Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 3, 2023

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; Susan Parker, Pharm.D.; and Emily Rogers, Pharm.D. Iowa Total Care.

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Jeannine Murray, R.Ph., Amerigroup.

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:35 a.m. Due to the current federal state of emergency, continually fluctuating numbers of coronavirus cases in various counties, the need for stability and pre-planning for the public, and due to increased workload of our members directly related to the COVID-19 pandemic, the committee finds that it is impossible/impractical to meet in person for the May 3, 2023, meeting and that it must be held electronically. The minutes from the February 1, 2023, meeting were reviewed. Jason Wilbur motioned to accept them, and John Ellis seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

IME Pharmacy Update

The legislature is still in session, so no update is available yet. Jeannine Murray will be replacing Lisa Todd as the MCO representative for Amerigroup until they refill that position. Emily Rogers will take over as the non-voting MCO committee member, and the MCO representative from Molina will be at the August meeting after their company is onboarded in July.

Prevalence Report Summaries

Amerigroup*:* Jeannine Murray provided an overview for ITC's statistics from December 2022 through February 2023, including: total paid amount ($133,980,502); total prescriptions (1,127,814); and unique users (183,165). 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 1 Hy-Vee made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, CVS Specialty Pharmacy, Community Walgreens Pharmacy, and Caremark Illinois Specialty Pharmacy. Similar to previous reports, 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, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Trulicity, and Trikafta. Amoxicillin had the highest prescription count, followed by: sertraline, ventolin hfa, omeprazole, and trazodone.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from December 2022 through February 2023, including: total paid amount ($98,179,999); total prescriptions (855,791); and unique users (148,185). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty Pharmacy, Walgreens Community Pharmacy, Unity Point at Home, and Nucara Specialty. The top 5 therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. The top 5 classes by prescription count were: Antidepressants; Antiasthmatic and Bronchodilator Agents; Anticonvulsants; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; and Antihypertensives. The most expensive drugs were Humira Pen, Trulicity, Vraylar, Vyvanse, and Biktarvy, while amoxicillin, sertraline, ventolin hfa, omeprazole, and trazodone had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from December 2022 through February 2023, including: total amount paid ($2,891,133), unique users (3,826); cost per user ($755.65), number of total prescriptions dispensed (22,068); and percent generic (88.0%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Antidepressants – Selected SSRIs. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Verzenio, Vijoice, Evrysdi, and Biktarvy. The five drugs with the highest prescription counts were: clonidine hcl, trazodone hcl, ventolin hfa, sertraline hcl, and escitalopram.

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 $ 235,051,634 was spent in total for 335,176 unique users who had 2,005,673 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira Pen was the most expensive drug for FFS and both MCO plans. The top 25 drugs by prescription count were also similar across FFS and both MCO plans, with amoxicillin

in the top spot for both MCOs. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,644. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

Public Comment

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

Name	Representing	Drug/Topic
Cassandra Lickert	Myovant	Myfembree
John Flatt	Marinus	Ztalmy
Shani Patel	Sanofi	Dupixent
Heather Freml	Abbvie	Rinvoq

Written Provider Comments Received: Dupixent

Written Manufacturer Comments Received: Myfembree, Ztalmy, Rinvoq

Retrospective DUR Data Presentations

Contraindications to Metformin: Metformin use is contraindicated in patients with the following:

- Acute or chronic metabolic acidosis including diabetic ketoacidosis with or without coma
- Severe renal impairment (eGFR below 30 mL/min/1.73 m^2)
- Hypersensitivity to metformin

After re-running the data to catch more current member claim information, the Commission would like to send letters to the presribers of members with a contraindication to metformin and a current pharmacy claim, alerting them to the potential contraindication(s) and asking if metformin could be switched to a different drug.

Underutilization of SGLT2i in Type 2 Diabetes, Chronic Kidney Disease, and/or Heart Failure: Patients with T2D in addition to CKD and/or HF are at increased risk of cardiovascular events and progression to kidney failure and/or worsening of HF. Preventative treatment strategies that reduce the risk of both kidney and cardiovascular outcomes are vital. After reviewing results, the Commission wants to provide informational outreach to providers to let them know these medications are preferred and available.

Retrospective DUR Proposals

Antidepressants 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.

The Commission would like to identify members with a claim for an antidepressant where the age is below the FDA approved minimum age for potential educational letters and/or ProDUR age edits. Pam Smith will bring the findings back to the next meeting.

Metabolic Monitoring in Children and Adolescents on Antipsychotics: Use of antipsychotic medications in children and adolescents increases the risk of developing diabetes and high cholesterol that can extend into adulthood. Metabolic monitoring can help ensure early detection and management of these potential complications. This is a current Healthcare Effectiveness Data and Information Set (HEDIS) measure for health care plans. Data will be gathered to help determine if metabolic testing occurred for members ages 0 to 17 who were dispensed an antipsychotic medication in the Iowa Medicaid population. Findings will be brought back to the next meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional recommendations.

Prospective DUR

90 Day Supply Limit: The DUR Commisison had the second review of a recommended 90-day drug supply allowance of select, cost-effective generic maintenance medications. Details of the proposed policy are as follows:

- Dispensing fee - pharmacy gets one dispensing fee per 90-day supply billed.
- Copayment - member gets charged one copay (if applicable) per 90-day supply billed.
- Member exclusions - none
- Initial fill – quantity would be at the discretion of prescriber, but consideration should be given to dispensing less than a 90-day supply with the initial fill when starting members on new medications or with dose adustments to minimize waste.
- 90-day drug selection process – will include select generic products from MediSpan maintenance drug categories.
- Exclusion criteria -
    - Safety – e.g., risks associated with a particular class
    - Controlled substances
    - Narrow therapeutic index (NTI) drugs
    - Drugs subject to frequent dose adjustments
    - OTC drugs
    - Brand drugs
    - PA drug categories (Clinical PA)
    - Nopreferred or nonrecommended drugs
    - Other therapeutic categories – antibiotics, ophthalmic, otic, and topical products

- Initial categories (select, generic drugs) – blood pressure; cholesterol lowering agents; antidepressants; diabetes mellitus
- Review list annually
- No change to the existing lost/stolen/destroyed medication policy
- No change to the existing vacation medication supply policy

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.

The Commission took a short break and open session resumed at 10:45 a.m.

Prior Authorization

Palivizumab (Synagis): The Commission reviewed the proposed prior authorization criteria as follows:

Respiratory Syncytial Virus (RSV) surveillance is tracked by the national respiratory and enteric virus surveillance system (NREVSS) on the centers for disease control and prevention of the United States department of health and human services website.

1. *Medicaid will use Iowa virology data reported to the NREVSS, as documented under RSV state trends.*
2. *Medicaid will provide coverage of prescription drugs that protect against RSV consistent with the current American Academy of Pediatrics (AAP) Guidelines for Infants and Children at Risk for Severe Illness due to RSV Infection.*
3. *The RSV season in Iowa is predefined as November 1st through March 31st of each RSV season. Prescribers and dispensing pharmacies should monitor state specific virology data and hold administration of palivizumab if data indicates RSV is not prevalent at the beginning of the predefined Iowa RSV season. Consideration of use of palivizumab during interseasonal spread of RSV may be considered by Medicaid with widespread RSV circulation.*

Prior authorization (PA) is required for therapy with palivizumab. PAs will be approved for administration during the RSV season for a maximum of five doses per patient. No allowances will be made for a sixth dose. Patients, who experience a breakthrough RSV hospitalization, in the prior 5 months, should have their monthly prophylaxis discontinued, as there is an extremely low likelihood of a second RSV hospitalization in the same season. Payment for palivizumab will be considered for patients who meet one of the following criteria:

Chronic Lung Disease (CLD) of Prematurity

1. *Patient is less than 12 months of age at start of therapy and has CLD of prematurity (defined as gestational age less than 32 weeks and required greater than 21% oxygen for at least the first 28 days after birth).*
2. *Requests for patients during their second year of life (12 months to < 24 months) will be considered for patients meeting the CLD of prematurity definition above and continue to require medical support (chronic*

corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

Prematurity (without CLD of Prematurity or Congenital Heart Disease)

1. *Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks.*

Neuromuscular Disorders or Anatomic Pulmonary Abnormalities

1. *Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway due to an ineffective cough.*

Hemodynamically Significant Congenital Heart Disease (CHD)

1. *Patient is less than 12 months of age at start of therapy and has hemodynamically significant CHD further defined by any of the following: Acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures, moderate to severe pulmonary hypertension, or cyanotic heart defects with documentation of consultation with a pediatric cardiologist that recommends palivizumab prophylaxis.*

Immunocompromised Children

1. *Patient is less than 24 months of age at start of therapy and is profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy).*

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

Naloxone Nasal Spray: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for a patient requiring more than 2 doses of naloxone nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. *Documentation is provided indicating why patient needs additional doses of naloxone nasal spray (accidental overdose, intentional overdose, other reason); and*
2. *Naloxone nasal spray is to be used solely for the patient it is prescribed for; and*
3. *The patient is receiving an opioid as verified in pharmacy claims; and*
4. *Patient has been reeducated on opioid overdose prevention; and*
5. *Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and*
6. *A treatment plan is included documenting a plan to lower the opioid dose.*

Jason Kruse motioned to remove current PA criteria and the current quantity limit to reduce barriers to naloxone. Rhea Hartley seconded, and all members were in favor.

The recommendation will be sent to the medical/pharmacy groups for comment and brought back to the next meeting for further discussion.

IL-5 Antagonists: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and*
    a. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells/mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells/ mcL within 12 months prior to initiation of therapy; 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 (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and*
    c. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and*
    d. *A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted in adults and < 90% in adolescents; or*
3. *Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and*
    a. *Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and*
    b. *One of the following:*
        i. *Eosinophil count > 1000 cells/mcL; or*
        ii. *Eosinophil count > 10% of the total leukocyte count; ~~and~~ or*
4. *Patient has a diagnosis of hypereosinophilic syndrome (HES); and*
    a. *Patient has been diagnosed with HES for ≥ 6 months prior to starting treatment; and*
    b. *Documentation that non-hematologic secondary causes of HES have been ruled out; and*
    c. *Documentation patient does not have FIP1L1-PDGFRα kinase-positive HES: and*
    d. *Documentation of ≥ 2 HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and*
    e. *Patient has a blood eosinophil count ≥ 1,000 cells/mcL; and*

f. Medication will be used in combination with stable doses of at least one other HES therapy; ~~and~~ or

5. Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); and
   a. Documentation mepolizumab will be used as an add-on maintenance treatment with a nasal corticosteroid spray; 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; and
6. Prescribed by or in consultation with an allergist, hematologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist.

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

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis or 6 months for a diagnosis of hypereosinophilic syndrome or CRSwNP to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:
Severe Asthma with an Eosinophilic Phenotype:
1. *Patient continues to receive therapy with an ICS, LABA and LTRA; and*
2. *Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or*
3. *Patient has experienced a decrease in administration of rescue medication (albuterol); or*
4. *Patient has experienced a decrease in exacerbation frequency; or*
5. *Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline.*

Eosinophilic Granulomatosis with Polyangiitis
1. *Patient has demonstrated a positive clinical response to therapy (increase in remission time).*

Hypereosinophilic Syndrome:
1. *Patient has demonstrated positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and*
2. *Medication continues to be used in combination with stable doses or at least one other HES therapy.*

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
1. *Patient has demonstrated positive clinical response to therapy (improvement in symptoms.); and*
2. *Continues to receive medication as add-on maintenance therapy with a nasal corticosteroid spray.*

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

Select Anticonvulsants: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for select anticonvulsants. 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 an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, tuberous sclerosis complex, or cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and*
3. *Is prescribed by or in consultation with a neurologist; and*
4. *Patient's current weight is provided; and*
5. *The total daily dose does not exceed the following:*
    a. *Cannabidiol*
        i. *Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day: or*
        ii. *Tuberous sclerosis complex: 25 mg/kg/day; or*
    b. *Fenfluramine*
        i. *With concomitant stiripentol (plus clobazam): 0.4 mg/kg/day with a maximum of 17 mg per day; or*
        ii. *Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or*
    c. *Stiripentol*
        i. *Prescribed concomitantly with clobazam; and*
        ii. *50 mg/kg/day with a maximum of 3,000 mg/day; or*
    d. *Ganaxolone*
        i. *Weight ≤ 28 kg: 63 mg/kg/day; or*
        ii. *Weight > 28 kg: 1800 mg/day.*

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

Cyclosporine Ophthalmic Emulsion (Verkazia): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for cyclosporine 0.1% ophthalmic emulsion (Verkazia). 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 vernal keratoconjunctivitis (VKC); and*
3. *Documentation of an adequate trial (2 to 3 weeks) and therapy failure with a preferred topical dual-acting mast cell stabilizer/topical antihistamine (e.g., olopatadine, azelastine); and*
4. *Documentation of an adequate trial (2 to 3 weeks) and therapy failure with a preferred topical ophthalmic corticosteroid (e.g., dexamethasone, prednisolone, fluorometholone, loteprednol); and*
5. *Is prescribed by or in consultation with an ophthalmologist or optometrist; and*
6. *Is not prescribed in combination with other ophthalmic cyclosporine products.*

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

Initial requests will be approved for 6 months. Additional authorizations will be considered upon documentation of clinical response to therapy.

The Commission also recommended a quantity limit of 120 single-dose vials (1 box) per 30 days.

Rhea Hartley motioned to accept the criteria and Jason Kruse seconded. All members were in favor.

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

Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered when member has an FDA approved or compendia indication for the requested drug, except for any drug or indication excluded from coverage, as defined in Section 1927 (2)(d) of the Social Security Act, Iowa's CMS approved State Plan, and the Iowa Administrative Code (IAC) 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. *Documentation of diagnosis; and*
3. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and*

4. *Payment for non-preferred topical antibiotic or topical retinoid acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and*
5. *Payment for non-preferred topical acne products outside of the antibiotic or retinoid class (e.g., Winlevi) will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred topical retinoid and at least two other topical acne agents. If criteria for coverage are met, initial requests will be approved for six months; and*
6. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and*
7. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and*
8. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and*
9. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

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

Jason Wilbur motioned to accept the criteria as amended, along with a quantity limit of one 60 gram tube per 30 days, and Rhea Hartley seconded. All members were in favor.

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

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

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and*
3. *Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine or a preferred stimulant; and*
5. *Dose does not exceed 400 mg per day for pediatric patients (< 18 years of age) and 600 mg per day for adult patients; and*

6. *Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.*

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

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

1. *Request adheres to all FDA approved labeling for requested drug and indication including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
    f. *Patient will continue with skin care regimen and regular use of emollients; or*
4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting $beta_2$*

agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and

   d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
      i. *Two (2) or more exacerbations in the previous year or*
      ii. *Require daily oral corticosteroids for at least 3 days; or*

5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
   a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
   b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
      i. *Nasal corticosteroid spray; and*
      ii. *Oral corticosteroid; or*
6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
   a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
   b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
   c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
   d. *Documentation of previous trials and therapy failures with all of the following:*
      i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
      ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and*
      iii. *Dietary therapy; 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 pruritus, 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.

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

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

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

e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
f. *Requests will be considered for a maximum duration of therapy of 24 months.*

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.

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, vitiligo, 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. *Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with*
   i. *A documented trial and inadequate response to intraarticular glucocorticoid injections; and*
   ii. *A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
   iii. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
e. *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*
f. *Atopic dermatitis; with*
   i. *Documentation patient has failed to respond to good skin care and regular use of emollients; and*
   ii. *A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
   iii. *A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
   iv. *For mild to moderate atopic dermatitis (ruxolitinib)*
      a. *A documented trial and therapy failure with crisaborole; and*
      b. *Affected area is less than 20% of body surface area (BSA); and*
      c. *Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or*
   v. *For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):*
      a. *A documented trial and therapy failure with cyclosporine or azathioprine; and*
      b. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.*

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

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

Miscellaneous

DUR Digest: The Commission members conducted the first review of DUR Digest Volume 35, Number 2.

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

At 11:47, Rhea Hartley motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for August 2, 2023, location to be determined.