Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 7, 2024

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Holly Randleman, Pharm.D.; Caitlin Reinking, Pharm.D.; Chuck Wadle, D.O.; Abby Cate, Pharm.D., Iowa Department of Health and Human Services; and Emily Rogers, Pharm.D., Iowa Total Care.

Staff
Pam Smith, R.Ph.

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

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:31 a.m., at the Grimes State Office Building in Des Moines, IA. The minutes from the May 1, 2024, meeting were reviewed. Jason Kruse 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. Annual chair and vice-chair elections were conducted. Chuck Wadle motioned to retain Melissa Klotz as chairperson, and Jason Kruse seconded. Melissa Klotz then motioned to retain Jason Kruse as vice-chairperson, and Chuck Wadle seconded. All members in attendance were in favor of both motions. Members were also asked to complete their annual conflict of interest disclosures.

Iowa Medicaid Pharmacy Update

Iowa Medicaid received approval to move forward with a rule change to allow a 90-day supply per prescription, rather than the 31 days currently allowed. Effective October 1, 2024, this change will go into effect for select drugs, initially generic maintenance medications, and the list will be posted this month. Pending CMS and DHHS leadership approval, DHHS was given a $500,000 budget increase allowing for a change to the dispensing fee making it $10.63 per prescription, separate from the ongoing cost of dispensing survey, which was sent out to providers in May with responses due back August 14, 2024. Data will be analyzed in preparation for the next legislative session and a proposed requested change to the dispensing fee. Dr. Caitlin Reinking was welcomed as a new Commission member.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from March 2024 through May 2024, including: total paid amount ($77,170,292.62); total prescriptions (714,463); and unique users (99,798). 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, 3 Walgreens locations, and Right Dose Pharmacy 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 Health Care, Caremark Kansas Specialty Pharmacy, Walgreens Community Pharmacy, Unity Point at Home, and Nucara Specialty Pharmacy. The top 5 therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Dermatologicals; and Antiasthmatic and Bronchodilator Agents. The top 5 classes by prescription count were: Antidepressants; Anticonvulsants; Antiasthmatic and Bronchodilator Agents; Antihypertensives; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. The most expensive drugs were Humira Pen, Ozempic, Vraylar, Trikafta, and Dupixent, while atorvastatin, sertraline, omeprazole, amoxicillin, and albuterol had the top 5 prescription counts.

Wellpoint Iowa*:* Jordan Thoman provided an overview for Wellpoint's statistics from March 2024 through May 2024, including: total paid amount ($98,955,499); total prescriptions (861,255); and unique users (108,084). 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, 3 Walgreens locations, and Right Dose Pharmacy 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 Health Care, CVS Specialty Pharmacy, Caremark Kansas Specialty Pharmacy, Community Walgreens Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Dermatologicals; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/ Anorexiants, Antiasthmatic and Bronchodilator Agents, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Ozempic, Vraylar, Stelara, and Trikafta. Omeprazole had the highest prescription count, followed by: sertraline, atorvastatin, levothyroxine, and escitalopram.

Molina Healthcare*:* Candace Jordan provided an overview for Molina's statistics from March 2024 through May 2024, including: total paid amount ($50,708,012.02); total prescriptions (512,644); and unique users (80,257). 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, 3 Walgreens locations, and Broadlawns 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 Pharmacy, Caremark Specialty Pharmacy, Community Walgreens Pharmacy, CVS Specialty Pharmacy, and Unity Point at Home. The top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Dermatologicals; Analgesics – Anti-inflammatory; and Antiasthmatic and Bronchodilator Agents. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Antihypertensives, Anticonvulsants, and Antidiabetics. Humira Pen was the most expensive medication,

followed by Ozempic, Trikafta, Vraylar, and Dupixent. Atorvastatin had the highest prescription count, followed by: sertraline, amoxicillin, omeprazole, and lisinopril.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2024 through May 2024, including: total amount paid ($2,736,578), unique users (3,800); cost per user ($720.15), number of total prescriptions dispensed (23,700); and percent generic (90.3%). The top 5 therapeutic classes by paid amount were: Antipsychotics - Atypicals; Anti-Inflammatories, Non-NSAID; Diabetic – Non-Insulin Injectables; Anticonvulsants; and Antidepressants – Selected SSRIs. The highest prescription count was from the Antidepressants SSRIs category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; GI – Proton Pump Inhibitor; and Antihypertensives. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Ozempic, Biktarvy, Vraylar, Humira Pen, and Taltz. The five drugs with the highest prescription counts were: trazodone, atorvastatin, gabapentin, fluoxetine, 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 $229,570,382 was spent in total for 2,122,062 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 all three MCO plans, and Antidepressants the top class by prescription count. FFS had Antipsychotics - Atypicals as the most expensive class, and Antidepressants - Selected SSRIs as the one with the most prescriptions. Humira Pen was the most expensive drug for all MCO plans, and Ozempic in second place. FFS had Ozempic first then Biktarvy. The top 25 drugs by prescription count were also similar across all MCO plans, with omeprazole, sertraline, and atorvastatin within the top 4 spots. For FFS, omeprazole was in fifth place, and atorvastatin second.

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
Uche Ndefo	UCB Inc.	Bimzelx
Lynda Finch	Biogen	Zurzuvae
Logan Poole	Novo Nordisk	Wegovy
Amy Hornig	AbbVie	Rinvoq (JAK Inhibitors)
April LaRow	Mirum Pharmaceuticals	Livmarli

Written Provider Comments Received: Stimulant quantity limits, postpartum depression treatment, zuranolone

Written Manufacturer Comments Received: Uzedy

Retrospective DUR Data Presentations

Stimulant Medication Utilization without Supporting Diagnosis:

- Prescription stimulant medication use has increased over the years. Based on prevalence reports from the MCOs and FFS, the ADHD/Narcolepsy agents are consistently in the top 20 therapeutic classes by paid amount and the top 20 therapeutic class by prescription count.
- Preferred stimulant medications do not require prior authorization (PA) for members under 21 years of age, while PA is required for all members 21 years of age or older.
- Several stimulant medications FDA approved for the treatment of ADHD, have other FDA approved indications, including narcolepsy and binge eating disorder.

At the last meeting, the Commission requested that data be pulled to identify members of all ages with claims for a stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) who do not have a supporting diagnosis in medical claims. Findings were broken into the following age groups: 0-3, 4-5, 6-7, 8-12, 13-17, 18-20, and 21 or more years old. 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. This data may not be easily retrievable. Data will be re-run, adding in additional diagnoses for sleep disorders, excluding insomnia. The Commission would also like to look at specific providers potentially writing a lot of stimulant prescriptions without a supporting diagnosis. Results will be brought back to the next meeting.

Non-Selective Beta-Blockers in Asthma:

- Beta-blockers can cause increased bronchial obstruction and airway reactivity.
- The 2023 Global Initiative for Asthma (GINA) report recommends avoidance of medications that may make asthma worse.
- Asthma is not an absolute contraindication to beta-blocker use. When there is no suitable alternative, a cardio-selective beta-blocker should be used.
- Cardio-selective oral beta-blockers include atenolol, betaxolol, bisoprolol, acebutolol, metoprolol, and nebivolol.
- Non-selective oral beta-blockers include carvedilol, labetalol, nadolol, pindolol, propranolol, sotalol, timolol.

Data from February 2024 through April 2024 was pulled to identify members with a diagnosis of asthma that had claims for a non-selective beta-blocker. The Commission wants to send letters to prescribers of the member identified pointing out the potential for non-selective beta-blockers to worsen asthma and recommend switching to a cardio-selective beta-blocker.

Retrospective DUR Proposals

Monitoring Prescribing of Antipsychotic Medications in Adults:

- H.R. 4366 – Consolidated Appropriations Act, 2024, Section 203 requires state Medicaid programs to monitor, through their DUR programs, the use of

antipsychotic medications by adults who receive home- and community-based services or who are in institutional care settings.

- Questions regarding monitoring of adult antipsychotic use will be added to the DUR FFY 2024 DUR survey (to be released to States for completion on April 1, 2025).
- Need to determine how to "monitor" adults who are prescribed antipsychotics.
- Documentation of process and plan to monitor in DUR meeting minutes would be the first step. To date, CMS has not provided formal guidance.
- Effective October 1, 2022, a ProDUR duplicate therapy edit was put in place for members 18 years of age and older. The edit limits adults to two chemically distinct antipsychotics. Prior authorization is required to exceed this limit.

Data from pharmacy claims from May 2024 through July 2024 will be run to identify the number of members on more than two chemically distinct antipsychotics for 60 or more days, with results brought to the next meeting for review.

Triple Therapy – Opioid, Benzodiazepine, and Muscle Relaxant:

- The combination of opioids with benzodiazepines and skeletal muscle relaxants has been reported to potentiate the high from the opioid. The combination of an opioid, benzodiazepine and carisoprodol is commonly referred to the street name of "Holy Trinity".
- When co-prescribed, this combination can cause euphoria, increased risk of respiratory depression, and increased risk of hospitalization.
- Current CDC guidelines state clinicians should use particular caution when prescribing opioids with benzodiazepines or other sedating medications (muscle relaxants, nonbenzodiazepine sedative hypnotics, and potentially sedating anticonvulsant medications such as gabapentin and pregabalin) and consider whether benefits outweigh the risks.
- Based on the Prescription Monitoring Program (PMP) data for 2022, Iowans received the following:
    - Opioid prescription – 499,153
    - Benzodiazepine prescription – 261,887
    - Opioid + benzodiazepine – 69,733 (PMP does not track muscle relaxant dispensations)

Data will be pulled for pharmacy claims from May through July 2024, to identify members with concurrent therapy of at least 30 days for all three of the following medications: opioid, benzodiazepine, and muscle relaxant. Results will also provide the number of members with an opioid + benzodiazepine + carisoprodol.

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.

The Commission took a short break and open session resumed at 11:00 a.m.

Prior Authorization

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.

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

Incretin Mimetics for Non-Diabetes Indications: The Commission reviewed the newly proposed prior authorization criteria 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 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; and*
c. *Patient is currently receiving cardiovascular standard of care treatment (e.g., lipid lowering therapy, platelet aggregation inhibitors, angiotensin converting enzyme [ACE] inhibitors or angiotensin II receptor blockers [ARBs], beta-blockers); 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.

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

Janus Kinase Inhibitors: The Commission reviewed the proposed 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, 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; 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; OR*

h. *Nonsegmental vitiligo (ruxolitinib); with*
i. *A documented trial and inadequate response with a potent topical corticosteroid; and*
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.

Chuck Wadle 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.

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 pruritis 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.

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

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.

IgE Mediated Food Allergy

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.

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

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.

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

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.

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

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.*

Holly Randleman motioned to accept the criteria as amended by striking the requirement a specialist prescribe the medication, and Jason Kruse seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Antidiabetic Non-Insulin Agents: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for select preferred anti-diabetic, non-insulin agents subject to clinical criteria. 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. *For the treatment of Type 2 Diabetes Mellitus, a current A1c is provided; and*
3. *Requests for non-preferred antidiabetic, non-insulin agents subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. Additionally, requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with at least 3 preferred agents from 3 different drug classes at maximally tolerated doses.*

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

Requests for weight loss are not a covered diagnosis of use and will be denied.

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 Axial Spondyloarthritis: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals used for axial spondyloarthritis conditions. Request must adhere to all approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of:*
    a. *ankylosing spondylitis (AS) or*
    b. *nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and*
2. *Patient has documentation of an inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least one month in duration; and*
3. *Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate; and*
4. *Requests for non-preferred biologicals for axial spondyloarthritis conditions will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents that are FDA approved or compendia indicated for the submitted diagnosis, when 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, no motion was necessary. The recommendation will be sent to the Department for consideration.

Biologicals for Plaque Psoriasis: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals used for plaque psoriasis. 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 plaque psoriasis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of moderate to severe plaque psoriasis; and*
2. *Patient has documentation of an inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine.*

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

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

Miscellaneous

DUR Digest: The Commission members conducted the second review of DUR Digest Volume 36, Number 2.

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

At 12:07, Jason Kruse motioned to adjourn, and Holly Randleman seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for November 6, 2024, location to be determined.