Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 2, 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.; and Chuck Wadle, D.O.

Staff
Pam Smith, R.Ph.

Guests
Rebecca Curtiss, Iowa Department of Health and Human Services; Erin Halverson, R.Ph., Change Healthcare; Gina Kuebler, R.Ph., Change Healthcare; Melissa Biddle, Change Healthcare; Candace Jordan, Pharm.D., Molina Healthcare; Jordan Thoman, Pharm.D., Amerigroup.; and Carroll Nelson, Pharm.D., Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:30 a.m., at the Grimes State Office Building in Des Moines, IA. The minutes from the May 3, 2023, meeting were reviewed. Rhea Hartley motioned to accept them, and Jason Wilbur seconded. All members were in favor. The recommendation letter sent to DHHS after the last DUR meeting was also reviewed. Chuck Wadle nominated Melissa Klotz to remain as chairperson, and Melissa Klotz then nominated Jason Kruse to remain vice-chairperson. All members in attendance were in favor of both nominations. Members were also asked to complete their annual conflict of interest disclosures.

Iowa Medicaid Pharmacy Update

There were no updates.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2023 through May 2023, including: total amount paid ($2,922,553), unique users (3,752); cost per user ($778.93), number of total prescriptions dispensed (22,512); and percent generic (88.0%). The top 5 therapeutic classes by paid amount were: Analgesics-Anti-Inflammatory; Antidiabetics; Antipsychotics/Antimanic Agents; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; and Antiasthmatic and Bronchodilator Agents. The highest prescription count was from the Antidepressants category, with Anticonvulsants in second place, followed by: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antiasthmatic and Bronchodilator Agents; and Antipsychotics/Antimanic Agents. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Evrysdi, Biktarvy; Vijoice; and Invega Sustenna. The five drugs with the highest prescription counts were: clonidine, sertraline, trazodone, fluoxetine, and escitalopram.

Iowa Total Care: Carroll Nelson provided an overview for ITC's statistics from March 2023 through May 2023, including: total paid amount ($104,727,784.72); total prescriptions (910,930); and unique users (152,588). 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; Dermatologicals; and Antiasthmatic and Bronchodilator Agents. The top 5 classes by prescription count were: Antidepressants; Anticonvulsants; Antiasthmatic and Bronchodilator Agents; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; and Antidiabetics. The most expensive drugs were Humira Pen, Trulicity, Vraylar, Vyvanse, and Ozempic, while amoxicillin, sertraline, ventolin hfa, omeprazole, and trazodone had the top 5 prescription counts.

Amerigroup*:* Jordan Thoman provided an overview for ITC's statistics from March 2023 through May 2023, including: total paid amount ($143,482,250); total prescriptions (1,162,154); and unique users (183,844). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy and 4 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Health Care, Caremark Kansas Specialty Pharmacy, Community Walgreens Pharmacy, CVS Specialty Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Dermatologicals, and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Trulicity, and Ozempic. Amoxicillin had the highest prescription count, followed by: sertraline, ventolin hfa, omeprazole, and trazodone.

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 $ 251,132,588 was spent in total for 340,184 unique users who had 2,095,596 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 5,190. 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
Kellie Murry	Neurelis	Valtoco
Lindsay Bebout	Indivior	Sublocade/Opvee
Jeffrey Olearczk	Amgen	Tezspire

Written Provider Comments Received: None

Written Manufacturer Comments Received: Tezspire, Sublocade, Valtoco, Ztalmy

Retrospective DUR Data Presentations

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.

Prior to taking further action with educational letters or ProDUR age edits, the commission would like to do more research by age bands on antidepressant use in the pediatric population, looking for duplicate therapy and those on high doses more than 100mg, possibly removing trazadone from the search to eliminate those using it for sleep, and examining trazodone usage separately. 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. At the last meeting, Pam Smith was asked to gather more information to help determine if metabolic testing occurred for members ages 0 to 17 who were dispensed an antipsychotic medication in the Iowa Medicaid population. After reviewing the findings, the commission would like to send letters to prescribers regarding members without any metabolic testing during the time frame from April 2022 through March 2023. As the initial data only included the number of members meeting the criteria, Pam Smith will also look up the number of prescribers involved and bring results back to the next meeting.

Retrospective DUR Proposals

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 antianxiety/sedative 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 antianxiety/sedative drugs.

The Commission wants to target drugs where the safety and effectiveness have not been established in pediatric patients less than the FDA approved age and look into duplicate therapy. The targeted drugs and ages are listed in the table below.

< 18 Years Old	**< 12 Years Old**	**< 9 Years Old**	**< 6 Years Old**
Alprazolam*	Lorazepam*	Clorazepate#	Chlordiazepoxide#
Buspirone*			Hydroxyzine*
Estazolam*			Oxazepam&
Eszopiclone*			
Temazepam*			
Trazodone*			
Triazolam			
Zaleplon*			
Zolpidem*			

*Preferred drug; # PA required < 9 years of age; & PA required < 6 years of age

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.

The Commission wants to review the use of mood stabilizers in children that will be meaningful, yet not disruptive to use for other indications (e.g., seizure). Prior to pulling data, the Commission requested additional information to assist in defining a mood stablizer. This informaiton will be brought to the next meeting for further discussion.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional recommendations.

Prospective DUR

Seizure Rescue Treatment, Nasal Spray – Quantity Limit: Recent review of monthly paid pharmacy claims found an instance where Valtoco (diazepam nasal spray) was being dispensed in large quantities to one member (receiving a quantity greater than the maximum dosage and treatment frequency, as stated in the FDA approved label, in a 30-day period). Valtoco is preferred on the Preferred Drug List (PDL) with no current quantity limit. After further review of preferred rescue medications indicated for the acute treatment of seizures, the quantity limits below are being recommended for Valtoco and Nayzilam (midazolam nasal spray) to ensure appropriate use.

Medication Name & Strength	**Quantity Limit Per 30 Days**
Nayzilam (midazolam) 5 mg	5 boxes (10 nasal spray units)
Valtoco (diazepam) 5 mg, 10 mg	5 cartons (10 blister packs)
Valtoco (diazepam) 15 mg, 20 mg	10 cartons (20 blister packs)

Rhea Hartley motioned to accept the proposed quantity limits, and Chuck Wadle seconded. The decision was unanimous.

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

Prior Authorization

Antidepressants: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for non-preferred antidepressants subject to clinical criteria. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Documentation of a previous trial and therapy failure at a therapeutic dose with two preferred generic SSRIs; and*
3. *Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SNRI; and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with one non-SSRI/SNRI generic antidepressant; and*
5. *Documentation of a previous trial and therapy failure at a therapeutic dose with vilazodone; and*
6. *Documentation of a previous trial and therapy failure at a therapeutic dose with vortioxetine; and*
7. *Documentation of a previous trial and therapy failure at a therapeutic dose with an antidepressant and adjunct; and*
8. *If the request is for dextromethorphan and bupropion extended-release tablet (Auvelity), one of the trials must include a previous trial and inadequate response at a therapeutic dose with an extended-release bupropion agent;*

and

9. *If the request is for an isomer, prodrug or metabolite of the requested medication, one of the trials must be with the preferred parent drug of the same chemical entity that resulted in a partial response with a documented intolerance.*

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, as well as the proposed quantity limit of 60 tablets per 30 days and an age edit requiring the member to be 18 years of age or older. Rhea Hartley seconded, and all members were in favor.

Deucravacitinib (Sotyktu): The Commission reviewed the proposed prior authorization criteria as follows:

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

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of plaque psoriasis; and*
    a. *Documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine is provided; and*
    b. *Documentation of a trial and inadequate response to the preferred adalimumab agent; and*
    c. *Will not be combined with any of the following systemic agents: biologic DMARD, Janus kinase inhibitor, phosphodiesterase 4 (PDE4) inhibitor, or potent immunosuppressant.*

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

There was a brief discussion regarding coverage of phototherapy. The Medical policy will be reviewed and brought to the next meeting as a follow-up. Rhea Hartley motioned to accept the criteria as written, as well as the proposed quantity limit of 30 tablets per 30 days. Jason Wilbur seconded, and all members were in favor.

Tezepelumab (Tezspire): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for tezepelumab-ekko (Tezspire) prefilled pen. Requests for tezepelumab-ekko (Tezspire) single dose vial or prefilled syringe will not be considered through the pharmacy benefit. 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 severe asthma; and*
    a. *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 beta2 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*
    b. *Patient must have of one of the following, in addition to the regular maintenance medications defined above:*
        i. *Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months, or*
        ii. *One or more asthma exacerbations resulting in hospitalization in the previous 12 months; and*
    c. *This medication will be used as an add-on maintenance treatment; and*
    d. *Patient/caregiver will administer medication in patient's home; and*
    e. *Is not prescribed in combination with other biologics indicated for asthma.*

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

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

Rhea Hartley motioned to accept the criteria as written, as well as the proposed quantity limit of one prefilled pen per 28 days. Holly Randleman seconded, and all members were in favor.

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. *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 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*
    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.

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

Jason Kruse indicated mesalamine is no longer recommended for the treatment of Crohn's disease. Rhea Hartley motioned to accept the criteria as amended. Holly Randleman seconded, and all members were in favor.

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 page 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:

<u>Chronic Lung Disease (CLD) of Prematurity</u>

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.*

<u>Prematurity (without CLD of Prematurity or Congenital Heart Disease)</u>

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

<u>Neuromuscular Disorders or Anatomic Pulmonary Abnormalities</u>

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.*

<u>Hemodynamically Significant Congenital Heart Disease (CHD)</u>

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.*

<u>Immunocompromised Children</u>

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).*

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.

Naloxone Nasal Spray: The Commission reviewed the proposed removal of 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.*

Naloxone nasal spray PA criteria and the number of naloxone doses allowed per year were reviewed by the DUR Commission due to provider confusion regarding coverage and requirements. After discussion, in order to remove barriers to access of naloxone, the DUR Commission made a recommendation to remove current PA criteria and current quantity limits and monitor for appropriate utilization post-payment. 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.

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.*

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.

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.

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.

Cyclosporine Ophthalmic Emulsion (Verkazia): The Commission reviewed the 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:

3. *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*
4. *Patient has a diagnosis of moderate to severe vernal keratoconjunctivitis (VKC); and*
5. *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*
6. *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*
7. *Is prescribed by or in consultation with an ophthalmologist or optometrist; and*
8. *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.

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.

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.

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 35, Number 2.

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

At 11:21, Rhea Hartley motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is scheduled for November 1, 2023.