 2024, including: total paid amount ($73,532,635.99); total prescriptions (663,331); and unique users (89,052). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, University of Iowa Health Care, Right Dose Pharmacy, two Walgreens locations, and Broadlawns made up the top five. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top five pharmacies being: University of Iowa Health Care, Walgreens Community Pharmacy, Caremark Kansas Specialty Pharmacy, Unity Point at Home, and Accredo Health Group. The top five therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Dermatologicals; and Antiasthmatic and Bronchodilator Agents. The top five classes by prescription count were: Antidepressants; Anticonvulsants; Antihypertensives; Antidiabetics; and Antiasthmatic and Bronchodilator Agents. The most expensive drugs were Humira Pen, Ozempic, Vraylar, Trikafta, and Dupixent, while atorvastatin, sertraline, omeprazole, levothyroxine, and albuterol had the top five prescription counts.

Molina Healthcare*:* Candace Jordan provided an overview for Molina's statistics from June 2024 through August 2024, including: total paid amount ($53,028,906.45); total prescriptions (503,230); and unique users (76,044). 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, three Walgreens locations, and Broadlawns made up the top five. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top five pharmacies being: University of Iowa Ambulatory Care Pharmacy, Caremark Specialty Pharmacy, Community Walgreens Pharmacy, CVS Specialty Pharmacy, and Unity Point at Home. The top five therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Dermatologicals; Analgesics – Anti-inflammatory; and Antivirals. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antihypertensives, Antidiabetics, and Antiasthmatic and Bronchodilator Agents. Ozempic was the most expensive medication, followed by Humira Pen, Dupixent, Vraylar, and Biktarvy. Atorvastatin had the highest prescription count, followed by: sertraline, omeprazole, lisinopril, and levothyroxine.

***Wellpoint Iowa**:* Jordan Thoman provided an overview for Wellpoint's statistics from June 2024 through August 2024, including: total paid amount ($97,248,376); total prescriptions (811,300); and unique users (98,025). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, University of Iowa Health Care, three Walgreens locations, and Right Dose Pharmacy made up the top five. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top five pharmacies being: University of Iowa Health Care, CVS Specialty Pharmacy, Community Walgreens Pharmacy, Caremark Kansas Specialty Pharmacy, and Unity Point at Home. Similar to previous reports, the top five therapeutics classes by paid amount were: Antidiabetics; Dermatologicals; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; and ADHD/Anti-Narcolepsy. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antihypertensives, ADHD/Anti-Narcolepsy, and Antiasthmatic and Bronchodilator Agents. Ozempic was the most expensive medication, followed by: Humira (CF) Pen, Vraylar, Trikafta, and Stelara. Omeprazole had the highest prescription count, followed by: atorvastatin, sertraline, levothyroxine, and escitalopram.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2024 through August 2024, including: total amount paid ($2,624,682), unique users (3,760); cost per user ($698.05), number of total prescriptions dispensed (23,798); and percent generic (90.4%). The top five therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Dermatologicals; Antivirals; and Antiasthmatic and Bronchodilator Agents. The highest prescription count was from the Antidepressants category, with Anticonvulsants in second place, followed by: Antihypertensives; ADHD/Anti-Narcolepsy; and Antidiabetics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Ozempic, Biktarvy, Taltz, Vraylar, and Humira Pen. The five drugs with the highest prescription counts were: sertraline, trazodone, albuterol, atorvastatin, 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 $226,434,600 was spent in total for 2,001,659 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Antidiabetics was the top therapeutic class by paid amount for FFS and all three MCO plans, and Antidepressants the top class by prescription count. Ozempic was the most expensive drug for FFS, Wellpoint, and Molina Healthcare, and in second place for Iowa Total Care. Humira Pen, the most expensive on Iowa Total Care's list, was second for Wellpoint and Molina Healthcare, and fifth for FFS. The top 25 drugs by prescription count were also similar across all MCO plans, with omeprazole, sertraline, and atorvastatin within the top three spots. For FFS, sertraline was in first place, atorvastatin fourth, and omeprazole fifth.

Public Comment

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

Name	Representing	Drug/Topic
Lynda Finch	Biogen	Zurzuvae
Amy Hornig	AbbVie	Select Preventative Migraine Treatments
Charlotte Wincott	Axsome	Auvelity
Valerie Ng	Leo Pharma	Adbry

Written Provider Comments Received: Livdelzi

Written Manufacturer Comments Received: None

Retrospective DUR Data Presentations

Stimulant Medication Utilization without Supporting Diagnosis:

At the last meeting, Dr. Kruse suggested searching for claims billed from the same tax ID, in case a member had visits at different office locations or multiple prescribers in the same practice not reflected on their pharmacy claims. However, that would be difficult with the current systems, and not an option at this point. Updated data presented, removing members where Medicaid is secondary and additional ICD-10 diagnosis codes were included.

In reviewing the new data, Dr. Kruse noticed that Iowa Total Care had a much lower 2.4% of members without a supporting diagnosis, versus 9.4% for Molina, 17% for Wellpoint, and 16.1% for FFS. Emily Rogers is not aware of additional follow-up efforts through home care visits or prior authorization requests listing new diagnoses updating member problem lists, etc. that would have attributed to the difference, but she will investigate. Pam Smith noted that there was no provider identified in the top 10 across all four plans. The highest number of members for a single provider was 44, and next at 41. Both were MDs and in the psychiatric field. For all plans, the majority of the claims are being prescribed by mental health providers. The Commission wants to hold off on additional action until Emily Rogers can confirm that the ITC data was not pulled differently than the rest, or she identifies additional actions that could be replicated by the other plans to bring down their percentages of members without a supporting diagnosis. Findings will be brought back to the next meeting in February; data will not be updated until discussed.

Monitoring Prescribing of Antipsychotic Medications in Adults:

As requested at the last meeting, data was run to identify the number of members, ≥ 18 years old, on three or more chemically distinct antipsychotics (first- and second-generation antipsychotics) for greater than 60 days over a 90-day period.

Across all plans, only 83 members were identified as using 3 or more chemically distinct antipsychotics concurrently. Letters will be sent to their prescribers, pointing out the lack of evidence for the safety and efficacy of using multiple antipsychotic medications and asking if the use of multiple antipsychotics outweighs the risks. Prescribers will also be

asked if the member is taking low-dose quetiapine as a hypnotic and suggest prescribing an alternative medication.

Triple Therapy – Opioid, Benzodiazepine, and Muscle Relaxant:
As requested at the last meeting, data was pulled to identify members with concurrent therapy of at least 30 days, of an opioid, benzodiazepine, and muscle relaxant (and identifying a subset of members where carisoprodol is the muscle relaxant) over a 90 day period. Members were broken out by < 18 and ≥ 18 years of age.

Pam Smith noted that zero members 0 to 17 years of age had been identified. Per Commission request, letters will be sent to prescribers of the adult members identified with an opioid + benzodiazepine + muscle relaxant for 30+ days and ask if the benefits outweigh the risks of triple therapy and if one or more drugs could be discontinued. Letters will also be sent to prescribers of members identified with an opioid + benzodiazepine + carisoprodol and point out the risk of triple therapy, that it has been shown to have limited efficacy in the relief of acute pain associated with musculoskeletal conditions, and the effectiveness of carisoprodol has not been established for use longer than 2 to 3 weeks. Pam Smith will discuss possible member outreach options with the MCOs and bring findings back to the February meeting.

Retrospective DUR Proposals
72-Hour Emergency Override Utilization Review:
Per 42 U.S. Code § 1396r-8(d)(5)(B) state must make arrangements that permit pharmacist to dispense at least a 72-hour supply of any covered drug in an emergency situation. According to the Iowa Medicaid Prescribed Drugs Provider Manual, the provision for a 72-hour supply can be used in an emergency situation only one time per member, per drug. A 7-day override of the prior authorization requirement will be allowed while the prescriber is requesting prior authorization for certain mental health drugs. A 72-hour emergency supply may not be available for medications intended for a short duration of therapy.

Dr. Kruse was curious if a lapse in prior authorization coverage dates created the need for an override, and if so, if providers could be contacted. He also asked how many drugs were continued after the 3-day override allowance or had an approved prior authorization after the 3 days. Molina thinks some medications are being submitted with the override code in order to bypass the PA requirements and/or to not have to change to preferred formulations. The Commission is interested in pursuing this focus study presented by Candace Jordan from Molina, with the data pull criteria below, to be presented at the February meeting:

- Time Period: November 1, 2023, to October 31, 2024
- Data to include:
    - Find all claims where the emergency 72-hour override (or 7-day override) process was used for a paid claim.
- Report:
    - Total number of claims with the 72-hour emergency override code
    - Top 50 drugs where the 72-hour override code was used

- Top 50 pharmacies that submitted a claim with the 72-hour override code
- Total number of pharmacies that use the 72-hour override code
- Number of non-preferred overrides vs preferred overrides

Concurrent Use of GLP-1 Receptor Agonist and DPP-4 Inhibitor:
Current American Diabetes Association (ADA) recommendations do not recommend combined use of a GLP-1 RA and DPP-4i due to overlapping mechanisms of action.

The Commission is interested in pursuing this focus study, with the data pull criteria below:

- Members with concurrent use of a GLP-1 RA and DPP-4i
- ≥ 60 days overlap
- Time period: July through September 2024

Pam Smith will bring findings to the next meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

- Top 10 hospital admission and/or discharge diagnoses, especially relating to chronic condition medications. Pam Smith will discuss the specifics and possible parameters for reporting of this with Holly Randleman, who had brought it up at the April meeting. There were no additional recommendations.

The Commission took a short break and open session resumed at 11:15 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
Adenosine Triphosphate-Citrate Lypase (ACL) Inhibitors	Review based on updates to drug label.
CNS Stimulants and Atomoxetine	Remove PA requirement for atomoxetine?
Direct Oral Anticoagulants	Remove criteria? Few PAs for NP agents
Fentanyl, Short Acting Products	Why does this have a 15-day limit instead of 7 like other drugs?
Letermovir (Prevymis)	Update age criteria
Lidocaine Patch (Lidoderm)	Possible for patient not on opioids?
Narcotic Agonist-Antagonist Nasal Sprays	Reference other newer agents along with triptans.
PCSK9 Inhibitors	Make sure all 470-5399 forms posted by FFS and HHS have updated language removing specialist requirement. Also, review criteria based on current label to determine if updates are needed (similar to ACL inhibitors)
Peanut Allergen Powder-dnfp (Palforzia)	New indication for 1-3 year olds.

Sodium Oxybate Products	Develop PA criteria for idiopathic hypersomnia and clean up current criteria.
Voxelotor (Oxbryta)	PA will be removed due to FDA withdrawl from market.

Dr. Kruse stated PA forms across plans were not consistent and some still contained language regarding specialist requirement for treatment inexperienced patients. PA forms were found doing a Google search. This issue will be reviewed internally and updated.

Ensifentrine (Ohtuvayre): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for ensifentrine (Ohtuvayre). 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 COPD when all of the following are met:*
    a. *FEV1/FVC ratio < 0.7; and*
    b. *Post-bronchodilator FEV1 % predicted of 30% to 79%; and*
    c. *Modified Medical Research Council (mMRC) dyspnea score of ≥ 2 or a COPD Assessment Test (CAT) score ≥ 10; and*
3. *Patient is adherent with COPD treatments, meeting one of the following criteria:*
    a. *The patient has a blood eosinophil of ≥ 100 and has experienced an exacerbation while adherent to a current 60-day trial of a triple combination regimen consisting of a long-acting beta agonist (LABA), a long-acting muscarinic antagonist (LAMA), and an inhaled corticosteroid (ICS); or*
    b. *The patient has a blood eosinophil of < 100 and has experienced an exacerbation while adherent to a current 60-day trial of a dual combination regimen consisting of a LABA and LAMA; and*
4. *Dual or triple combination regimen will be continued in combination with ensifentrine (Ohtuvayre).*

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

If the criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Additional authorizations will be considered upon

documentation of a response to treatment (e.g. improved dyspnea, decreased exacerbations) and patient continues their dual or triple combination regimen.

Rhea Hartley motioned to accept the criteria as amended, and Holly Randleman 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.

Select Preventative Migraine Treatments: The Commission reviewed the proposed 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 headaches 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 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.*

6. *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.

Holly Randleman motioned to accept the criteria as amended, 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.

Topical Roflumilast (Zoryve): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for topical roflumilast (Zoryve). Payment 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. *Patient has a diagnosis of plaque psoriasis with involvement estimated to affect ≤ 20% of the body surface area; and*
   a. *Request is for roflumilast 0.3% cream; and*
   b. *Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred medium to high potency topical corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks; or*
3. *Patient has a diagnosis of seborrheic dermatitis; and*
   a. *Request is for roflumilast 0.3% foam; and*
   b. *Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred topical corticosteroid (scalp - medium to high potency or nonscalp –*

low-potency) and preferred topical antifungal for a minimum of 4 consecutive weeks; or

4. *Patient has a diagnosis of mild to moderate atopic dermatitis; and*
    a. *Request is for roflumilast 0.15% cream; 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; or*
    d. *Patient has documentation of an adequate trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks;*

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

Rhea Hartley motioned to accept the criteria as amended, and Holly Randleman 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.

Vonoprazan (Voquezna): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for vonoprazan (Voquezna), Voquezna Dual Pak, and Voquezna Triple Pak. 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 healing of erosive esophagitis (attach endoscopy results for initial diagnosis), maintenance of healed erosive esophagitis (attach endoscopy results for initial diagnosis), and relief of heartburn associated with non-erosive gastroesophageal reflux disease (GERD); and*
    a. *Documentation of an 8-week trial and therapy failure, based on ongoing symptoms, with two preferred PPIs, each twice-daily dosing; or*
3. *Patient has an active Helicobacter pylori (H. pylori) infection (attach documentation); and*
    a. *Patient has documentation of a recent trial and therapy failure with a preferred agent(s) for the treatment of H. pylori infection; and*
    b. *Request is for the triple pak or dual pak.*

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

If the criteria for coverage are met, requests will be evaluated for the dosage and duration of therapy according to the indications specified on the FDA approved label.

Holly Randleman motioned to accept the criteria as amended, 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.

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

Prior authorization (PA) 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. *Patient has failed to respond to good skin care and regular use of emollients; and*
    b. *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*
    c. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    d. *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. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and*
    b. *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*
    c. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. *One (1) 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. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    b. *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*
    c. *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; or*
7. *Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and*
    a. *Patient has experienced severe to very severe pruritits, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and*
    b. *Patient has ≥ 20 nodular lesions (attach documentation); and*
    c. *Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; or*
8. *Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype; and*
    a. *Patient has moderate to severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:*
        i. *FEV1/FVC ratio < 0.7, and*
        ii. *FEV1 % predicted between 30% to 79%; and*
    b. *Patient has a minimum blood eosinophil count of 300 cells/mcL, measured within the past 12 months; and*
    c. *Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to:*
        i. *Triple therapy with all of the following treatments:*
            1. *Long-acting muscarinic antagonist/anticholinergic (LAMA); and*
            2. *Long-acting beta agonist (LABA); and*
            3. *Inhaled corticosteroid (ICS); or*
        ii. *Double therapy with all of the following if ICS is contraindicated*
            1. *LABA; and*
            2. *LAMA; and*

d. *Patient has history of at least 2 moderate or 1 severe exacerbation(s) in the previous 12 months despite receiving maximal triple therapy or double therapy (defined above). Moderate exacerbation is defined as patient required treatment with systemic corticosteroids and/or antibiotics and severe exacerbation is defined as hospitalization or observation for over 24 hours in an emergency department or urgent care facility; and*
e. *Patient will continue to receive maintenance therapy (as documented above) concomitantly with dupilumab; and*

9. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD, which will receive an initial authorization of 12 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.

Rhea Hartley motioned to accept the criteria as amended, and Caitlin Reinking 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.

Biologicals for Inflammatory Bowel Disease: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals used for inflammatory bowel disease. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of moderate to severe Crohn's Disease; or*
2. *Patient has a diagnosis of moderate to severe Ulcerative Colitis; and*
3. *Medication will be administered in the patient's home by patient or patient's caregiver.*

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.

Incretin Mimetics for Non-Diabetes Indications: The Commission reviewed the proposed prior authorization criteria and made changes to already voted upon PA criteria based on MCO feedback. Amended criteria are as follows:

Prior authorization (PA) is required for incretin mimetics not otherwise covered by the Anti-Diabetics Non-Insulin Agents PA criteria for covered FDA approved or compendia indications. Payment for excluded medical use(s) (e.g. weight loss), as defined in the Iowa State Plan and Iowa Administrative Code 441 – 78.2(4) will be denied. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient is ≥ 45 years of age; and*
3. *Patient has been screened for and does not have type 1 or type 2 diabetes mellitus (attach current lab results, obtained within 6 months of request, documenting an A1C < 6.5% or a fasting plasma glucose < 126 mg/dL); and*
4. *The requested drug will be used to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in an adult with established cardiovascular disease (CVD) and either obesity or overweight; and*
    a. *Patient has established CVD with history of one of the following (attach chart notes documenting diagnosis):*
        i. *Prior myocardial infarction (MI);*
        ii. *Prior stroke (ischemic or hemorrhagic);*
        iii. *Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; and*
    b. *Patient has a baseline body mass index (BMI) ≥ 27 kg/m^2, obtained within 6 months of request; and*
    c. *Patient has been evaluated for cardiovascular standard of care treatment; and*
    d. *For Wegovy dosing:*
        i. *Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and*
        ii. *Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment; and*
5. *Patient will use medication in combination with a reduced calorie diet and increased physical activity; and*
6. *The requested agent will not be used in combination with other incretin mimetics.*

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

Requests will be considered for initiation and appropriate dosage escalation. Requests for continuation of therapy, once at an established maintenance dose will be considered at 12-month intervals when:

1. *The requested drug will be used to reduce the risk of MACE; and*
    a. *Patient does not have type 1 or type 2 diabetes; and*
    b. *Patient has been evaluated for cardiovascular standard of care treatment; and*
    c. *For Wegovy, a maintenance dose of 1.7 mg or 2.4 mg once weekly is requested; and*
2. *Patient continues to use medication in combination with a reduced calorie diet and increased physical activity; and*
3. *The requested agent will not be used in combination with other incretin mimetics.*

Caitlin Reinking motioned to accept the criteria as amended, and Rhea Hartley seconded. All members were in favor. Due to the changes to already voted upon PA criteria, the recommendations will be sent to the medical/pharmacy associations again for comment and brought back to the next meeting for further discussion.

Janus Kinase Inhibitors: The Commission reviewed the proposed prior authorization criteria, after additional changes were made after the initial review. Updated criteria are 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, excluding requests for the FDA approved indication of alopecia areata, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules 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 with a preferred TNF inhibitor; and*
   ii. *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. *Moderately to severely active Crohn's disease (upadacitinib); with*
   i. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
e. *Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with*
   i. *A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
   ii. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
f. *Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis) (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*
g. *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; or*
   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. *Affected area is less than 20% of body surface area (BSA); and*
      b. *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 a systemic drug product for the treatment of moderate to severe atopic dermatitis including biologics; and*
b. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg; OR*

h. *Nonsegmental vitiligo (ruxolitinib); with*
   i. *A documented trial and inadequate response with a potent topical corticosteroid; or*
   ii. *A documented trial and inadequate response with a topical calcineurin inhibitor; and*
   iii. *The patient's body surface area (BSA) is less than or equal to the affected BSA per FDA approved label, if applicable.*

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, and the minor changes were positive in nature, no motion was necessary. The recommendation will be sent to the Department for consideration.

Maralixibat (Livmarli): The Commission reviewed the proposed 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. *Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS or PFIC; and*
3. *Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 mutation or deletion; and*
   a. *Patient has cholestasis with moderate to severe pruritus; and*
   b. *Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:*
      i. *Ursodeoxycholic acid (ursodiol)*
      ii. *Cholestyramine*
      iii. *Rifampin; or*
4. *Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) demonstrating a gene mutation affiliated with PFIC (i.e., ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B); and*

b. *Genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and*
c. *Patient has moderate to severe pruritus associated with PFIC; and*

5. *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.

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): The Commission reviewed the proposed 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. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations. Payment for omalizumab (Xolair) prefilled syringe will be considered under the following conditions:

1. *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*
2. *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*
3. *Prescriber is an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist; and*
4. *For a diagnosis of asthma, chronic rhinosinusitis with nasal polyps, IgE-mediated food allergy, and any other FDA approved diagnosis where dosing is dependent on serum IgE level and body weight, the pretreatment IgE level and body weight, in kilograms (kg), is provided. 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; and*
5. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab; and*

6. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

Moderate to Severe Persistent Asthma

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Patient has a history of positive skin or RAST test to a perennial aeroallergen; and*
3. *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.*

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. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
3. *Will be used concurrently with a nasal corticosteroid.*

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.

<u>IgE Mediated Food Allergy</u>

1. *Medication is being prescribed for the reduction of allergic reactions (Type 1) that may occur with accidental exposure to one or more foods in a patient that has an IgE-mediated food allergy; and*
2. *Diagnosis is confirmed by a skin prick test or in vitro test (attach results); and*
3. *Will be used in conjunction with food allergen avoidance.*

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.

Oral Glucocorticoids for Duchenne Muscular Dystrophy: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for oral glucocorticoids for Duchenne muscular dystrophy. 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 for patients when the following criteria are met:

1. *Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; 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. *Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and*
4. *Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose.*

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.

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

Prior authorization (PA) is required for tralokinumab-Idrm (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 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.

Zuranolone (Zurzuvae): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for zuranolone (Zurzuvae). 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 postpartum depression (PPD); and*

3. *Patient is 12 months or less postpartum on the date of request (state date of delivery); and*
4. *The onset of the current depressive episode was during the third trimester or within 4 weeks postpartum; and*
5. *Patient has not received brexanolone for the current PPD episode; and*
6. *Only one course of treatment (i.e., 14 days) per pregnancy will be considered. Extension of therapy beyond 14 days will not be authorized.*

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 37, Number 1. Pam Smith will add information about the new committee member Dr. Bryon Schaffer and update the stats page. There were no additional changes.

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

At 12:48, Chuck Wadle motioned to adjourn, and Holly Randleman seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for February 5, 2025, and it will have a virtual format.