Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes May 5, 2021

Attendees:

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

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:32 a.m. This meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the March 3, 2021 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Jason Wilbur seconded. All members were in favor. The recommendation letter sent to DHS after the last DUR meeting was also reviewed.

IME Pharmacy Update

Jason Kruse and Melissa Klotz will begin their second terms in July. Meeting dates for 2022 will be reverting back to the previous schedule, with a meeting in February rather than March, to allow more time between that meeting and the following one in May. Liz Matney has been announced as the new Medicaid Director, effective June 1, 2021. The dispensing fee change included in the appropriations bill is still pending, with the legislature still in session.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from December 2020 through February 2021, including: total paid amount ($63,709,647.82); total prescriptions (761,500); and unique users (109,822). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns Outpatient Pharmacy, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Unity Point at Home, Hy-Vee Pharmacy Solutions, Nucara Specialty, and CVS. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Anti-TNF-alpha-Monoclonal Antibodies; Antipsychotics – Misc.; and Antiretrovirals. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and

HMG CoA Reductase Inhibitors. The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Synagis, and Invega Sustenna, while omeprazole, sertraline, albuterol, atorvastatin, and lisinopril had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from December 2020 through February 2021, including: total amount paid ($2,213,577), unique users (3,755); cost per user ($589.50), number of total prescriptions dispensed (22,870); and percent generic (89.1%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Anti-Inflammatories, Non-NSAID; Muscular Dystrophy Agents; and Stimulants – Amphetamines – Long Acting. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and GI – Proton Pump Inhibitors. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Evrysdi, Fintepla, Humira Pen, Vyvanse, and Invega Sustenna. The five drugs with the highest prescription counts were: trazodone hcl, clonidine hcl, sertraline hcl, omeprazole, and escitalopram.

Amerigroup*:* Lisa Todd provided an overview for Amerigroup's statistics from December 2020 through February 2021, including: total paid amount ($103,221,148); unique users (151,293); total prescriptions (1,079,016); generic prescriptions (967,324 totaling $19,956,404); brand prescriptions (111,692 totaling $83,264,743). The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Caremark Kansas Specialty, CVS Specialty, Hy-Vee Pharmacy Solutions, and Unity Point at Home. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Imflammatory; Antiasthmatic and Bronchodilator Agents; 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. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Latuda, Vraylar, and Ozempic. Omeprazole had the highest prescription count, followed by: sertraline hcl, trazodone hcl, atorvastatin calcium, and gabapentin.

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 $172,210.79 was spent in total for 261,123 unique users who had 1,833,413 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira and Vyvanse were the two most expensive drugs for the MCO plans. Humira was in third place for FFS, but Everysdi and Fintepla had the top 2 spots. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Jeffrey Wilharm had the overall highest prescription count at

4,345. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted on https://iadur.org on the Meeting Materials page.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet on https://iadur.org on the Meeting Materials page and summarized below, they heard oral public comment from the speakers shown below.

Name	Representing	Drug/Topic
Joseph Dang	Novartis	Entresto
Kevin Durkopf	Genzyme	Aubagio
Maggie Murphy	Teva	Austedo

Written Provider Comments Received:
Dermatologic disease prior authorization requirements, Risdiplam, various criteria and edit issues at the pharmacy level, Hepatitis C, Xofluza

Written Manufacturer Comments Received: Austedo

Retrospective DUR Data Presentations

Concurrent Opioids and Benzodiazepines: Pam Smith and the MCO staff will research what other payors and states are doing with regards to this issue. Melissa Klotz thought it might be helpful to look at the strengths of medications and not just overall number of members, as those on higher dosages would be at more risk. Kellen Ludvigson also suggested looking at reviewing current quantity limits on benzodiazepines to narrow some down as they are not very stringent. This topic is included in the SUPPORT Act and required for CMS reporting, optional this year, but mandatory in 2 years.

Duplicate Therapy – Benzodiazepines: Letters will be sent to prescribers for members taking 2 or more anxiolytic benzodiazepines or sedative hypnotics, pointing out the duplicative therapy and increased risk of adverse effects, including physical and psychological dependence, and asking if one agent could be slowly tapered and discontinued or if alternatives to benzodiazepines could be used (i.e. antidepressants, buspirone or cognitive behavior therapy for anxiety; sleep hygiene for insomnia). Kellen Ludvigson also motioned to implement a ProDUR duplicate therapy benzodiazepine edit, and Jason Wilbur seconded. All members were in favor.

Single Ingredient Buprenorphine: Susan Parker suggested combining data sets from both MCOs and FFS to identify any recurring providers, then target those providers rather than approaching the issue from a member perspective. Letters will then be sent to prescribers inquiring about use of single ingredient buprenorphine tablets and asking if buprenorphine/naloxone would be appropriate for the member and encouraging use of buprenorphine/naloxone for all patients.

Retrospective DUR Proposals

Montelukast for Allergic Rhinitis: Data will be re-run to exclude members with an asthma diagnosis from the results. Updated data will be brought to the next meeting.

GERD and PPI Therapy: Discussion centered around the large number of members that would most likely be identified with ≥ 90 days therapy and suggested narrowing the focus. After discussion, the Commission recommended focusing on members newly started on a PPI and members on high dose PPI. Updated data will be brought back to the next meeting.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional topic suggestions.

The Commission took a short break and open session resumed at 11:40 a.m.

Prospective DUR

Budesonide/Formoterol Inhalation Aerosol & Mometasone/Formoterol Inhalation Aerosol: Jason Kruse motioned to accept the recommended quantity limit, allowing 2 inhalers per 30 days. Kellen Ludvigson seconded, and Jason Wilbur abstained as he felt he did not have sufficient knowledge of the topic. All other members were in favor, and the motion passed. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Prior Authorization

Proton Pump Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day.

Requests for PPIs exceeding one unit per day will be considered for the following diagnoses with additional documentation regarding the medical necessity:

1. *Barrett's esophagus, Erosive esophagitis, or Peptic stricture (Please fax a copy of the scope results with the initial request); or*
2. *Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, and multiple endocrine adenomas); or*
3. *Recurrent peptic ulcer disease; or*
4. *Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with the requested PPI at maximal dose within the established quantity limit of one unit per day. Requests for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a dose reduction to the recommended once daily dosing will be required. A trial of the recommended once daily*

dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day; or

5. *Helicobacter pylori will be considered for up to 14 days of treatment with documentation of active infection.*

Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products.

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

Valsartan/Sacubitril (Entresto): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for valsartan/sacubitril (Entresto). Requests above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and*
    a. *Patient has a left ventricular ejection fraction (LVEF) ≤40%; and*
    b. *Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and*
    c. *Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); or*
3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class ll to IV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤40%; and*
4. *Will not be used in combination with an ACE inhibitor or ARB; and*
5. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
6. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
7. *Patient is not pregnant; and*
8. *Patient does not have severe hepatic impairment (Child Pugh Class C); and*

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

Jason Kruse motioned to remove the prior authorization criteria, and Jason Wilbur seconded. All members were in favor. Kellen Ludvigson then motioned to implement a quantity limit of 60 for 30 for all strengths, which John Ellis seconded. This decision was unanimous, as well. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Initial Days Supply Limit Override: The Commission reviewed the prior authorization criteria as follows:

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

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

Requests for non-opioid drugs subject to the initial days' supply limit will be considered on an individual case-by-case basis, based on medical necessity documentation provided.

Jason Kruse motioned to accept the criteria as amended, and Kellen Ludvigson 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.

Mannitol Inhalation Powder (Bronchitol): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for mannitol inhalation powder (Bronchitol). Payment will be considered when the following criteria are met:

1. *Patient has a diagnosis of cystic fibrosis; and*
2. *Patient meets the FDA approved age; and*
3. *Prescriber is a cystic fibrosis specialist or pulmonologist; and*
4. *Documentation is provided that patient has successfully completed the Bronchitol tolerance test (BTT); and*
5. *Patient will pre-medicate with a short-acting bronchodilator; and*
6. *Dose does not exceed the FDA approved dose.*

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. *Adherence to mannitol inhalation powder (Bronchitol) therapy is confirmed; and*
2. *Patient has demonstrated improvement or stability of disease symptoms, such as improvement in FEV_1, decrease in pulmonary exacerbations, decrease in hospitalizations, or improved quality of life.*

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

Vesicular Monoamine Transporter (VMAT) 2 Inhibitors: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:
<u>Tardive Dyskinesia</u> (Ingrezza or Austedo)

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:*
    a. *Involuntary athetoid or choreiform movements*
    b. *Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)*
    c. *Symptoms lasting longer than 4-8 weeks; and*
3. *Prescribed by or in consultation with a neurologist or psychiatrist; and*
4. *Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and*
5. *Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and*
6. *For Ingrezza:*
    a. *Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and*
    b. *Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and*
    c. *Is prescribed within the FDA approved dosing; or*
7. *For Austedo:*
    a. *Patient does not have hepatic impairment;*

b. *Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and*
c. *Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and*
d. *Is prescribed within the FDA approved dosing.*

If criteria for coverage are met, initial requests will be given for 3 months.
Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to meet the criteria for initial approval; and*
2. *Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS).*

Chorea associated with Huntington's disease (Austedo or tetrabenazine)

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of Huntington's disease with chorea symptoms; and*
3. *Prescribed by or in consultation with a neurologist or psychiatrist; and*
4. *Is prescribed within the FDA approved dosing; and*
5. *Patient is not suicidal, or does not have untreated or inadequately treated depression; and*
6. *Patient does not have hepatic impairment; and*
7. *Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and*
8. *For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and*
9. *In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following:*
    a. *Austedo - 36mg per day (18mg single dose) or*
    b. *Tetrabenazine – 50mg per day (25mg single dose)*

If criteria for coverage are met, initial requests will be given for 3 months.
Continuation of therapy will be considered when the following criteria are met:

1. *Patient continues to meet the criteria for initial approval; and*
2. *Documentation of improvement in chorea symptoms is provided.*

Chuck Wadle motioned to accept the criteria as amended, and Jason Kruse 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.

Risdiplam (Evrysdi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for risdiplam (Evrysdi). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of spinal muscular atrophy (SMA); and*
2. *Patient meets the FDA approved age for diagnosis; and*
3. *Dosing follows FDA approved dose for age and weight; and*

4. *A negative pregnancy test for females of reproductive potential prior to initiating treatment; and*
5. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least 1 month after last dose and male patients of reproductive potential have been counseled on the potential effects on fertility; and*
6. *Patient does not have impaired liver function; and*
7. *Will not be prescribed concomitantly with other SMA treatments, such as Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec), or any other new products that are approved by the FDA and released; and*
8. *Documentation of previous SMA therapies and response to therapy is provided; and*
    a. *For patients currently on Spinraza, documentation Spinraza will be discontinued is provided, including date of last dose, and the appropriate interval based on the dosing frequency of the other drug has been met (i.e. 4 months from the last dose when on maintenance therapy); or*
    b. *For patients treated with Zolgensma, requests will not be considered; and*
9. *Is prescribed by or in consultation with a neurologist; and*
10. *Pharmacy will educate the member, or member's caregiver, on the storage and administration of Evrysdi, as replacements for improper storage or use will not be authorized.*

If the criteria for coverage are met, requests will be approved for 1 year. Requests for continuation of therapy will require documentation of a positive response to therapy including stabilization or improved function unless intercurrent event (fracture, illness, other) affects functional testing.

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.

Binge Eating Disorder: The Commission reviewed the prior authorization criteria as follows:

Binge Eating Disorder (Vyvanse only)

a. *Patient is 18 to 55 years of age; and*
b. *Patient meets DSM-5 criteria for Binge Eating Disorder (BED); and*
c. *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and*
d. *Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month*

period, that did not significantly reduce the number of binge eating episodes; and

e. *Prescription is written by a psychiatrist, psychiatric nurse practitioner, or psychiatric physician assistant; and*
f. *Patient has a BMI of 25 to 45; and*
g. *Patient does not have a history of cardiovascular disease; and*
h. *Patient has no history of substance abuse; and*
i. *Is not being prescribed for the treatment of obesity or weight loss; and*
j. *Doses above 70mg per day will not be considered.*
k. *Initial requests will be approved for 12 weeks.*

Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

<u>DSM-5 Criteria</u>

i. *Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and*
ii. *The binge eating episodes are marked by at least three of the following:*
    1. *Eating more rapidly than normal*
    2. *Eating until feeling uncomfortably full*
    3. *Eating large amounts of food when not feeling physically hungry*
    4. *Eating alone because of embarrassment by the amount of food consumed*
    5. *Feeling disgusted with oneself, depressed, or guilty after overeating; and*
iii. *Episodes occur at least 1 day a week for at least 3 months; and*
iv. *No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and*
v. *Does not occur solely during the course of bulimia nervosa or anorexia nervosa.*

<u>Moderate to Severe BED</u>

Based on the number of binge eating episodes per week:
Moderate - 4 to 7
Severe – 8 to 13
Extreme – 14 or more

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.

IL-5 Antagonists: The Commission reviewed the 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 under the following conditions:

1. *Is requested for an FDA approved or compendia indicated diagnosis; and*
2. *Patient meets the FDA approved or compendia indicated age and dose for submitted diagnosis; and*
3. *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*
4. *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*
5. *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-PDGFR□ 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; and*
6. *Prescribed by or in consultation with an allergist, hematologist, immunologist, 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 or 6 months for a diagnosis of hypereosinophilic syndrome to assess the need for continued therapy. Requests for continuation of

therapy will be based on continued medical necessity and will be considered when 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 a 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 of at least one other HES 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.

Isotretinoin (Oral): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for oral isotretinoin therapy. Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Payment will be considered for preferred oral isotretinoin products for moderate to severe acne under the following conditions:

1. *There are documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative (tretinoin or adapalene) therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical vitamin A derivative therapy are not required for approval for treatment of acne conglobata; and*
2. *Prescriber attests patient has enrolled in and meets all requirements of the iPLEDGE program.*

Initial authorization will be granted for up to 24 weeks. A minimum of 8 weeks without therapy is required to consider subsequent authorizations.

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.

Multiple Sclerosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

For patients initiating therapy with a preferred oral multiple sclerosis agent, a manual prior authorization (PA) is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *Request must adhere to all FDA approved labeling, including indication, age, dosing, contraindications, and warnings and precautions; and*
3. *Documentation of a previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.*

Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

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.

Nonsteroidal Anti-Inflammatory Drugs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for all non-preferred nonsteroidal anti-inflammatory drugs (NSAIDs). Payment for a non-preferred NSAID will be considered under the following conditions:

1. *Documentation of previous trials and therapy failures with at least three preferred NSAIDs; and*
2. *Requests for a non-preferred extended release NSAID must document previous trials and therapy failures with three preferred NSAIDs, one of which must be the preferred immediate release NSAID of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance.*

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.

Alpha$_2$ Agonists, Extended Release: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:

1. *The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
2. *Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
3. *Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant.*

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

At the March meeting, the commission voted to remove the criteria as recommended, but keep the ProDUR age edit. A claim for a preferred alpha$_2$ agonist, extended release, will adjudicate when the member is between 6 and 17 years of age (and meets already established quantity limits); requests for a non-preferred agent will require prior authorization. No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the initial review of the draft DUR Digest Volume 33, Number 2. A typo in the second paragraph will be corrected.

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

At 12:19, Kellen Ludvigson motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for August 4, 2021, and will be a virtual meeting.