Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes February 1, 2023

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 9:32 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 February 1, 2023, meeting and that it must be held electronically. The minutes from the November 2, 2022, meeting were reviewed. Jason Wilbur motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed, along with a letter from the P&T Committee requesting development of specific prior authorization (PA) criteria for Winlevi, due to the concern of hypothalamic-pituitary-adrenal (HPA) axis suppression and lack of long-term safety data.

IME Pharmacy Update

The federal COVID-19 public health emergency will be ending in May, and informational letters will be sent out regarding unwind plans, providing a minimum of 60 days notification before any changes are implemented or reverted back to standard policy. There were no additional updates.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2022 through November 2022, including: total amount paid ($2,584,295), unique users (3,850); cost per user ($671.25), number of total prescriptions dispensed (21,450); and percent generic (88.7%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Muscular Dystrophy Agents. 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, Evrysdi, Biktarvy, Vijoice, and Vyvanse. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, sertraline hcl, escitalopram, and omeprazole.

Amerigroup*:* Lisa Todd provided an overview for ITC's statistics from September 2022 through November 2022, including: total paid amount ($121,126,342); total prescriptions (1,083,320); and unique users (180,883). 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, 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 Antiasthmatic and Bronchodilator Agents. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Trulicity, Vyvanse, Vraylar, and Latuda. Amoxicillin had the highest prescription count, followed by: sertraline hcl, omeprazole, trazodone hcl, and escitalopram.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from September 2022 through November 2022, including: total paid amount ($91,554,504.95); total prescriptions (835,803); and unique users (143,112). 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, omeprazole, trazodone, and atorvastatin had the top 5 prescription counts.

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 $ 215,265,142 was spent in total for 327,845 unique users who had 1,940,573 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 4,661. 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
Nila Stevens	Sanofi	Dupixent
Erin Hohman	AbbVie	Orilissa and Oriahnn

Written Provider Comments Received: Dupixent (3 different providers)

Written Manufacturer Comments Received: Qelbree

Retrospective DUR Data Presentations

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. Pam Smith researched to find more information regarding increased harm with specific drug combinations. Data results were split out to identify how many members are on high doses 90 MME or greater combined with these listed sedatives: chloral hydrate, daridorexant, eszopiclone, lemborexant, phenobarbital, ramelteon, suvorexant, tasimelteon, zaleplon, and zolpidem. Letters will be sent to prescribers of all identified members with claims for a sedative from the list above and an opioid with at least one day overlap from August through October 2022.

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 in patients with chronic HFrEF is recommended for all adult patients with current or prior symptoms of HFrEF, unless contraindicated or not tolerated. Beta-blockers proven to reduce mortality in patients with HFrEF include bisoprolol, carvedilol, or sustained-release metoprolol succinate. Data was run to identify members with heart failure with reduced ejection fraction, looking for proven beta-blockers, metoprolol tartrate, and Entresto in their claim histories. Letters will be sent to prescribers of members with heart failure, without a beta blocker and Entresto recommending the addition of a proven beta blocker and Entresto, if not contraindicated. Letters will also be sent to prescribers of members using metoprolol tartrate and recommend a change to metoprolol succinate.

Retrospective DUR Proposals

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 m2)
- Hypersensitivity to metformin

The Commission would like to do a look-back to identify members with acute or chronic metabolic acidosis or severe renal impairment taking metformin, to see how big this issue is before taking further action. Dr. Kruse commented that since SGLT2 medications are relatively new, prescribers were hesitant to change patients to those given issues with side effects, but agreed the evidence-based trials were robust and it was important to get members in line with the current guidelines. Pam Smith will bring results back to the next meeting.

Underutilization of SGLT2i in Type 2 Diabetes and Chronic Kidney Disease: Patients with T2D and CKD are at increased risk of cardiovascular events and progression to kidney failure. Preventative treatment strategies that reduce the risk of both kidney and cardiovascular outcomes are vital. Current guidelines recommend use of a SGLT2i with proven kidney or cardiovascular benefit for patients with T2D, CKD, and eGFR ≥ 20 mL/min/1.73 m2. SGLT2i with proven cardiorenal benefit include canagliflozin, dapagliflozin, and empagliflozin. The Commission would like to pull data to identify adult members with type 2 diabetes (T2D) and chronic kidney disease (CKD) without a sodium-glucose cotransporter 2 inhibitor (SGLT2i) in pharmacy claims, and also look at heart failure. Pam Smith will bring results 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 discussed and recommended a 90-day drug supply allowance of select, cost-effective generic maintenance medications (motion by Holly Randleman, second by Jason Wilbur, and all members in favor). 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 – at 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 policy.

The Commission took a short break and open session resumed at 11:10 a.m.

Prior Authorization

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.

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

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.

Jason Kruse motioned to accept the criteria as amended, and John Ellis 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.

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.

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

Janus Kinase Inhibitors: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved indication of alopecia areata, 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.

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

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.

At the November meeting, the Commission voted to remove criteria as recommended and implement quantity limits.
Quantity Limits

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

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

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.

At the November meeting, the Commission voted to remove criteria as recommended, and to implement an age edit and quantity limits on both medications, leaving sodium polystyrene sulfonate preferred so as not to restrict access.

- Age Edit – 18 years of age and older for Lokelma and Veltassa
- Quantity Limit
    - Lokelma – 34 packets per 30 days
    - Veltassa – 30 packets per 30 days

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 Topical Psoriasis Agents: The Commission reviewed the 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.

No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The Commission also recommended to implement a quantity limit for Vtama 1%, 60 g per 30 days. The recommendations will be sent to the Department for consideration.

Initial Days' Supply Limit Override, Benzodiazepines: The Commission reviewed the 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.*

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.

High Dose Opioids: The Commission reviewed the 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 Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022 at https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1.htm_w. 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.*

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 1.

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

At 11:44, Jason Wilbur motioned to adjourn, and Rhea Hartley seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for May 3, 2023, location to be determined.