Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 2, 2022

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; John Ellis, Pharm.D.; Jason Wilbur, M.D.; Chuck Wadle, D.O.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; Susan Parker, Pharm.D.; and Lisa Todd, R.Ph. Amerigroup.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Emily Rogers, Pharm.D. Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:34 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 November 2, 2022, meeting and that it must be held electronically. The minutes from the August 3, 2022, meeting were reviewed. Jason Kruse 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

Providers received Informational Letter 2370-MC-FFS related to PDL and prior authorization criteria changes that went into effect October 1, 2022, following the August P&T and DUR Meetings. There were no additional updates.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from June 2022 through August 2022, including: total paid amount ($88,493,857.90); total prescriptions (797,260); and unique users (128,701). 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, Unity Point at Home, Nucara Specialty, and Walgreens Community Pharmacy. 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;

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2022 through August 2022, including: total amount paid ($2,513,938), unique users (3,532); cost per user ($711.76), number of total prescriptions dispensed (20,784); and percent generic (88.2%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Anticonvulsants; Antipsychotics – Atypicals; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Antiretroviral Combinations. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and GI – Proton Pump Inhibitor. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Evrysdi, Biktarvy, Emflaza, and Trulicity. The five drugs with the highest prescription counts were: clonidine hcl, trazodone hcl, sertraline hcl, escitalopram, and omeprazole.

Amerigroup*:* Lisa Todd provided an overview for ITC's statistics from June 2022 through August 2022, including: total paid amount ($129,596,815); total prescriptions (1,134,449); and unique users (172,028). 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 Ambulatory Care, Caremark Kansas Specialty Pharmacy, Caremark Illinois Specialty Pharmacy, Community Walgreens 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; Antiasthmatic and Bronchodilator Agents; and Dermatologicals. 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 Trulicity, Vyvanse, Vraylar, and Trikafta. Sertraline hcl had the highest prescription count, followed by: omeprazole, trazodone hcl, escitalopram, and atorvastatin.

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 $ 220,604,611 was spent in total for 304,261 unique users who had 1,952,493 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 sertraline in the top spot for both MCOs and third for FFS. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at 4,483. 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
Bradley Jones	AbbVie	Vraylar
Nila Stevens	Sanofi	Dupixent
Jennifer Kammerer	CSL	Veltassa
Mary Claire Wohletz	Merck	Verquvo

Written Provider Comments: Kerendia, Humira, anticonvulsant quantity limits, Xyway

In response to the comment received regarding issues with anticonvulsant quantity limits, the Iowa Department of Health and Human Services (HHS) will be reviewing the quantity limits, specifically on the lower strengths of lamotrigine, as that appears to be the medication giving providers the most access issues. To eliminate the need to keep multiple strengths on hand, Pam Smith suggested that lamotrigine quantity limits be adjusted to the following to accommodate dosing in pediatric patients:

Drug Product	Quantity	Days' Supply
Lamotrigine 25 MG tab & ODT, 50MG ODT, 100MG tab & ODT	120	30
Lamotrigine 150 MG tab	60	30

Retrospective DUR Data Presentations

LABA without ICS: LABAs as monotherapy increase the risk of asthma-related death and should be prescribed only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on an inhaled corticosteroid (ICS). Salmeterol xinafoate inhalation powder (Serevent Diskus) is the only single-ingredient LABA indicated for the treatment of asthma. Data was run to identify members with an asthma diagnosis and a claim for Serevent Diskus in their pharmacy claims from May through July 2022 that do not have a claim for an ICS. Letters will be sent to prescribers of members using Serevent Diskus without an ICS pointing out the increased risks associated of monotherapy use in the treatment of asthma and recommending the addition of an ICS to Serevent Diskus or switch to a combination LABA/ICS product. This topic will be reviewed again in a year. No PA criteria will be implemented for now.

Retrospective DUR Proposals

Concurrent Use of Opioids and Sedatives: Opioids carry an FDA boxed warning of increased risk of respiratory and CNS depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives. Currently, there are no hard POS edits to stop this combination or an automated retrospective claims review process for concurrent use of an opioid and sedative. Questions related to this issue appeared in the FFY21 CMS DUR Survey. As requested at the last meeting, Pam Smith researched to find more information regarding increased harm with specific drug

combinations, along with a more complete list of sedatives that would be included in the claims data search. Dosing will be further split out to identify how many members from those initial findings are on high dose opioids (≥ 90 MME) combined with the listed sedatives below, and results brought back to the next meeting.

- o Chloral hydrate
- o Daridorexant
- o Eszopiclone
- o Lemborexant
- o Phenobarbital
- o Ramelteon
- o Suvorexant
- o Tasimelteon
- o Zaleplon
- o Zolpidem

Underutilization of Beta-Blockers in Heart Failure: Evidence based beta-blocker therapy in patients with HFrEF can reduce all-cause and cardiovascular mortality, sudden cardiac death, and heart failure hospitalizations. Use of a beta-blocker proven to reduce mortality (bisoprolol, carvedilol, or sustained-release metoprolol succinate) in patients with chronic HFrEF is recommended for all adult patients with current or prior symptoms of HFrEF, unless contraindicated or not tolerated. Data will be run to identify members with heart failure with reduced ejection fraction, looking for proven beta-blockers, metoprolol tartrate, and Entresto in their claim histories.

Commission Recommendations for Retrospective DUR Agenda Topics

Jason Kruse suggested looking at Chronic Kidney Disease and Diabetes, as there's a strong recommendation to get people on an SGLT2 early, along with an ACE or ARB, to make providers aware of the firm guidance change.

The Commission took a short break and open session resumed at 10:50 a.m.

Prior Authorization

Annual Review of Prior Authorization (PA) Criteria: The Commission reviewed all categories from the October 1, 2022 PA criteria chart. Changes were suggested for the following categories, to be brought to upcoming meetings for further discussion.

PA Category	Recommended Changes
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors	Is there a reason concurrent use with PCSK9 Inhibitors is not considered?
Biologicals for Arthritis	Hep B guidance discrepancy between this and other Biologicals categories.
Naloxone Nasal Spray	Allow additional if history of overdose? State that rather than just "other reason"? Discuss abstinence and treatment programs.

Nebivolol (Bystolic) – Removal of Criteria: Due to the availability of a cost effective generic, a recommendation was made to remove PA criteria for nebivolol as follows:

Prior authorization is required for Bystolic. Payment will be considered in cases where there are documented trials and therapy failures with two preferred cardio-selective beta-blockers of a different chemical entity at a therapeutic dose. 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 remove criteria as recommended and implement the proposed quantity limits below, and Jason Kruse seconded. All members were in favor.

- 2.5 mg, 5 mg, 10 mg tablets – 30 tablets per 30 days
- 20 mg tablet – 60 tablets per 30 days

Potassium Binders – Removal of Criteria: Due to the availability of safer, effective products, a recommendation was made to remove PA criteria (shown below) to allow access to the preferred potassium binders without requiring a trial with sodium polystyrene sulfonate (SPS).

Prior authorization (PA) is required for potassium binders subject to clinical criteria. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older; and*
2. *Patient has a diagnosis of chronic hyperkalemia; and*
3. *Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.*

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 remove criteria as recommended, and Jason Wilbur seconded. However, they also wanted to implement an age edit (18 years of age or older) and quantity limits on both medications, but leave sodium polystyrene sulfonate preferred so as not to restrict access. Recommended quantity limits: Veltassa (patiromer) - 30 packets per 30 days and Lokelma (sodium zirconium cyclosilicate (34 packets per 30 days). All members were in favor.

Select Topical Psoriasis Agents: The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization is required for select topical psoriasis agents. Payment for a non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of plaque psoriasis with involvement estimated to affect ≤ 20% of the body surface area; and*
3. *Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred medium to high potency topical*

corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks.

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

Rhea Hartley motioned to accept the criteria as recommended and to implement the proposed quantity limit for tapinarof (Vtama) of one 60 g tube per 30 days, 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.

Initial Days' Supply Limit Override, Benzodiazepines: The Commission reviewed updated, proposed prior authorization criteria as follows:

Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indication for the requested drug; 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. *Medical rationale for exceeding the initial days' supply limit is provided; and*
4. *Requests for opioids exceeding the 7 day initial supply limit will be considered:*
    a. *For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and*
    b. *Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:*
        i. *Quantity Limit Override Form (exceeds established quantity limit)*
        ii. *High Dose Opioid PA Form (exceeds established MME limit)*
        iii. *Short-Acting Opioids PA Form (non-preferred short-acting opioids)*
        iv. *Long-Acting Opioids PA Form (non-preferred long-acting opioids); or*
5. *Requests for benzodiazepines exceeding the 7 day initial supply limit will be considered:*

a. *For patients with active cancer; end-of-life/palliative care, seizure disorder, or on an individual case-by-case basis based on medical necessity documentation provided; and*
b. *For patients taking concurrent opioids, the prescriber must document the following:*
    i. *The risks of using an opioid and benzodiazepine concurrently have been discussed with the patient; and*
    ii. *Documentation is provided as to why concurrent use is medically necessary; and*
    iii. *A plan to taper the opioid is provided, if appropriate; and*
c. *Request must meet all other benzodiazepine requirements (quantity limit, PDL, etc.). If requests do not comply with these requirements, separate, additional prior authorization is required. Please use the following PA forms at www.iowamedicaidpdl.com where appropriate:*
    i. *Benzodiazepines (non-preferred benzodiazepine)*
    ii. *Quantity Limit Override (as posted at www.iowamedicaidpdl.com under Billing/Quantity Limits); and*

6. *Requests for drugs or drug classes subject to the initial days' supply limit not listed above, will be considered on an individual case-by-case basis, based on medical necessity documentation provided.*

Jason Kruse 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 associations for comment and brought back to the next meeting for further discussion.

High Dose Opioids: The Commission reviewed the updated, proposed prior authorization criteria as follows:

Prior authorization (PA) is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day (See CDC Guideline for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. *Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and*
2. *Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and*
3. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
4. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and*
5. *There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and*

6. *Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and*
7. *Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and*
8. *Chart notes from a recent office visit or telehealth visit for pain management are included documenting the following:*
    a. *Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and*
    b. *Treatment goals; and*
9. *Patient has been informed of the risks of high-dose opioid therapy; and*
10. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and*
11. *The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and*
12. *A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and*
13. *The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and*
14. *Patient has documentation of receipt of an opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within the prior 24 months of high dose opioid request for the emergency treatment of an opioid overdose; and*
15. *Patient has been educated on opioid overdose prevention; and*
16. *Patient's household members have been educated on the signs of opioid overdose and how to administer an opioid reversal agent; and*
17. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and*
18. *A documented dose reduction is attempted at least annually.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. *High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and*
2. *Patient has not experienced an overdose or other serious adverse event; and*
3. *Patient is not exhibiting warning signs of opioid use disorder; and*
4. *The benefits of opioids continue to outweigh the risks; and*
5. *A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and*
6. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and*

7. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.*
8. *Patient has documentation of receipt of an opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within 24 months of high dose opioid request for the emergency treatment of an opioid overdose; and*
9. *Patient has been reeducated on opioid overdose prevention; and*
10. *Patient's household members have been reeducated on the signs of opioid overdose and how to administer an opioid reversal agent.*

Rhea Hartley motioned to accept the criteria as amended, and Holly Randleman seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion. Pam Smith will research private payor and other Medicaid states' criteria, specifically regarding drug screen requirements, to ensure the above is in line with other payors and states.

Sedative/Hypnotics, Non-Benzodiazepine: The Commission reviewed the updated, proposed prior authorization criteria as follows:

Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *A diagnosis of insomnia; and*
3. *Medications with a side effect of insomnia are decreased in dose, changed to a short acting product, and/or discontinued; and*
4. *Enforcement of good sleep hygiene is documented; and*
5. *All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses; and*
6. *Will not be used concurrently with a benzodiazepine sedative/hypnotic agent.*
7. *In addition to the above criteria, requests for an orexin receptor antagonist will require documentation of a trial and therapy failure with at least one non-preferred agent prior to consideration of coverage.*
8. *Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.*

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.

Vericiguat (Verquvo): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for vericiguat (Verquvo). 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 symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and*
3. *Patient meets one of the following:*
    a. *Recent hospitalization for heart failure (within the last 6 months); or*
    b. *Recent need for outpatient intravenous diuretics (within the last 3 months); and*
4. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and*
5. *Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and*
6. *Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:*
    a. *Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and*
    b. *Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and*
    c. *Mineralocorticoid receptor antagonist (MRA); and*
    d. *Sodium-glucose cotransporter 2 inhibitor (SGLT2i) indicated for the treatment of heart failure (empagliflozin or dapagliflozin); and*
7. *Initial requests for vericiguat (Verquvo) 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.*

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.

Maralixibat (Livmarli): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 mutation or deletion; and*
3. *Patient has cholestasis with moderate to severe pruritus; and*
4. *Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and*
5. *Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:*
    a. *Ursodeoxycholic acid (ursodiol)*
    b. *Cholestyramine*
    c. *Rifampin; and*
6. *Patient's current weight in kilograms (kg) is provided.*

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

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

PIK3CA-Related Overgrowth Spectrum (PROS) Treatments *(Vijoice):* The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for alpelisib (Vijoice). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

2. *Patient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by genetic testing demonstrating a PIK3CA mutation; and*
3. *Patient's condition is severe or life-threatening requiring systemic therapy as determined by treating prescriber; and*
4. *Patient has at least one target lesion identified on imaging.*

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by a reduction in sum of measurable lesion volume assessed across 1 to 3 target lesions.

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.

Mavacamten (Camzyos): The Commission reviewed the newly proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for mavacamten (Camzyos). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and*
3. *Patient exhibits symptoms of New York Heart Association (NYHA) class II or III symptoms; and*
4. *Is prescribed by or in consultation with a cardiologist; and*
5. *Patient has a left ventricular ejection fraction (LVEF) ≥ 55%; and*
6. *Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation; and*
7. *Documentation of a previous trial and therapy failure, at a maximally tolerated dose, with all of the following:*
    a. *Non-vasodilating beta-blocker (atenolol, metoprolol, bisoprolol, propranolol); and*
    b. *Non-dihydropyridine calcium channel blocker (verapamil, diltiazem); and*
    c. *Combination therapy with disopyramide plus beta-blocker or disopyramide plus a non-dihydropyridine calcium channel blocker.*

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 clinical 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; and*
7. *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.

Viloxazine (Qelbree): The Commission reviewed the proposed clinical 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; 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.

CNS Stimulants and Atomoxetine: The Commission reviewed the proposed clinical prior authorization criteria as follows:

Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. Payment for CNS stimulants and atomoxetine will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). 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). 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. Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the

dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening, and will be limited to one unit dose per day. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. Use of an amphetamine agent plus a methylphenidate agent will not be considered for a diagnosis of ADHD.

*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. *If a non-preferred long-acting medication is requested, a trial with the preferred extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.*

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 initial review of DUR Digest Volume 35, Number 1.

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

At 11:51, Jason Wilbur motioned to adjourn, and Rhea Hartley and Holly Randleman both seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for February 1, 2023, location to be determined.