Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 7, 2025

Attendees:

Commission Members Present
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.; Abby Cate, Pharm.D., Iowa Department of Health and Human Services; and Emily Rogers, Pharm.D., Iowa Total Care.

Commission Members Absent
None

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; and Jeannine Murray, Wellpoint Iowa.

Welcome & Introductions

Chairperson Melissa Klotz called the virtual meeting to order at 9:31 a.m. The minutes from the February 5, 2025, 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. Following up from previous meetings, Pam Smith said that MCO system programming for the 72-hour override has now been corrected, and that member outreach for DUR studies is not possible at this time. Additionally, the DUR web site www.iadur.org that had been down following the Change Healthcare cyber attack is now restored, and all meeting materials are posted there.

DUR Recommendation Process

In order to speed up the prior authorization criteria implementation process, Pam Smith proposed a plan that most criteria under review would only be discussed and voted on at one DUR Commission Meeting rather than two before being submitted to DHHS for consideration. If, however, recommended PA criteria under review was amended significantly by the Commission, then it would be held and brought back to the next meeting for an additional updated review with the revised wording and member vote. All members were in agreement with this plan, and Pam Smith will bring a formal written process to the August meeting, to also be implemented in August.

Iowa Medicaid Pharmacy Update

Thus far all legislative bills with potential impact introduced in the current session have not made it out of the sub-committee. The appropriations bills that set the budget for the

next fiscal year, potentially affecting allocation for the dispensing fee increase, are still under review.

Prevalence Report Summaries

***Wellpoint Iowa**:* Jeannine Murray provided an overview for Wellpoint's statistics from December 2024 through February 2025.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from December 2024 through February 2025.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from December 2024 through February 2025.

***Molina Healthcare**:* Candace Jordan provided an overview for Molina's statistics from December 2024 through February 2025.

Comparative Prevalence Report Summary

Pam Smith also created a report that compared the FFS stats with those from each MCO. Its side-by-side statistics showed that $235,531,239 was spent in total for 1,995,868 prescriptions. The complete comparative summary, as well as the four individual prevalence reports, can be found in the meeting packet posted on www.iadur.org.

Public Comment

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

Name	Representing	Drug/Topic
Carla McSpadden	Galderma	Nemluvio
Elizabeth Lubelczyk	Lilly USA	Tirzepatide (Zepbound) for OSA

Written Provider Comments Received: Evrysdi

Written Manufacturer Comments Received: None

Retrospective DUR Data Presentations

Stimulant Medication Utilization without Supporting Diagnosis: Pam Smith provided an update on items requested at previous meetings. The Commission does not wish to take further action at this time due to the low volume of claims.

Evaluation of Dornase Alpha in Cystic Fibrosis Patients on Modulator Therapy: Emily Rogers from Iowa Total Care presented this study recommendation. The Commission would like to send letters to prescribers highlighting recent studies that suggest Dornase alfa may not provide additional benefits in lung function outcomes for patients who are stable on modulator therapy and asking prescribers to assess the necessity of continuing Dornase alpha and consider discontinuing the medication.

LABA + ICS in COPD: Letters will be sent to prescribers regarding the members identified as having a COPD diagnosis using a LABA + ICS, providing recommendations from the 2025 GOLD Report, and asking the prescriber to review the patient's current COPD regimen to consider if a change in therapy is needed based on the current recommendations and patient history.

Retrospective DUR Proposals

Drug-Drug Interaction: Amlodipine with Simvastatin or Lovastatin: The Commission does not think action is needed, and does not wish to proceed with this proposal.

Opioid Reversal Agent Frequency in Members with MME ≥90: Jeannine Murray from Wellpoint presented this study recommendation. Per the Commission's request, data will be run and brought back to the next meeting for review.

Commission Recommendations for Retrospective DUR Agenda Topics

Jason Kruse suggested that SGLT2 Inhibitors used by members with a diagnosis of chronic kidney disease should be reviewed.

Prospective DUR Proposals

Concurrent Use of GLP-1 RA and DPP-1 Inhibitor: Rhea Hartley motioned to implement a ProDUR edit to prevent the concurrent use of GLP-1 RA and DPP-4i, with a 90-day lookback for overlapping therapy. Caitlin Reinking seconded, and all members were in favor.

90-Day Supply Allowance Prescription List: An updated list will be effective 7/1/25. The MCO representatives provided usage statistics since initial implementation.

The Commission took a short break and open session resumed at 11:31 a.m.

Prior Authorization

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication(s), including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to lipid lowering medication therapy; and*
3. *Patient will continue to follow an appropriate low-fat diet; and*
4. *Patient has one of the following diagnoses:*
    a. *Heterozygous familial hypercholesterolemia (HeFH); or*
    b. *Primary hyperlipidemia; or*
    c. *Established cardiovascular disease (CVD) (e.g. previous myocardial infarction, history of an acute coronary syndrome, angina, previous stroke or transient ischemic attack, coronary*

artery disease, peripheral arterial disease, coronary or other arterial revascularization); or

   d. *At risk for a CVD event but without established CVD (e.g. diabetes mellitus (type 1 or type 2), a Reynolds Risk score > 20% or a SCORE Risk score > 7.5% over 10 years, a coronary artery calcium score > 300 Agatston units); and*

5. *Meets one of the following:*
   a. *Patient must be adherent to lipid lowering medication therapy and is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials, including atorvastatin and rosuvastatin, at maximally tolerated doses, used in combination with ezetimibe for a minimum of 90 consecutive days; or*
   b. *Patient is statin intolerant as documented by an inability to tolerate at least two chemically distinct statins; or*
   c. *Patient has an FDA labeled contraindication to all statins; and*
6. *Goal is defined as a 50% reduction in untreated baseline LDL-C.*
7. *Concurrent use with a PCSK9 inhibitor will not be considered.*

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

1. *Patient continues with lipid lowering therapy at a maximally tolerated dose; or*
2. *Patient is intolerant to or has a contraindication to statins; and*
3. *Patient continues to follow an appropriate low-fat diet; and*
4. *Documentation of a positive response to therapy (e.g., LDL-C reduction).*

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 proposed, 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.

Givinostat (Duvyzat): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for givinostat (Duvyzat). 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 for patients when the following criteria are met:

1. *Patient has a diagnosis of Duchene muscular dystrophy (DMD) with documented mutation of the dystrophin gene; 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. *Is prescribed by or in consultation with a physician who specializes in treatment of DMD; and*

4. *Patient has documentation of a trial and inadequate response to an oral glucocorticoid for at least 6 months; and*
5. *Givinostat will be prescribed concurrently with an oral glucocorticoid; and*
6. *Patient's current body weight in kilograms (kg) is provided.*

If criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 12-month intervals when the following criteria are met:

1. *Documentation of a positive response to therapy (e.g. improved strength, pulmonary function test, or functional assessments); and*
2. *Patient continues to receive concomitant glucocorticoid therapy; and*
3. *Patient's current body weight in kg is provided.*

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 proposed, 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.

Lebrikizumab-lbkz (Ebglyss): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Ebglyss (lebrikizumab-lbkz). 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.*

If criteria for coverage are met, initial authorization will be given for 16 weeks to allow for initial dosing. Requests for continuation of therapy will be considered at 12-month intervals with documentation of an adequate response to therapy and a dose reduction to maintenance dosing.

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 proposed, 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.

Nemolizumab-ilto (Nemluvio): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Nemluvio (nemolizumab-ilto). 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. *For initial therapy, will be used in combination with a topical corticosteroid and/or a topical immunomodulator; and*
    e. *Patient will continue with skin care regimen and regular use of emollients; or*
4. *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.*

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess response to therapy. Requests for continuation of therapy will be considered at 12-month intervals with documentation of an adequate response to therapy and a dose reduction to maintenance dosing, where appropriate.

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

Holly Randleman motioned to accept the criteria as proposed, 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.

Aprocitentan (Tryvio): The Commission reviewed the 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.

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 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.*

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.

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.

Additionally, the DUR Commission recommends implementing the following ProDUR quantity limits:

Drug Product	Quantity	Days' Supply
Eliquis 2.5 mg (apixaban)	60	30
Eliquis 5 mg (apixaban)	74	30

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.

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.*

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.

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.*

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.

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.

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.

Tirzepatide (Zepbound) for OSA: The Commission reviewed two options for proposed criteria. Option 1 was the original criteria discussed and recommended at the February 5, 2025 DUR meeting. Option 2 was a modification of option 1 with changes less restrictive than originally recommended. Abby Cate explained the reason for bringing option 2 to the Commission for review and consideration (there is a new supplemental rebate offer, just for OSA as weight loss is not a covered diagnosis). Jason Kruse motioned to accept option 2 criteria as presented, and Caitlin Reinking seconded. All members were in favor. Option 2 prior authorization criteria are 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. *Prescriber attests patient has a recent (within prior three years) apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a polysomnography (PSG) or at-home sleep study (document AHI); and*
   c. *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. *Documentation of a positive response to therapy is provided; 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.*

Since criteria are less restrictive than originally recommended, the recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the initial review of DUR Digest Volume 37, Number 2. There were no additional recommended changes beyond a typo correction on page 2.

MedWatch: The Commission members received FDA announcements pertinent to the program.

At 12:15, Chuck Wadle motioned to adjourn, and Rhea Hartley seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for August 6, 2025, format to be determined.