Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes February 5, 2025

Attendees:

Commission Members Present
Voting: Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Holly Randleman, Pharm.D.; Caitlin Reinking, Pharm.D.; Chuck Wadle, D.O.; Bryon Schaeffer, MD, FAAFP; Rhea Hartley, M.D.; Jennifer Johnson, Pharm.D. Non-voting: Abby Cate, Pharm.D., Iowa Department of Health and Human Services

Commission Members Absent
Non-voting: Emily Rogers, Pharm.D., Iowa Total Care

Staff in Attendance
Pam Smith, R.Ph.

Guests in Attendance
Erin Halverson, R.Ph., Iowa Medicaid; Gina Kuebler, R.Ph., Iowa Medicaid; Melissa Biddle, Iowa Medicaid; Darian Forcier, Iowa Department of Health and Human Services; Candace Jordan, Pharm.D., Molina Healthcare; Caroll Nelson, Pharm.D., Iowa Total Care; and Jordan Thoman, Pharm.D., Wellpoint Iowa.

Welcome & Introductions

Chairperson Melissa Klotz called the virtual meeting to order at 9:33 a.m. The minutes from the November 6, 2024, meeting were reviewed. Bryon Schaeffer motioned to accept them, and Rhea Hartley seconded. All members were in favor. The recommendation letter sent to DHHS after the last DUR meeting was also reviewed, as well as a letter from the P&T Committee sent after their November meeting, recommending that Tryvio be reviewed for development of prior authorization criteria due to the specific indication for use in resistant hypertension.

Iowa Medicaid Pharmacy Update

Results of the cost of dispensing survey increasing the dispensing fee from $10.63 to $11.37 per prescription are now available to the public and have been published on the state's rate setting vendor Myers & Stauffer's web page. This increase request is now in the governor's recommendations for the DHHS budget currently being discussed in the legislative session. Pending budget approval, the new fee will be effective July 1, 2025. Jennifer Johnson, Pharm.D. was welcomed as a new commission member. The DUR website is still down following the Change Healthcare cyber-attack but is anticipated to be back up within the next couple weeks, and will keep the same address www.iadur.org.

Prevalence Report Summaries

***Molina Healthcare**:* Candace Jordan provided an overview for Molina's statistics from September 2024 through November 2024, including: total paid amount ($52,445,320.09);

total prescriptions (493,379); and unique users (78,347). 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, 2 Walgreens locations, Broadlawns, and 1 Hy-Vee location made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: Caremark Specialty Pharmacy, University of Iowa Ambulatory Care Pharmacy, Community Walgreens Pharmacy, CVS Specialty Pharmacy, and Unity Point at Home. The top 5 therapeutics classes by paid amount were: Antidiabetics; Dermatologicals; Antipsychotics/Antimanic Agents; Analgesics – Anti-inflammatory; and Antivirals. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Ozempic was the most expensive medication, followed by Humira Pen, Dupixent, Trikafta, and Vraylar. Sertraline had the highest prescription count, followed by: atorvastatin, amoxicillin, omeprazole, and albuterol.

Wellpoint Iowa*:* Jordan Thoman provided an overview for Wellpoint's statistics from September 2024 through November 2024, including: total paid amount ($96,311,159); total prescriptions (823,629); and unique users (102,831). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, University of Iowa Health Care, 3 Walgreens locations, and Right Dose Pharmacy made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Health Care, CVS Specialty Pharmacy, Caremark Kansas Specialty Pharmacy, Community Walgreens Pharmacy, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Dermatologicals; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/ Anorexiants, and Antihypertensives. Ozempic was the most expensive medication, followed by: Humira (CF) Pen, Vraylar, Trikafta, and Jardiance. Omeprazole had the highest prescription count, followed by: atorvastatin, sertraline, levothyroxine, and trazodone.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2024 through November 2024, including: total amount paid ($3,048,055), unique users (3,881); cost per user ($785.38), number of total prescriptions dispensed (23,346); and percent generic (90.4%). The top 5 therapeutic classes by paid amount were: Antidiabetics; Dermatologicals; Antipsychotics/Antimanic Agents; Antivirals; and Analgesics – Anti-Inflammatory. The highest prescription count was from the Antidepressants category, with Anticonvulsants in second place, followed by: ADHD/Anti-Narcolepsy/Anti-Obesity/ Anorexiants; Antihypertensives; and Antiasthmatic and Bronchodilator Agents. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Ozempic, Humira Pen, Biktarvy, Evrysdi, and Vraylar. The five drugs with the highest prescription counts were: albuterol, sertraline, trazodone, cetirizine, and omeprazole.

Iowa Total Care: Caroll Nelson provided an overview for ITC's statistics from September 2024 through November 2024, including: total paid amount ($74,968,759.36); total prescriptions (670,341); and unique users (93,981). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, University of Iowa Health Care, Right Dose Pharmacy, 2 Walgreens locations, and Broadlawns made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Health Care, Walgreens Community Pharmacy, Caremark Kansas Specialty Pharmacy, Accredo Health Group, and Unity Point at Home. The top 5 therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Dermatologicals; Analgesics – Anti-Inflammatory; 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 Antihypertensives. The most expensive drugs were Humira Pen, Ozempic, Trikafta, Dupixent, and Vraylar, while albuterol, sertraline, atorvastatin, omeprazole, and trazodone 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 $226,773,293 was spent in total for 2,010,695 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Antidiabetics was the top therapeutic class by paid amount for FFS and all three MCO plans, and Antidepressants the top class by prescription count. Ozempic was the most expensive drug for FFS, Wellpoint, and Molina Healthcare, and in second place for Iowa Total Care. Humira Pen, the most expensive on Iowa Total Care's list, was second for Wellpoint, Molina Healthcare, and FFS. The top 25 drugs by prescription count were also similar across all MCO plans, with omeprazole, sertraline, and atorvastatin within the top 4 spots. For FFS, sertraline was in second place, atorvastatin sixth, and omeprazole fifth.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comment from the speakers shown below.

Name	Representing	Drug/Topic
Heather Bullard	Idorsia	Tryvio
Mary Claire Wohletz	Merck	Prevymis
Brett Stephenson	Arcutis Biotherapeutics	Zoryve
Lori Blackner	Pfizer	Nurtec OTC
Amy Hornig	AbbVie	Select Preventative Migraine Treatments

Written Provider Comments Received: Mental health treatments

Written Manufacturer Comments Received: Endari

Retrospective DUR Data Presentations

Stimulant Medication Utilization without Supporting Diagnosis:

Pam Smith provided an update on items requested at previous meetings. With regards to whether there were diagnosis codes other than the primary diagnosis code pulled into data results, it was different for each of the MCOs and FFS. Molina pulls claims from a table that pulls all diagnosis codes per claim. Wellpoint only had the primary diagnosis, but said it could be expanded up to five to be more comprehensive. Iowa Total Care included the primary and secondary diagnosis, and FFS had up to five diagnosis codes pulled. Encounter data was included by Wellpoint and Iowa Total Care, but not by Molina and FFS. There were no other sources used for diagnosis codes. Tax ID on pharmacy claims is not something that is regularly used for Pharmacy Point of Sale. However, Molina said they could pull that in if needed. Wellpoint could pull the address from the POS and require a crosswalk for Tax ID. For Iowa Total Care, the NPI links to the system with prescriber address of record, and FFS also uses NPI to identify provide and link that back to their primary address. Data will be re-run after ensuring all reporting is using the same parameters and brought back to the next meeting for further review.

72-Hour Emergency Override Utilization Review: Candace Jordan reviewed the results of the data pull. The committee does not believe the low volume of claim overrides warrants additional action at this time, especially as they don't want to cause patient access issues in rural areas or acute situations. Pam Smith said they needed to make sure everyone was on the same page as far as only allowing the override for medications requiring prior authorization with a 75 edit in POS and not allowing more than a three days' supply or non-emergency repetitive overrides month after month. As the plan has established rules of 1 override per member per drug per year, the MCOs will also be updating system programming to prevent any exception to that rule. These sort of system and program corrections should eliminate a lot of the misuse of 72-hour overrides, but the topic will be reviewed on a regular basis to keep an eye on it, especially for brand/generic changes that may fall through the cracks. A progress update will be provided at the next meeting in May.

Concurrent Use of GLP-1 Receptor Agonist and DPP-4 Inhibitor:

Current American Diabetes Association (ADA) recommendations do not recommend combined use of a GLP-1 RA and DPP-4i due to overlapping mechanisms of action. Letters will be sent to prescribers regarding the concurrent use of a GLP-1 RA and DPP-4 inhibitor, pointing out the overlapping mechanisms of action and lack of additional significant improvements in A1C and recommending one agent be discontinued. Member outreach options will also be discussed internally by DHHS, FFS, and MCO staff.

Retrospective DUR Proposals

Evaluation of Dornase Alpha in Cystic Fibrosis Patients- on Modulator Therapy

Presented by Caroll Nelson, Iowa Total Care: Cystic Fibrosis patients often have a high medication treatment burden and scheduled daily regimen. Some recent newer studies suggest that Dornase alfa (Pulmozyme) has a potential for being discontinued without any difference in lung function outcomes for some patients. Educating providers about this possibility and encouraging them to evaluate their patients for the ability to

discontinue, could lead to a reduced medication burden for some members. Data will be pulled and brought to the next meeting.

LABA + ICS in COPD: The 2025 GOLD Report no longer encourages the use of a LABA+ICS in combination for treating patients with COPD. If there is an indication for use of ICS, then LABA+LAMA+ICS has been shown to be superior to LABA+ICS. Patients currently on LABA+ICS should be reviewed to determine whether there was a relevant prior exacerbation history and whether there was a previous positive response to ICS treatment. Data will be run to identify preferred and non-preferred triple agent options, with results brought back to the next meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional recommendations.

The Commission took a short break and open session resumed at 11:43 a.m.

Prior Authorization

Aprocitentan (Tryvio): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for aprocitentan (Tryvio). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered 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 resistant hypertension; and*
3. *Secondary causes of hypertension have been ruled out; and*
4. *Patient has been adherent with standard background antihypertensive therapy, which includes at least one agent from each of the following classes, taken concurrently at maximally tolerated doses:*
    a. *Angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB);*
    b. *Calcium channel-blockers (CCB);*
    c. *Diuretics;*
    d. *Mineralocorticoid receptor antagonist (MRA); and*
5. *Patient's blood pressure remains above target goal despite adherence with the above agents; and*
6. *Will be used in combination with at least three other antihypertensive agents at maximally tolerated doses.*

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

Holly Randleman motioned to accept the newly proposed criteria as written, and Jason Kruse 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.

CNS Stimulants and Atomoxetine: The Commission reviewed the proposed prior authorization criteria as follows, removing atomoxetine:

Prior authorization (PA) is required for CNS stimulants 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 will be considered when patient has an FDA approved or compendia indication for requested drug under the following conditions:

1. *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.*
2. *Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).*
3. *Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.*

Chuck Wadle motioned to accept the criteria as proposed, as well as implementation of the age edit requiring members be 6 years of age or older, and Caitlin Reinking

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.

Direct Oral Anticoagulants: The Commission reviewed the proposed removal of prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred direct oral anticoagulants (DOACs). PA is required for non-preferred DOACs. Requests will be considered for FDA approved dosing and length of therapy for submitted diagnosis. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications for the requested drug under the following conditions:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient does not have a mechanical heart valve; and*
3. *Patient does not have active bleeding; and*
4. *For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1; and*
5. *A recent creatinine clearance (CrCl) is provided; and*
6. *A recent Child-Pugh score is provided; and*
7. *Patient's current body weight is provided; and*
8. *Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred DOACs; and.*
9. *For requests for edoxaban, when prescribed for the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE), documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin) is provided.*

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

Holly Randleman motioned to remove PA criteria, along with the proposed quantity limits allowing a quantity of 60 per 30 days on Eliquis 2.5 mg (apixaban) and 74 per 30 days on Eliquis 5 mg (apixaban) per the dosing requirements for certain diagnoses. Rhea Hartley seconded, and 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.

Letermovir (Prevymis): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for oral letermovir. Requests for intravenous letermovir should be directed to the member's medical benefit. 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. *Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and*
3. *Patient has received an allogeneic hematopoietic stem cell transplant (HSCT); and*
    a. *Patient or donor is CMV-seropositive [R+] (attach documentation); and*
    b. *Treatment is initiated between day 0 and day 28 post-transplantation with IV and/or oral therapy (before or after engraftment); and*
    c. *Therapy duration will not exceed 100 days post-transplantation or up to 200 days if patient is at high risk for late CMV infection (attach documentation); or*
4. *Patient is a kidney transplant recipient; and*
    a. *Donor is CMV-seropositive/recipient is CMV seronegative [D+/R-] (attach documentation); and*
    b. *Treatment is initiated between day 0 and day 7 post-transplantation with IV and/or oral therapy (before or after engraftment); and*
    c. *Therapy will not exceed 200 days post-transplantation; and*
5. *Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and*
6. *Date of transplant is provided; and*
7. *Patients weight (in kg) is provided.*

Rhea Hartley motioned to accept the proposed criteria as amended, and Bryon Schaeffer 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.

Peanut (Arachis hypogaea) Allergen Powder-DNFP (Palforzia): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Peanut (Arachis hypogaea) Allergen Powder-dnfp (Palforzia). Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indications, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and*
3. *Patient is 1 to 17 years of age at initiation of therapy or 1 year of age and older for continued up-dosing and maintenance therapy; and*
4. *Prescribed by or in consultation with an allergist or immunologist; and*
5. *Patient has access to injectable epinephrine; and*
6. *Will be used in conjunction with a peanut-avoidant diet; and*

7. *The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the initial dose escalation is administered in the provider office and should be billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and*
8. *PA is required for all up-dosing dose levels (dose 1 through 11); and*
9. *Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.*

Rhea Hartley motioned to accept the proposed criteria as written, and Holly Randleman 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.

Oxybate Products: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for oxybate products. Payment for non-preferred agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. *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 cataplexy associated with narcolepsy*
    a. *Confirmed by a sleep study (including PSG, MSLT, and ESS) and verified by a sleep specialist (attach results); and*
    b. *Previous trial and therapy failure with dextroamphetamine; or*
3. *A diagnosis of excessive daytime sleepiness associated with narcolepsy*
    a. *Confirmed by a sleep study (including PSG, MSLT, and ESS) and verified by a sleep specialist (attach results); and*
    b. *Previous trial~~s~~ and therapy failure~~s~~ at a therapeutic dose with modafinil; or*
4. *A diagnosis of idiopathic hypersomnia*
    a. *Confirmed by a sleep study (including PSG, MSLT, and ESS) and verified by a sleep specialist (attach results); and*
    b. *Previous trial and therapy failure at a therapeutic dose with modafinil; and*
5. *Will not be used in combination with other oxybate products or with pitolisant and/or solriamfetol; and*
6. *Patient has been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and*

dependence; and

7. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website prior to requesting PA.*

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

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

Tirzepatide (Zepbound) for OSA: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for incretin mimetics not otherwise covered by the Anti-Diabetics Non-Insulin Agents PA criteria for covered FDA approved or compendia indications. Payment for excluded medical use(s) (e.g. weight loss), as defined in the Iowa State Plan and Iowa Administrative Code 441 – 78.2(4) will be denied. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has been screened for and does not have type 1 or type 2 diabetes mellitus (attach current lab results, obtained within 6 months of request, documenting an A1C < 6.5% or a fasting plasma glucose < 126 mg/dL); and*
3. *The requested drug will be used to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in an adult with established cardiovascular disease (CVD) and either obesity or overweight; and*
    a. *Patient has established CVD with history of one of the following (attach chart notes documenting diagnosis):*
        i. *Prior myocardial infarction (MI);*
        ii. *Prior stroke (ischemic or hemorrhagic);*
        iii. *Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; and*
    b. *Patient has a baseline body mass index (BMI) ≥ 27 kg/m^2 (attach documentation), obtained within 6 months of request; and*
    c. *Patient has been evaluated for cardiovascular standard of care treatment; and*
    d. *For Wegovy:*
        i. *Patient is ≥ 45 years of age; and*

ii. *Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and*
iii. *Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment; or*

4. *Patient has a diagnosis of moderate to severe obstructive sleep apnea (OSA); and*
    a. *Patient has a baseline BMI ≥ 30 kg/m^2; and*
    b. *Patient has a baseline apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a polysomnography (PSG)(attach documentation); and*
    c. *Patient continues to have an AHI ≥ 15 events per hour, as documented by a PSG, after optimization of positive airway pressure (PAP), unless PAP is not tolerated or contraindicated (attach documentation), and*
    d. *Patient is currently receiving and compliant with PAP (the device was used for 70% of nights for four or more hours per night, for two or more months) unless PAP is not tolerated or contraindicated; and*
    e. *For Zepbound:*
        i. *Patient meets the FDA approved age for OSA; and*
        ii. *Initiation and escalation dosages will be permitted up to a maximum of 20 weeks prior to reaching the recommended maintenance dosage of 10 mg to 15 mg once weekly; and*
        iii. *Maintenance dosages other than 10 mg to 15 mg once weekly will not be approved for maintenance treatment; and*
5. *Patient will use medication in combination with a reduced calorie diet and increased physical activity; and*
6. *The requested agent will not be used in combination with other incretin mimetics.*

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

Requests will be considered for initiation and appropriate dosage escalation. Requests for continuation of therapy, once at an established maintenance dose will be considered at 12-month intervals when:

1. *The requested drug will be used to reduce the risk of MACE; and*
    a. *Patient has been evaluated for cardiovascular standard of care treatment; and*
    b. *For Wegovy, a maintenance dose of 1.7 mg or 2.4 mg once weekly is requested; or*
2. *The requested drug will be used to treat moderate to severe OSA; and*
    a. *Patient's current AHI with PAP is provided (attach PAP device report or PSG), if indicated; and*
    b. *The maintenance dose is requested and maintained (Zepbound 10 mg to 15 mg once weekly); and*
3. *Patient does not have type 1 or type 2 diabetes; and*

4. *Patient continues to use medication in combination with a reduced calorie diet and increased physical activity; and*
5. *The requested agent will not be used in combination with other incretin mimetics.*

Holly Randleman motioned to accept the criteria as amended, and Bryon Schaeffer 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.

Dupilumab (Dupixent): The Commission reviewed the proposed prior authorization criteria as follows:

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

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Patient has failed to respond to good skin care and regular use of emollients; and*
    b. *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*
    c. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    d. *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. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and*
    b. *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*
    c. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. *One (1) or more exacerbations in the previous year or*

ii. *Require daily oral corticosteroids for at least 3 days; or*

5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
    a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
    b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
        i. *Nasal corticosteroid spray; and*
        ii. *Oral corticosteroid; or*
6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
    a. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    b. *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*
    c. *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. *Patient has experienced severe to very severe pruritits, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and*
    b. *Patient has ≥ 20 nodular lesions (attach documentation); and*
    c. *Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; or*
8. *Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype; and*
    a. *Patient has moderate to severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:*
        i. *FEV1/FVC ratio < 0.7, and*
        ii. *FEV1 % predicted between 30% to 79%; and*
    b. *Patient has a minimum blood eosinophil count of 300 cells/mcL, measured within the past 12 months; and*
    c. *Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to:*
        i. *Triple therapy with all of the following treatments:*
            1. *Long-acting muscarinic antagonist/anticholinergic (LAMA); and*
            2. *Long-acting beta agonist (LABA); and*
            3. *Inhaled corticosteroid (ICS); or*
        ii. *Double therapy with all of the following if ICS is contraindicated*

1. *LABA; and*
2. *LAMA; and*

d. *Patient has history of at least 2 moderate or 1 severe exacerbation(s) in the previous 12 months despite receiving maximal triple therapy or double therapy (defined above). Moderate exacerbation is defined as patient required treatment with systemic corticosteroids and/or antibiotics and severe exacerbation is defined as hospitalization or observation for over 24 hours in an emergency department or urgent care facility; and*
e. *Patient will continue to receive maintenance therapy (as documented above) concomitantly with dupilumab; and*

9. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD, which will receive an initial authorization of 12 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.

Ensifentrine (Ohtuvayre): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for ensifentrine (Ohtuvayre). 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 moderate to severe COPD when all of the following are met:*
   a. *FEV1/FVC ratio < 0.7; and*
   b. *Post-bronchodilator FEV1 % predicted of 30% to 79%; and*
   c. *Modified Medical Research Council (mMRC) dyspnea score of ≥ 2 or a COPD Assessment Test (CAT) score ≥ 10; and*
3. *Patient is adherent with COPD treatments, meeting one of the following criteria:*
   a. *The patient has a blood eosinophil of ≥ 100 and has experienced an exacerbation while adherent to a current 60-day trial of a triple*

combination regimen consisting of a long-acting beta agonist (LABA), a long-acting muscarinic antagonist (LAMA), and an inhaled corticosteroid (ICS); or

   b. *The patient has a blood eosinophil of < 100 and has experienced an exacerbation while adherent to a current 60-day trial of a dual combination regimen consisting of a LABA and LAMA; and*

4. *Dual or triple combination regimen will be continued in combination with ensifentrine (Ohtuvayre).*

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

If the criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Additional authorizations will be considered upon documentation of a response to treatment (e.g. improved dyspnea, decreased exacerbations) and patient continues their dual or triple combination regimen.

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.

Incretin Mimetics for Non-Diabetes Indications: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for incretin mimetics not otherwise covered by the Anti-Diabetics Non-Insulin agents PA criteria for covered FDA approved or compendia indications. Payment for excluded medical use(s) (e.g. weight loss), as defined in the Iowa State Plan and Iowa Administrative Code 441 – 78.2(4) will be denied. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient is ≥ 45 years of age; and*
3. *Patient has been screened for and does not have type 1 or type 2 diabetes mellitus (attach current lab results, obtained within 6 months of request, documenting an A1C < 6.5% or a fasting plasma glucose < 126 mg/dL); and*
4. *The requested drug will be used to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in an adult with established cardiovascular disease (CVD) and either obesity or overweight; and*
   a. *Patient has established CVD with history of one of the following (attach chart notes documenting diagnosis):*
      i. *Prior myocardial infarction (MI);*
      ii. *Prior stroke (ischemic or hemorrhagic);*
      iii. *Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less*

than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; and

b. *Patient has a baseline body mass index (BMI) ≥ 27 kg/m^2, obtained within 6 months of request and*
c. *Patient has been evaluated for cardiovascular standard of care treatment; and*
d. *For Wegovy dosing:*
    i. *Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and*
    ii. *Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment; and*

5. *Patient will use medication in combination with a reduced calorie diet and increased physical activity; and*
6. *The requested agent will not be used in combination with other incretin mimetics.*

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

Requests will be considered for initiation and appropriate dosage escalation. Requests for continuation of therapy, once at an established maintenance dose will be considered at 12-month intervals when:

1. *The requested drug will be used to reduce the risk of MACE; and*
    a. *Patient does not have type 1 or type 2 diabetes; and*
    b. *Patient has been evaluated for cardiovascular standard of care treatment; and*
    c. *For Wegovy, a maintenance dose of 1.7 mg or 2.4 mg once weekly is requested; and*
2. *Patient continues to use medication in combination with a reduced calorie diet and increased physical activity; and*
3. *The requested agent will not be used in combination with other incretin mimetics.*

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 Preventative Migraine Treatments: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for select preventative migraine agents. Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent. Payment will be considered under the following conditions:

1. *Patient has one of the following diagnoses:*
    a. *Chronic Migraine, defined as:*
        i. *≥ 15 headache days per month for a minimum of 3 months; and*
        ii. *≥ 8 migraine headaches days per month for a minimum of 3 months; or*
    b. *Episodic Migraine, defined as:*
        i. *4 to 14 migraine days per month for a minimum of 3 months; or*
    c. *Episodic Cluster Headache, defined as:*
        i. *Occurring with a frequency between one attack every other day and 8 attacks per day; and*
        ii. *With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and*
        iii. *Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and*
2. *Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings and precautions; and*
3. *The requested agent will not be used in combination with another CGRP inhibitor for the preventative treatment of migraine; and*
4. *Patient has been evaluated for and does not have medication overuse headache; and*
5. *For Episodic Cluster Headache, patient has documentation of*
    a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*
    b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*
6. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

Initial requests will be approved for 3 months. Additional PAs will be considered upon documentation of clinical response to therapy (i.e., reduced migraine

frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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

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

Select Topical Agents (agenda originally listed name as Topical Roflumilast (Zoryve)): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for select topical 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*
    a. *Request is for roflumilast 0.3% cream or tapinarof 1% cream; and*
    b. *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; or*
3. *Patient has a diagnosis of seborrheic dermatitis; and*
    a. *Request is for roflumilast 0.3% foam; and*
    b. *Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred topical corticosteroid (scalp - medium to high potency or nonscalp – low-potency) and preferred topical antifungal for a minimum of 4 consecutive weeks; or*
4. *Patient has a diagnosis of mild to moderate atopic dermatitis; and*
    a. *Request is for roflumilast 0.15% cream or tapinarof 1% cream; 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; or*
    d. *Patient has documentation of an adequate trial and therapy failure with a topical immunomodulator for a minimum of 4 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 prior authorization name will be revised to 'Select Topical Agents' to allow consideration of other topical agents to be considered and added to the form, when appropriate. The recommendation will be sent to the Department for consideration.

Vonoprazan (Voquezna): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for vonoprazan (Voquezna), Voquezna Dual Pak, and Voquezna Triple Pak. 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 healing of erosive esophagitis (attach endoscopy results for initial diagnosis), maintenance of healed erosive esophagitis (attach endoscopy results for initial diagnosis), and relief of heartburn associated with non-erosive gastroesophageal reflux disease (GERD); and*
    a. *Documentation of an 8-week trial and therapy failure, based on ongoing symptoms, with two preferred PPIs, each twice-daily dosing; or*
3. *Patient has an active Helicobacter pylori (H. pylori) infection (attach documentation); and*
    a. *Patient has documentation of a recent trial and therapy failure with a preferred agent(s) for the treatment of H. pylori infection; and*
    b. *Request is for the triple pak or dual pak.*

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

If the criteria for coverage are met, requests will be evaluated for the dosage and duration of therapy according to the indications specified on the FDA approved label.

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 37, Number 1. There were no additional recommended changes.

MedWatch: The Commission members received links to FDA announcements.

At 12:56, Bryon Schaeffer motioned to adjourn, and Chuck Wadle seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for May 7, 2025, and it will have a virtual format.