Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 6, 2025

The meeting was conducted in hybrid format, with participants attending both in person and remotely via Zoom. Those Commission members attending virtually notated below.

Attendees:

Commission Members Present
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Holly Randleman, Pharm.D.; Caitlin Reinking, Pharm.D. (via Zoom); Chuck Wadle, D.O.; Bryon Schaeffer, MD, FAAFP; Rhea Hartley, M.D. (via Zoom); Jennifer Johnson, Pharm.D.; Abby Cate, Pharm.D., Iowa Department of Health and Human Services; and Jordan Thoman, Wellpoint Iowa.

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 Emily Rogers, Pharm.D., Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the meeting to order at 9:33 a.m. The minutes from the May 7, 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, as well as a letter from the P&T Committee requesting the DUR Commission review and consider development of specific prior authorization (PA) criteria for Yorvipath were also reviewed. Annual chair and vice-chair elections were conducted. Chuck Wadle motioned to retain Melissa Klotz as chairperson, and Jason Kruse seconded. Melissa Klotz then motioned to retain Jason Kruse as vice-chairperson, and Bryon Schaeffer seconded. All members in attendance were in favor of both motions. Members were also asked to complete their annual conflict of interest disclosures.

DUR Recommendation Process

In order to speed up the DUR recommendation 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 when it was discussed at the May meeting. Pam

Smith brought a formal written process to this August meeting, and it will be implemented with this meeting with DHHS approval.

Iowa Medicaid Pharmacy Update

Lee Grossman will be the new Medicaid Director, effective September 2, 2025. He is an Iowa native and has been working for Wyoming Medicaid for the past 14 years. Jason Kruse and Melissa Klotz were just reappointed to the Commission for their third and final 4-year terms. Chuck Wadle's current term goes through the current state fiscal year to next July, but he has agreed to be re-appointed for a third term when it expires too. Rhea Hartley is also eligible for re-appointment, and Holly Randleman has agreed to serve a second term. Jordan Thoman will be the MCO representative on the Commission for the next two years. Going forward, one DUR Commission meeting per year, in August pending meeting room availability, will be held with a hybrid option, and the other three, in February, May and November, will be purely virtual. Location information will be available on the meeting agendas when they're posted to the www.iadur.org site.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2025 through May 2025.

Iowa Total Care: Emily Rogers provided an overview for ITC's statistics from March 2025 through May 2025.

Molina Healthcare*:* Candace Jordan provided an overview for Molina's statistics from March 2025 through May 2025.

Wellpoint Iowa*:* Jordan Thoman provided an overview for Wellpoint's statistics from March 2025 through May 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 $247,233,189 was spent in total for 1,971,207 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 comment(s) provided to Commission members, they heard oral public comments from the speakers shown below.

Name	Representing	Drug/Topic
Michele Rayes	HypoParathyroidism Association	Yorvipath
Jay Mehta	Axsome Therapeutics	Symbravo
Amy Hornig	Abbvie	Rinvoq

Written Provider Comments Received: None

Written Manufacturer Comments Received: Rinvoq

Retrospective DUR Data Presentations

Opioid Reversal Agent Frequency in Members with MME ≥90: Jordan Thoman from Wellpoint presented data for this initiative. Custom letters will be sent out directed at all in-network pharmacies regarding statewide protocol vs. the standing order. They will also include general education on opioid antagonists and how they are covered, noting no prior authorization is needed with correct NDCs from a provided list. A letter will also be posted to the www.iadur.org website and utilization monitored to confirm no additional actions or edits are needed.

Retrospective DUR Proposals

Risk of Hyperthermia with Scopolamine Patch: Data will be pulled to check the rate of utilization and to see if letters are warranted. Information will be brought back to the next meeting.

Utilization of SGLT2 Inhibitors in Members with CKD: Data will be pulled as recommended and results brought to the next meeting for review.

Commission Recommendations for Retrospective DUR Agenda Topics

1. Metformin utilization in Type 2 Diabetes
2. Quinolone over usage/Antibiotic resistance

Prospective DUR Proposals

Concurrent Use of GLP-1 RA and DPP-1 Inhibitor: At the May meeting, the Commission 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. There were no additional changes, so this recommendation will now go on to HHS as this was the second review of the proposal.

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

Prior Authorization

Anti-Diabetic Non-Insulin Agents: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for select preferred anti-diabetic, non-insulin agents subject to clinical criteria. 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. *For the treatment of Type 2 Diabetes Mellitus, a current A1C is provided; and*
3. *Requests for combination therapy with a DPP-4 inhibitor containing agent with a GLP-1 receptor agonist containing agent will not be considered; and*
4. *Requests for non-preferred antidiabetic, non-insulin agents subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class.*

Additionally, requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with at least 3 preferred agents from 3 different drug classes at maximally tolerated doses.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated. Requests for weight loss, which is not a covered diagnosis of use, will be denied.

Holly Randleman motioned to accept the criteria as amended, and Chuck Wadle seconded. All members were in favor. The recommendation will be sent to the Department for consideration.

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], or leukotriene receptor antagonist [LTRA] 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 both 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; or*

9. *Patient has a diagnosis of chronic spontaneous urticaria (CSU) with no known cause; and*
   a. *Patient has documentation of an adequate trial and therapy failure with a preferred second generation H1 receptor antihistamine for at least 2 weeks.*

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD and CSU, 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 and continued use of add-on maintenance therapy, where indicated.

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 amended, and Rhea Hartley seconded. All members were in favor. The recommendation will be sent to the Department for consideration.

Janus Kinase (JAK) 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 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; 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; 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; with*
      i. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
   d. *Moderately to severely active Crohn's disease; with*
      i. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
   e. *Polyarticular Course Juvenile Idiopathic Arthritis; with*
      i. *A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
      ii. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
   f. *Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis); with*
      i. *A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and*
      ii. *A documented trial and inadequate response with at least one preferred TNF inhibitor; OR*
   g. *Atopic dermatitis; with*
      i. *Documentation patient has failed to respond to good skin care and regular use of emollients; and*
      ii. *A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; or*
      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:*

1. *Affected area is less than 20% of body surface area (BSA); and*
2. *Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or*

v. *For moderate to severe atopic dermatitis:*
1. *A documented trial and therapy failure with a systemic drug product for the treatment of moderate to severe atopic dermatitis, including biologics; and*
2. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg; or*

h. *Nonsegmental vitiligo; with*
i. *A documented trial and inadequate response with a potent topical corticosteroid; or*
ii. *A documented trial and inadequate response with a topical calcineurin inhibitor; and*
iii. *The patient's body surface area (BSA) is less than or equal to the affected BSA per FDA approved label, if applicable; or*

i. *Giant Cell Arteritis; with*
i. *Documentation patient is currently taking a glucocorticoid, with a tapering dose, or has discontinued use of glucocorticoids.*

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 recommendation will be sent to the Department for consideration.

IL-5 Antagonists: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and*
a. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells/mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells/ mcL within 12 months prior to initiation of therapy; and*
b. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting*

beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and

c. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and*
d. *A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted in adults and < 90% in adolescents; or*

3. *Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and*
   a. *Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and*
   b. *One of the following:*
      i. *Eosinophil count > 1000 cells/mcL; or*
      ii. *Eosinophil count > 10% of the total leukocyte count; or*
4. *Patient has a diagnosis of hypereosinophilic syndrome (HES); and*
   a. *Patient has been diagnosed with HES for ≥ 6 months prior to starting treatment; and*
   b. *Documentation that non-hematologic secondary causes of HES have been ruled out; and*
   c. *Documentation patient does not have FIP1L1-PDGFRα kinase-positive HES: and*
   d. *Documentation of ≥ 2 HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and*
   e. *Patient has a blood eosinophil count ≥ 1,000 cells/mcL; and*
   f. *Medication will be used in combination with stable doses of at least one other HES therapy; or*
5. *Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); and*
   a. *Documentation mepolizumab will be used as an add-on maintenance treatment with a nasal corticosteroid spray; and*
   b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
      i. *Nasal corticosteroid; and*
      ii. *Oral corticosteroid; or*
6. *Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype; and*
   a. *Patient has moderate to very severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:*
      i. *FEV_1/FVC ratio < 0.7, and*
      ii. *FEV_1% predicted of 20% and 80%; and*

b. *Patient has a minimum blood eosinophil count of 150 cells/mcL, measured with in the past 12 months; and*
c. *Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to therapy with:*
    i. *Triple therapy with all of the following treatments:*
        1. *Long-acting muscarinic antagonist/anticholinergic (LAMA); and*
        2. *Long-acting beta2-agonist (LABA); and*
        3. *Inhaled corticosteroid (ICS); or*
    ii. *Double therapy with both of the following if ICS is contraindicated:*
        1. *LABA; and*
        2. *LAMA; and*
d. *Patient has a 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. *Documentation mepolizumab will be used as an add-on maintenance treatment with triple or double therapy (as defined above); and*

7. *Medication will be administered in the patient's home; and*
8. *Prescribed by or in consultation with an allergist, hematologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist.*

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis, 6 months for a diagnosis of hypereosinophilic syndrome or CRSwNP, or 12 months for a diagnosis of COPD to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

Severe Asthma with an Eosinophilic Phenotype:

1. *Patient continues to receive therapy with an ICS, LABA and LTRA; and*
2. *Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or*
3. *Patient has experienced a decrease in administration of rescue medication (albuterol); or*
4. *Patient has experienced a decrease in exacerbation frequency; or*
5. *Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline.*

Eosinophilic Granulomatosis with Polyangiitis

1. *Patient has demonstrated a positive clinical response to therapy (increase in remission time).*

Hypereosinophilic Syndrome:

1. *Patient has demonstrated positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and*
2. *Medication continues to be used in combination with stable doses or at least one other HES therapy.*

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. *Patient has demonstrated positive clinical response to therapy (improvement in symptoms); and*
2. *Continues to receive medication as add-on maintenance therapy with a nasal corticosteroid spray.*

Chronic Obstructive Pulmonary Disease (COPD)

1. *Patient has demonstrated positive clinical response to therapy; and*
2. *Continues to receive add-on maintenance therapy with triple or double therapy (as defined above).*

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 Holly Randleman seconded. All members were in favor. The recommendation will be sent to the Department for consideration.

Olezarsen (Tryngolza): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for olezarsen (Tryngolza). 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 familial chylomicronemia syndrome (FCS) confirmed by genetic testing, (e.g., biallelic pathogenic variants in FCS-causing genes [LPL, GPIHBP1, APOA5, APOC2, or LMF1]) (attach genetic testing results); and*
3. *The patient has a current fasting triglyceride level of 880 mg/dL or greater (attach current lipid panel obtained within the past 30 days); and*
4. *The patient will use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and*
5. *Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.*

If the criteria for coverage are met, initial requests will be given for 6 months. Requests for continuation of therapy will be considered at 12-month intervals under the following conditions:

1. *Documentation of a decrease in fasting triglyceride level from baseline (attach current lipid panel obtained within the past 30 days); and*
2. *Patient continues to use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and*
3. *Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.*

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 Department for consideration.

Omalizumab (Xolair): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe and autoinjector. Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit. 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 omalizumab (Xolair) prefilled syringe and autoinjector will be considered when patient has an FDA approved or compendia indication under the following conditions:

1. *Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and*
2. *The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and*
3. *Prescriber is an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist; and*
4. *For a diagnosis of asthma, chronic rhinosinusitis with nasal polyps, IgE-mediated food allergy, and any other FDA approved diagnosis where dosing is dependent on serum IgE level and body weight, the pretreatment IgE level and body weight in kilograms (kg), is provided. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment IgE levels and body weight. PA requests will be denied in these instances; and*
5. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and*
6. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

Moderate to Severe Persistent Asthma

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*

2. *Patient has a history of positive skin or RAST test to a perennial aeroallergen; and*
3. *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], or a leukotriene receptor antagonist [LTRA]), for a minimum of three (3) consecutive months of therapy. Patient must be compliant with therapy, based on pharmacy claims.*

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a high dose corticosteroid and controller medication (as defined above).

Chronic Spontaneous Urticaria

1. *Patient has a diagnosis of moderate to severe chronic spontaneous urticaria; and*
2. *Patient has documentation of an adequate trial and therapy failure with a preferred second generation H1 receptor antihistamine for at least two weeks.*

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. *Patient has a diagnosis of chronic rhinosinusitis with nasal polyps; and*
2. *Patient has documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
   a. *Nasal corticosteroid spray; and*
   b. *Oral corticosteroid; and*
3. *Will be used as an add on maintenance treatment.*

If criteria for coverage are met, the initial authorization will be given for 24 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.

IgE Mediated Food Allergy

1. *Medication is being prescribed for the reduction of allergic reactions (Type 1) that may occur with accidental exposure to one or more foods in a patient that has an IgE-mediated food allergy; and*
2. *Diagnosis is confirmed by a skin prick test or in vitro test (attach results); and*
3. *Will be used in conjunction with food allergen avoidance.*

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

Bryon Schaeffer motioned to accept the criteria as amended, and Jennifer Johnson seconded. All members were in favor. The recommendation will be sent to the Department for consideration.

Palopegteriparatide (Yorvipath): The Commission reviewed the newly proposed prior authorization criteria as follows:

Prior authorization (PA) is required for palopegteriparatide (Yorvipath). Payment will be considered when patient has an FDA approved or compendia indication 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 chronic hypoparathyroidism; and*
3. *Patient has had an inadequate response to maximally tolerated oral calcium and vitamin D analog (e.g., calcitriol) therapy; and*
4. *Documentation of baseline lab results (attach results obtained within 2 weeks prior to starting therapy) for:*
    a. *Serum 25 hydroxyvitamin D (25(OH)D) level within the normal range (20 to 80 ng/mL); and*
    b. *Albumin-corrected serum calcium level ≥ 7.8 g/dL; and*
5. *Is prescribed by or in consultation with an endocrinologist or nephrologist.*

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

1. *Documentation of a positive response to therapy, as evidenced by normalized albumin-corrected serum calcium level of 8.3 to 10.6 g/dL (attach lab results).*

Holly Randleman motioned to accept the criteria as amended, and Rhea Hartley seconded. All members were in favor. The recommendation will be sent to the Department for consideration.

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 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.

Givinostat (Duvyzat): The Commission reviewed the 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.

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.

Lebrikizumab-lbkz (Ebglyss): The Commission reviewed the 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.

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.

Nemolizumab-ilto (Nemluvio): The Commission reviewed the 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.

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 2. There were no additional recommended changes.

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

At 12:00, Jason Kruse motioned to adjourn, and Rhea Hartley seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for November 5, 2025, and will be in a virtual format only.