Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 5, 2020

Attendees:

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

Welcome & Introductions

Pam Smith called the meeting to order at 9:35 a.m. She performed the usual chairperson duties as this meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the March 4, 2020 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Jason Kruse seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed.

Commission Recommendations for Retrospective DUR Agenda Topics

The Commission did not have any new recommendations.

Public Comment Policy – Virtual Meetings

Pam Smith read through the proposed public comment policy. The Commission would like to allow both written and verbal public comment, but requested that those submitting written comment also fill out a conflict of interest form in advance of the meeting. They also felt use of video when providing verbal comment would be helpful, and wanted to add an amendment to the policy to encourage video usage if possible, though it would not be mandatory. Pam Smith suggested that those asking to provide verbal comment be required to sign up prior to the meeting, rather than the morning of the meeting. Jason Wilbur motioned to accept the policy as amended, and Kellen Ludvigson seconded. The decision was unanimous.

IME Pharmacy Update

Medicaid Director Mike Randol has resigned, and Julie Lovelady will be Interim Director. A set of rules relating to pharmacists enrolling as providers have been delayed due to COVID-19. Informational Letter 2153 notified providers that the effective date for these rules was changed to June 1, 2021. The legislature also extended the related Iowa Code changes. Providers received Informational Letter 2119-MC-FFS-CVD and Informational Letter 2123-MC-FFS-CVD in response to COVID-19 regarding PA extensions, copayment issues, early refills, signature guidelines, and audit suspension. CMS has provided an update to a provision on the SUPPORT Act, requiring state Medicaid

programs to cover Medication Assisted Treatment (MAT) for opioid use disorder, including the behavioral therapy component as well as the medication component, effective October 1, 2020 for a five-year period. As a result, these drugs, when used as a component of MAT, will no longer be eligible for the national Medicaid drug rebate, because that rebate applies only to drugs covered under an optional prescription drug benefit. This will also remove their eligibility for 340B and supplemental rebate programs. The impact in Iowa will not be as substantial as in many states, due to Iowa preferring buprenorphine-naloxone tablets on the PDL.

There is still an opening for a doctor on the DUR Commission, as Mark Graber has reached the end of his 3 allowable terms, and was unfortunately not able to attend his last meeting that was cancelled due to COVID-19.

The updated DUR Meeting schedule has been posted on the https://iadur.org/ site, with the next one being in November 2020, then March and May 2021.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2020 through June 2020, including: eligible users (38,120); total amount paid ($2,025,281), unique users (4,003); cost per user ($505.94), number of total prescriptions dispensed (24,362); and percent generic (87.8%). The top 100 pharmacies by paid amount report was largely influenced by specialty drugs. Meskwaki, which was #1 on the list, gets an encounter rate of the same flat rate for each drug; encounter claims do not qualify for dispensing fees. The top 5 prescribing providers by prescription count were: Michael Ciliberto, Joada Jean Best, Leighton Frost, Molly Earleywine, and Melissa Konken. The top 5 therapeutic classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Antipsychotics – Atypicals; Antineoplastics – Protein-Tyrosine Kinase Inhibitors; and Diabetic – Insulin Penfills. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Vyvanse, Invega Systenna, Sutent, and Enbrel Sureclick. The five drugs with the highest prescription counts were: trazodone hcl, montekulast sodium, gabapentin, omeprazole, and clonidine hcl.

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from March through June 2020, including: eligible users (approximately 274,000); total paid amount ($61,817,075.08); total prescriptions (730,717); and unique users (98,907). 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, Nucara Specialty, Hy-Vee Pharmacy Solutions, Unity Point at Home, and CVS

Caremark. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Antiretrovirals; Anti-TNF-alpha-Monoclonal Antibodies; and Antipsychotics - Misc. 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, Trikafta, Invega Sustenna, and Novolog, while omeprazole, atorvastatin, lisinopril, sertraline, and levothyroxine sodium had the top 5 prescription counts.

Amerigroup *(provided at the end of the meeting as Lisa Todd was not yet present at this point in the agenda):* Lisa Todd provided an overview for Amerigroup's statistics from March 2020 through June 2020, including: eligible users (approximately 385,000); total paid amount ($100,195,886); unique users (143,428); total prescriptions (1,145,753); generic prescriptions (1,024,019 totaling $21,440,670); brand prescriptions (121,734 totaling $78,755,216). 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, CVS Specialty, Caremark Kansas Specialty, Hy-Vee Pharmacy Solutions, and Caremark Illinois Specialty. On the top 100 prescribing providers by prescription count report, Jeffrey Wilham took the top spot, followed by: Thomas Earwood, Charles Tilley, Mark Mittauer, and Jennifer Zalaznik. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; and Analgesics – Anti-Inflammatory. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Humira (CF) Pen, Latuda, Invega Sustenna, and Vraylar. Omeprazole had the highest prescription count, followed by: atorvastatin calcium, sertraline hcl, lisinopril, and trazodone hcl.

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 $164,038,242 was spent in total for 246,338 unique users who had 1,900,832 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 all 3 plans. 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 4,706. All three complete prevalence reports and the comparative summary can be found in the finalized meeting packet posted at https://iadur.org/sites/default/files/ghs-files//08-06-20-dur-packet-updated-3.pdf.

Public Comment

As this meeting was purely virtual, only written public comment was accepted. The committee members reviewed the received comments, which have been posted in the finalized meeting packet at: https://iadur.org/sites/default/files/ghs-files//08-06-20-dur-packet-updated-3.pdf.

Retrospective DUR Data Presentations

Duplicate SNRIs: Educational letters will be sent to the the providers regarding members identified as having had fills of 2 or more concurrent SNRIs within 60 days. The letters will be educational in nature, pointing out the combined use of two or more chemically distinct SNRIs asking if one of the agents could be discontinued, while also warning that a ProDUR edit may be implemented in the future. The Commission will follow-up on this issue in 12 months.

Gabapentin and Baclofen: Educational letters will be sent to providers regarding members exceeding 80mg baclofen per day, alerting the provider the dose exceeds the maximum daily dose and asking if the dose could be decreased. Educational letters will also be sent to providers regarding members with concurrent baclofen and opioid use, warning them of the increased risk of respiratory and CNS depression and asking if one or both agents could be discontinued or if the dose of either agent could be decreased. In addition, Kellen Ludvigson motioned to implement a quantity limit of 4 tablets daily (120/30 days) across all strengths of baclofen as recommended. Jason Kruse seconded, and all members were in favor.

Retrospective DUR Proposals

Concurrent Use of Gabapentin and Pregabalin: Claims will be queried to identify members with multiple claims for both gabapentin and pregabalin over a 3-month period and bring the results back to the next meeting for further discussion.

Concurrent Use of a SSRI and SNRI: Claims will be queried to identify members with multiple claims for both an SNRI and SSRI over a 3-month period to see how many members and prescribers would be involved. The data will be brought back to the next meeting for further discussion.

The Commission took a short break and open session resumed at 11:02.

Prior Authorization

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

No prior authorization (PA) is required for preferred acute migraine treatments, as

indicated on the Preferred Drug List (PDL). PA is required for acute migraine treatments under the following conditions:

1. *A diagnosis of acute migraine; and*
2. *Patient meets the FDA approved age for requested agent; and*
3. *For preferred acute migraine treatments where PA is required, as indicated on the PDL, documentation of previous trials and therapy failures with two preferred agents that do not require PA; and/or*
4. *For non-preferred acute migraine treatments, documentation of previous trials and therapy failures with two preferred agents that do not require PA. Requests for non-preferred CGRP inhibitors will also require documentation of a trial and therapy failure with a preferred CGRP inhibitor; and/or*
5. *For quantities exceeding the established quantity limit for each agent, documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications; and/or*
6. *For non-preferred combination products, documentation of separate trials and therapy failures with the individual ingredients, in addition to the above criteria for preferred or non-preferred acute migraine treatments requiring PA.*

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

Jason Kruse motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. Melissa Klotz then motioned to implement the suggested quantity limits shown below, changing lasmiditan 50mg to 8 per 30 days, and Jason Kruse seconded. This was also unanimous.

- Triptans – keep current limit of 12 unit doses of tablets, syringes or sprays per 30 days.
- Other acute migraine treatments – based on label dosing and safety of treating more than the specified number of migraines in a 30-day period.
    - Ubrogepant – 16 tablets per 30 days for each strength
    - Rimegepant – 15 tablets per 30 days
    - Lasmiditan – 50mg tablet – 8 tablets per 30 days; 100 mg tablet - 8 tablets per 30 days

The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Perfenidone (Esbriet)/Nintedanib (Ofev): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Is prescribed by a pulmonologist; and*

3. *Patient does not have hepatic impairment as defined below:*
    a. *Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or*
    b. *Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and*
4. *Patient does not have renal impairment as defined below:*
    a. *Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or*
    b. *Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and*
5. *Patient does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib, and*
6. *Patient has a diagnosis of idiopathic pulmonary fibrosis (nintedanib or pirfenidone) as confirmed by one of the following (attach documentation):*
    a. *Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or*
    b. *A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and*
    c. *Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity;): and*
    d. *Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and*
    e. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; or*
7. *Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib)as confirmed by the following (attach documentation); and*
    a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
    b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and*
    c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted; or*
8. *Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) as confirmed by the following (attach documentation); and*
    a. *Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and*
    b. *Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and*
    c. *Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted; and*

d. *Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:*
    i. *A relative decline in the FVC of at least 10% predicted; or*
    ii. *A relative decline in the FVC of 5-9% predicted combined with at least one of the following:*
        1. *Worsening respiratory symptoms; or*
        2. *Increased extent of fibrosis on HRCT; or*
    iii. *Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.*

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

1. *Adherence to pirfenidone (Esbriet) or nintedanib (Ofev) is confirmed; and*
2. *Documentation of a positive response to therapy, defined as meeting at least one of the following:*
    a. *Rate of lung function decline slowed; or*
    b. *Improved or no worsening of symptoms of cough or shortness of breath; and*
3. *Documentation is provided that the patient has remained tobacco-free; and*
4. *ALT, AST, and bilirubin are assessed periodically during therapy.*

Jason Kruse motioned to accept the criteria as modified, and Melissa Klotz 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.

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors: The Commission reviewed the 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. *Patient meets the FDA approved age; and*
2. *Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and*
3. *Documentation is provided that medication will be used in combination with a maximally tolerated statin; and*
4. *A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and*
5. *Patient will continue to follow an appropriate low fat diet; and*
6. *Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and*
7. *If patient is taking in combination with:*
    a. *Simvastatin, dose does not exceed 20mg per day; or*
    b. *Pravastatin, dose does not exceed 40 mg per day; and*

8. *Concurrent use with a PCSK9 inhibitor will not be considered; and*
9. *Goal is defined as a 50% reduction in untreated baseline LDL-C; and*
10. *Is prescribed for one of the following diagnoses:*
    a. *Heterozygous Familial Hypercholesterolemia (HeFH):*
        i. *Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:*
            1. *Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma); or*
            2. *Confirmation of diagnosis by gene or receptor testing; and*
        ii. *Documentation of untreated LDL-C ≥ 190 mg-dL; and*
        iii. *Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or*
    b. *Clinical Atherosclerotic Cardiovascular Disease (ASCVD):*
        i. *History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and*
        ii. *Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.*

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:

a. *Patient continues therapy with a maximally tolerated statin dose and remains at goal; and*
b. *Patient continues to follow an appropriate low fat diet; and*
c. *Documentation of LDL reduction is provided.*

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

Brett Faine motioned to accept the criteria as recommended, 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.

Peanut Allergen Powder-dnfp: The Commission reviewed the 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. *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*
2. *Patient is 4 to 17 years of age at initiation of therapy or 4 years of age and older for continued up-dosing and maintenance therapy; and*
3. *Prescribed by or in consultation with an allergist or immunologist; and*
4. *Patient has access to injectable epinephrine; and*
5. *Will be used in conjunction with a peanut-avoidant diet; and*
6. *Patient does not have any of the following:*
    a. *Uncontrolled asthma; and/or*
    b. *A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and*
7. *Patient will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility; and*
8. *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 dose is provided via the Office Dose Kit; and*
9. *Follows FDA approved dosing; and*
10. *PA is required for all up-dosing dose levels (dose level 1 through 11); and*

Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

Jason Kruse motioned to accept the criteria as recommended, 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.

Cystic Fibrosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for oral cystic fibrosis agents. Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of cystic fibrosis (CF); and*
3. *Patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test (attach test results) for which the requested drug is indicated; and*

4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST, ALT, and bilirubin) are provided; and*
6. *Requests for Trikafta will not be considered for patients with severe hepatic impairment (Child-Pugh Class C); and*
7. *Will not be used with other CFTR modulator therapies.*

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 oral cystic fibrosis therapy is confirmed; and*
2. *Liver function tests (AST, ALT, and bilirubin) are assessed every 3 months during the first year of treatment and annually thereafter.*

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.

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 II 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 II 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).*

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.

Novel Oral Anticoagulants: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred novel oral anticoagulants (NOACs). PA is required for non-preferred NOACs. 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 NOACs; 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.

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.

Voxelotor (Oxbryta): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Oxbryta (voxelotor). Payment will be considered for patients when the following criteria are met:

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of sickle cell disease (SCD); and*
3. *Requested dose is within the FDA approved dosing; and*
4. *Patient has experienced at least two sickle cell-related vasoocclusive crises within the past 12 months (documentation required); and*

5. *Patient has documentation of an adequate trial and therapy failure with hydroxyurea; and*
6. *Baseline hemoglobin (Hb) range is ≥5.5 to ≤10.5 g/dL; and*
7. *Is prescribed by or in consultation with a hematologist; and*
8. *Patient is not receiving concomitant blood transfusion therapy.*

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. *Documentation of an increase in hemoglobin by ≥1 g/dL from baseline; and*
2. *Documentation of a decrease in the number of sickle cell-related vasoocclusive crises.*

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.

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 will be considered under the following conditions:

1. *Patient meets the FDA approved age for submitted diagnosis; and*
2. *Is dosed within FDA approved dosing for submitted diagnosis and age; 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 per mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells per 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 greater than 1000 cells/mcL; or*
    ii. *Eosinophil count greater than 10% of the total leukocyte count; and*

5. *Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.*

If criteria for coverage are met, an initial authorization will be given for 3 months 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).*

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.

Insulin, Pre-Filled Pens: The Commission reviewed the prior authorization criteria recommended to be removed as follows:

Prior authorization (PA) is required for pre-filled insulin pens as designated on the Preferred Drug List (PDL). For pre-filled insulin pens requiring PA where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. *The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and*
2. *There is no caregiver available to provide assistance, and*
3. *Patient does not reside in a long-term care facility, and*

4. *For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).*

For pre-filled insulin pens requiring PA where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. *Preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and*
2. *Non-preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).*

Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.

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 the draft DUR Digest Volume 32, Number 2.

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

At 12:14, Jason Kruse motioned to adjourn, and Chuck Wadle seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for November 4, 2020, with location or virtual status to be determined.