Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 1, 2024

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; and Chuck Wadle, D.O.

Staff
Pam Smith, R.Ph.

Guests
Abby Cate, Iowa Department of Health and Human Services; Erin Halverson, R.Ph., Iowa Medicaid; Gina Kuebler, R.Ph., Iowa Medicaid; Melissa Biddle, Iowa Medicaid; Candace Jordan, Pharm.D., Molina Healthcare; Jeannine Murray, Wellpoint Iowa; and Emily Rogers, Pharm.D., Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the virtual meeting to order at 9:32 a.m. The minutes from the February 7, 2024, meeting were reviewed. Rhea Hartley motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHHS after the last DUR meeting was also reviewed.

Iowa Medicaid Pharmacy Update

Medicaid is currently conducting an AAC rebate survey. Participating pharmacies must submit invoices this week, and this is the first time that two months' worth of invoices, for February and March 2024, will be evaluated. The rate analysis will take four to five weeks, with new rates tentatively implemented by the end of June or July 1, 2024. A cost of dispensing survey also will go out to providers this month, with responses due back in August, and legislative review for an updated fee next year. Medicaid did receive approval for $500,000 in the last legislative bill to increase the dispensing fee. Additionally, Iowa Medicaid received approval to move forward with a rule change to allow a 90-day supply per prescription for select drugs, rather than the 31 days currently allowed, with a tentative implementation date of September 11, 2024. A 90-day allowance was implemented during the Public Health Emergency (PHE), and had a positive impact on the pharmacy program, as well as the members. The DUR Commission reviewed and recommended a re-implementation of the 90-day supply limit for certain reviewed drugs, mostly generic maintenance medications, not all PDL medications like during the PHE. The Change Healthcare cyber-attack did affect the pharmacy fee-for-service program. The Point-of-Sale system, including eligibility look-up, prior authorization, and billing applications, were unavailable from February 21, 2024 to March 28, 2024. The prior authorization mandates and refill too soon edits were removed during that time span but are now back in place for dispensing dates after March 28, 2024. House File 555, which updates Iowa's Pharmacy Practice Act to reflect current training and education for Iowa's pharmacists, has passed and is awaiting the governor's

signature. House File 2099, related to updated regulation of pharmacy benefit managers, has also passed and is awaiting the governor's signature. This is the last Commission meeting for Jason Wilbur, as he has served the maximum 12 years allowed. Pam Smith thanked him for his service and contributions to the Commission and the people of Iowa.

Prevalence Report Summaries

***Molina Healthcare**:* Candace Jordan provided an overview for Molina's statistics from December 2023 through February 2024, including: total paid amount ($45,140,114.51); total prescriptions (462,441); and unique users (73,621). 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; Analgesics – Anti-inflammatory; Dermatologicals; and Antiasthmatic and Bronchodilator Agents. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. Humira Pen was the most expensive medication, followed by Vraylar, Ozempic, Trikafta, and Dupixent. Amoxicillin had the highest prescription count, followed by: sertraline, atorvastatin, omeprazole, and lisinopril.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from December 2023 through February 2024, including: total paid amount ($74,716,427.84); total prescriptions (709,792); and unique users (102,826). 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 were largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Walgreens Community Pharmacy, Caremark Kansas Specialty Pharmacy, Unity Point at Home, and Accredo Health Group. 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 Antidiabetics. 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**:* Jeannine Murray provided an overview for Wellpoint's statistics from December 2023 through February 2024, including: total paid amount ($97,072,823); total prescriptions (864,795); and unique users (111,435). 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 Healthcare, 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, CVS Specialty Pharmacy, Caremark Illinois Specialty Pharmacy, and Community Walgreens Pharmacy. Similar to previous reports, 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, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, 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 amoxicillin.

Fee-for-Service: Reporting for this time frame was not available due to the recent Change Healthcare cyber-attack and resulting system outages.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the stats from each MCO. She noted again that the FFS columns were not completed due to the recent Change Healthcare cyber-attack. For the MCO plans, side-by-side statistics showed that $216,929,365 was spent in total for 2,037,028 prescriptions. Antidiabetics was the top therapeutic class by paid amount for all three MCO plans, and Antidepressants the top class by prescription count. Humira Pen was the most expensive drug for all MCO plans. The top 25 drugs by prescription count were also similar across all MCO plans, with omeprazole, sertraline, atorvastatin, and amoxicillin within the top 5 spots.

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
Jeremy Whalen	Genentech	Xolair
Hiten Patadia	Incyte	Opzelura
Shirley Quach	Novartis	Biologicals for HS/Cosentyx
Amy Hornig	AbbVie	Rinvoq (JAK Inhibitors)
Loral Showalter	UCB	Bimzelx (Biologicals for Plaque Psoriasis)

Written Provider Comments Received: None

Written Manufacturer Comments Received: None

Retrospective DUR Data Presentations

Antianxiety/Sedatives in Children: The annual federal Drug Utilization Review (DUR) report (Sec. 1927. [42 U.S.C. 1396r–8]) issued by the Centers for Medicare and Medicaid Services (CMS) contains various survey questions relative to drug utilization and practice topics. The most recent survey includes the following questions:

- Does your state have a documented program in place to either manage or monitor the appropriate use of antidepressant drugs in children? If “yes”, does your state either manage or monitor only children in foster care, all children, or other.
- Does your state have edits in place to monitor child’s age, dosage, indication, polypharmacy, other.

After reviewing the tables on age bands, duplicate therapy, and chronic benzodiazepine use, the Commission decided to send letters to the prescribers of members on 3 or more chemically distinct agents for 60 or more days, as well as those with 30 or more days of benzodiazepine utilization in their claim histories. No age edits or duplicate therapy edits will be implemented at this time, but this topic will be re-evaluated at a future meeting to determine if additional action is needed.

Mood Stabilizers in Children: The annual federal Drug Utilization Review (DUR) report (Sec. 1927. [42 U.S.C. 1396r–8]) issued by the Centers for Medicare and Medicaid Services (CMS) contains various survey questions relative to drug utilization and practice topics. The most recent survey includes the following questions:

- Does your state have a documented program in place to either manage or monitor the appropriate use of mood stabilizing drugs in children? If “yes”, does your state either manage or monitor only children in foster care, all children, or other.
- Does your state have edits in place to monitor child’s age, dosage, indication, polypharmacy, other.
- CMS does not define mood stabilizers.

As requested at the February meeting, data was re-run to identify members on three or more concurrent medications (carbamazepine, divalproex, eslicarbazepine, gabapentin, lamotrigine, lithium, oxcarbazepine, pregabalin, topiramate, and valproic acid), focusing on the members less than 4 years of age, and excluding those with a seizure diagnosis. The Commission recommends implementing an age edit to block claims for members 0-17 years of age on 3 or more mood stabilizer medications, and require an explanation why they’re needed. Letters will also be sent to prescribers of the members with 3 or more chemically distinct mood stablizers for 60 or more days and the members 0-3 years of age on one or more mood stabilizers.

Low Dose Quetiapine in Children: Currently there are no FDA approved indications for low-dose quetiapine (< 150 mg per day) in adults or pediatric/adolescents. Additionally, there is no compendia indication for the use of quetiapine in the pediatric/adolescent population and evidence is inconclusive for adults. Quetiapine doses less than 150 mg per day may be used for the off-label treatment of insomnia. As requested at the February meeting, Pam Smith ran a new data set to identify members less than 18 years of age on more than one concurrent medication, including quetiapine, trazadone, and other medications used for sedation, along with diphenhydramine. Letters will be sent to the prescribers of members combining quetiapine with a sedative pointing out the potential duplication and asking if one or both agents could be discontinued.

Concurrent use of Levetiracetam and Clobazam:
The U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication warning of a rare but serious drug reaction to the antiseizure medications levetiracetam and clobazam. This potentially life-threatening sensitivity reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and typically occurs 2 weeks to 8 weeks after starting these medications. The reaction can cause severe inflammation and organ injury that may require hospitalization or lead to death, particularly if diagnosis and treatment are delayed. Educational outreach to prescribers will bring attention to this serious drug reaction and assist prescribers in educating patients/care givers on the signs and symptoms of DRESS should the combination of levetiracetam and clobazam be prescribed to future patients. As requested at the February meeting, data was run to identify members with concurrent claims for levetiracetam and clobazam for 30 days or more. Letters will be sent to prescribers identified as prescribing this combination to educate and notify them of the newly documented serious drug reaction. The Commission noted that it was likely that prescribers might be unaware of what other prescribers had prescribed concurrently.

Retrospective DUR Proposals

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. The Commission requested that data be pulled to identify members of all ages with claims for a stimulant who do not have a supporting diagnosis in medical claims. Findings will be broken into age bands for members under 21 years of age and 21 years and older. When possible due to eligibility date spans, the claim history look-back will attempt to go back 5 years rather than the two years initially suggested. Molina noted that their claim data would be limited to two years since they are new to Iowa Medicaid.

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 November 2023 through April 2024 will be pulled to identify members with a diagnosis of asthma that had claims for a non-selective beta-blocker.

Commission Recommendations for Retrospective DUR Agenda Topics

- Increased risk of GI Bleeds with DOACs versus warfarin
- Systolic heart failure diagnosis and GDMT
- Top 10 hospital admission and/or discharge diagnoses for potential drug therapy related issues, related to chronic condition medications

The Commission took a short break and open session resumed at 11:13 a.m.

Prior Authorization

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.

Jason Wilbur 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.

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.

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

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; with*
    a. *Documentation of an adequate trial and inadequate response to two preferred conventional therapies including aminosalicylates (sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; or*
2. *Patient has a diagnosis of moderate to severe Ulcerative Colitis; with*
    a. *Documentation of an adequate trial and inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine; 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.

This criteria was not voted on and will be brought back in order to review revise the definition of severity.

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.

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

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 to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
   ii. *A documented trial and inadequate response with a preferred TNF inhibitor; and*
   iii. *If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR*
d. *Moderately to severely active Crohn's disease (upadacitinib); with*
   i. *A documented trial and inadequate response to two preferred conventional therapies including aminosalicylates (sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; and*
   ii. *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.

Jason Kruse motioned to accept the criteria above, 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.

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

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

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *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.

<u>Chronic Idiopathic Urticaria</u>

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. *Will be used in conjunction with food allergen avoidance; and*
3. *Patient is allergic to peanut and at least two other foods, including milk, egg, wheat, cashew, hazelnut, or walnut; and*
4. *Patient does not have a history of severe anaphylaxis to the food allergens above.*
5. *Treatment should be discontinued if patient is accidentally exposed to the food allergen(s) above and experiences the same or worse reaction as before treatment.*

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

Based on public comments, Pam Smith will revise the IgE mediated food allergy criteria to make it less specific and bring it back to the next meeting. No vote was taken on the proposed criteria.

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

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

1. *Patient has a diagnosis of rheumatoid arthritis (RA); with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (hydroxycholoroquine, sulfasalazine, or leflunomide may be used if methotrexate is contraindicated); or*

2. *Patient has a diagnosis of moderate to severe psoriatic arthritis; with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
3. *Patient has a diagnosis of juvenile idiopathic arthritis with oligoarthritis; with*
    a. *Documentation of a trial and inadequate response to intraarticular glucocorticoid injections and methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
4. *Patient has a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) with;*
    a. *Documentation of a trial and inadequate response to methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
5. *Patient has a diagnosis of systemic juvenile idiopathic arthritis (sJIA).*

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

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

Payment will be considered under the following conditions:

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

If criteria for coverage are met, initial requests will be given for 4 months. Additional authorizations will be considered upon documentation of clinical response to

therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

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

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

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. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient will continue with skin care regimen and regular use of emollients; and*
4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) or with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long-acting beta $_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral*

theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and

   d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
      i. *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. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
   b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
   c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
   d. *Documentation of previous trials and therapy failures with all of the following:*
      i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
      ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension): and*
      iii. *Dietary therapy; or*
7. *Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and*
   a. *Is prescribed by, or in consultation with an allergist, immunologist, or dermatologist; and*
   b. *Patient has experienced severe to very severe pruritits, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and*
   c. *Patient has ≥ 20 nodular lesions (attach documentation); and*
   d. *Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; and*
8. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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

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.

Febuxostat (Uloric) – Removal of Criteria: The Commission reviewed prior authorization criteria as follows:

Prior authorization (PA) is required for febuxostat (Uloric). Payment for febuxostat (Uloric) will only be considered for cases in which symptoms of gout still persist while currently using 300mg per day of a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.

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

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 headache days per month for a minimum of 3 months; or*
    b. *Episodic Migraine, defined as:*
        i. *4 to 14 migraine days per month for a minimum of 3 months; or*
    c. *Episodic Cluster Headache, defined as:*
        i. *Occurring with a frequency between one attack every other day and 8 attacks per day; and*
        ii. *With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and*
        iii. *Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and*
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions and use in specific populations; and*
3. *The requested agent will not be used in combination with another CGRP inhibitor for the preventative treatment of migraine; and*

4. *Patient has been evaluated for and does not have medication overuse headache; and*
5. *For Episodic and Chronic Migraine, patient has documentation of two trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with ~~a~~ two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or*
6. *For Episodic Cluster Headache, patient has documentation of*
    a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*
    b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*
7. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

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

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

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

Hepatitis C Treatment, Direct Acting Antivirals: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). 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. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of chronic hepatitis C; and*
2. *Patient has had testing for hepatitis C virus (HCV) genotype; and*

3. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
4. *Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and*
5. *DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines and patient's weight is provided; and*
6. *Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.*
7. *If patient is recently eligible for Iowa Medicaid and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.*
8. *The 72-hour emergency supply rule does not apply to DAAs.*

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

1. *Patient must meet all criteria for treatment approval above; and*
2. *The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and*
3. *HCV retreatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and*
4. *Patient has not been previously treated with and failed the requested DAA therapy; and*
5. *Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.*

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 36, Number 2.

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

At 11:56, Jason Wilbur motioned to adjourn, and Jason Kruse seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for August 7, 2024, location to be determined.