Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 4, 2020

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.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Emily Rogers, Iowa Total Care; and Lisa Todd, Amerigroup.

Welcome & Introductions

Pam Smith called the meeting to order at 9:31 a.m. She performed most of the usual chairperson duties as this meeting was purely virtual and done through WebEx teleconference due to COVID-19. The minutes from the August 5, 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 DUR meeting was also reviewed, along with a recommendation letter from the P&T Committee to the DUR Commission requesting development of prior authorization (PA) criteria for Nexletol, Nurtec ODT, Oxbryta, Palforzia, Reyvow, and Ubrelvy. Kellen Ludvigson motioned to retain Brett Faine as chairperson, and Jason Wilbur seconded. Jason Kruse then motioned to retain Kellen Ludvigson as vice-chairperson, and Brett Faine seconded. All members in attendance were in favor of both motions. Members were also asked to complete their annual conflict of interest disclosures. The revised public comment policy as discussed at the August meeting is now posted online at www.iadur.org. Conflict of interest forms are now required for both written and verbal comments, and those wanting to speak during the meeting will need to register in advance, as long as meetings continue to be held virtually.

Commission Recommendations for Retrospective DUR Agenda Topics

Fraud, Waste, and Abuse: The commission did not have any new recommendations. Pam Smith said that IME and MCO staff had discussed some ideas and will bring those back to future meetings. Jason Wilbur asked if the IME had access to PMP reports. Pam Smith said that IME had limited access to PMP information, likely not down to prescriber level. Susan Parker added that there were provisions in the SUPPORT Act, she believed effective in 2023, that do require obtaining some information from the PMP programs relative to Medicaid provider prescribing. The IME is still figuring out how to comply with those provisions given the current level of PMP access. CMS has not provided much guidance as of yet, but more will hopefully be coming in the future.

IME Pharmacy Update

The potential loss of rebates on Medication Assisted Treatment (MAT) medications due to a provision of the SUPPORT Act passed by Congress was discussed at the last meeting. However, since then, Congress has fixed the language in the SUPPORT Act, so states and the federal government can continue to receive the applicable rebates. The IME has moved into the Hoover Building in the Capitol Complex, 1305 East Walnut Street, though most employees continue to work remotely. The cost of dispensing study report, final in June 2020, has been posted on the reimbursement website. $10.38 per prescription was the mean cost reflected from that study, for all pharmacies including specialty. $9.71 was the mean without specialty pharmacies included. The current dispensing fee of $10.07 will remain in place until additional state funding is appropriated by the legislature, and a state plan amended has been completed thereafter.

Prevalence Report Summaries

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from June through August 2020, including: total paid amount ($58,155,843.50); total prescriptions (700,820); and unique users (100,698). 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, CVS, and Unity Point at Home. 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, Invega Sustenna, Trikafta, and Novolog, while omeprazole, atorvastatin, sertraline, lisinopril, and trazodone had the top 5 prescription counts.

Amerigroup*:* Lisa Todd provided an overview for Amerigroup's statistics from June 2020 through August 2020, including: total paid amount ($97,831,718); unique users (145,254); total prescriptions (1,091,035); generic prescriptions (979,720 totaling $20,006,784); brand prescriptions (111,315 totaling $77,824,934). 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 Nucara Specialty. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; Analgesics – Anti-Inflammatory; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Antipsychotics/Antimanic Agents. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Latuda, Invega Sustenna,

and Vraylar. Omeprazole had the highest prescription count, followed by: sertraline hcl, atorvastatin calcium, trazodone hcl, and lisinopril.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2020 through August 2020, including: total amount paid ($1,891,467), unique users (3,679); cost per user ($514.13), number of total prescriptions dispensed (22,615); and percent generic (89.0%). The top 5 therapeutic classes by paid amount were: Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Anticonvulsants; Diabetic – Insulin Penfills; 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: Humira Pen, Vyvanse, Latuda, Invega Systenna, and Enbrel Sureclick. The five drugs with the highest prescription counts were: clonidine hcl, omeprazole, trazodone hcl, sertraline hcl, and lisinopril.

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 $157,879,029 was spent in total for 249,631 unique users who had 1,814,470 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 4,428. 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//november42020dur-packet.pdf. Kellen Ludvigson asked how long COVID-19 POS overrides would be an option, and Susan Parker replied that was not yet decided, but that providers and pharmacies would be notified in advance of any changes. Pam Smith will pull additional information on providers with 40-50+ prescriptions per day, and bring that to the next meeting.

Public Comment

In addition to the written public comments provided to Commission members, posted in the finalized meeting packet at: https://iadur.org/sites/default/files/ghs-files//november42020dur-packet.pdf, they heard oral public comment from the speakers listed below. Kellen Ludvigson suggested adding a check box to the conflict of interest form for those wishing to provide comment, specifying whether it would be written or oral, to make administrative planning easier while meetings are being held remotely.

Name	Representing	Drug/Topic
Stephanie Kennedy	Greenwich Biosciences	Epidiolex
Brett McCabe	Aimmune Therapeutics	Palforzia
Jim Baumann	Pfizer	Eucrisa & Xeljanz/XR
Jenna Gianninoto	AbbVie	Oriahnn
Craig Biggs	Genentech	Evrysdi & Enspryng

ProDUR Edits

Baclofen Quantity Limits: At the August meeting, the DUR voted to make a recommendation to implement a quantity limit of 120 tablets per 30 days on all strengths of baclofen tablets. As this was the second review, with no further changes, the recommendation will be sent to the Department for consideration.

Retrospective DUR Data Presentations

Concurrent Use of Gabapentin and Pregabalin: Educational letters will be sent to providers regarding members identified as having concurrent claims of gabapentin and pregabalin, alerting the provider to the therapeutic duplication, the lack of evidence of an increased therapeutic benefit with the use of these medications concurrently, and asking if one agent could be discontinued. Given the small number of members meeting the criteria, Kellen Ludvigson also suggested phone calls to providers instead.

Concurrent Use of an SSRI and SNRI: The Commission questioned how the MCOs had found such varying member counts in their results. The data will be re-run, confirming specific drugs that are included, and brought to the next meeting.

Duplicate Therapy – Opioids: Educational letters will be sent to providers regarding members identified as using 3 or 4 unique opioids, alerting the provider to the therapeutic duplication and asking if one or more opioids could be discontinued. More information will be gathered for those members on 2 unique opioids, and brought back to the next meeting.

Retrospective DUR Proposals

Duplicate Therapy – Skeletal Muscle Relaxants: There is no evidence that concurrent use of two or more skeletal muscle relaxants offers any additional therapeutic benefit and puts patients at an increased risk of adverse effects. The Commission would like to proceed with this study proposal, identifying members with two more chemically distinct skeletal muscle relaxants, with at least 45 days overlap, over a 3 month period. Data results will be brought back to the next meeting.

Concurrent Gabapentinoid and Opioid: Data will be run to identify members with claims for a gabapentinoid and opioid, with at least 60 days overlap, over a 3 month period. The Commission will review the findings at the next meeting before deciding on any potential course of action.

The Commission took a short break and open session resumed at 11:32.

Prior Authorization

Annual Review of Prior Authorization Criteria: Changes were suggested for the following categories, to be discussed at upcoming meetings.

PA Category	Recommended Changes
Alpha2 Agonists, Extended-Release	Possibly remove criteria, check utilization first.
Anti-Diabetics, Non-Insulin Agents	Add criteria for SGLT2 use for heart failure, if agent is not already preferred on the PDL.
Crisaborole (Eucrisa)	Modify to account for member age and appropriate use of high-potency corticosteroids.
Hepatitis C Treatments	Look at ways Medicaid might help get people referred to specialists.
Isotretinoin (Oral)	Re-evaluate iPLEDGE enrollment and allow 24 week therapy needs.
Janus Kinase Inhibitors	Request P&T evaluate requirement for two preferred biological DMARDs as patients often do not want to try the injectables.
Multiple Sclerosis Agents-Oral	Try to simplify and shorten as criteria is getting long with so many oral options now available.
Nonsteroidal Anti-inflammatory Drugs	Possibly simplify now that there are so many preferred agents.
PCSK9 Inhibitors	On #6 allow consultation with a specialist.
Proton Pump Inhibitors	Consider revising #5 with regards to once daily dosing.
Topical Acne and Rosacea Products	Review due to reported prior authorization denial rate.
Vesicular Monoamine Transporter (VMAT) 2 Inhibitors	For 7a, that criteria is actually only intended for patients with Huntington's Disease.

Elagolix/Estradiol/Norethindrone Acetate (Oriahnn): The Commission reviewed the update prior authorization criteria as follows:

Prior authorization (PA) is required for elagolix containing drugs. Payment will be considered for patients when the following is met:

1. *Pregnancy has been ruled out; and*
2. *Patient does not have osteoporosis; and*
3. *Patient does not have severe hepatic impairment; and*
4. *Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and*
5. *Requests for elagolix (Orilissa) will be considered under the following conditions:*
    a. *Patient has a diagnosis of moderate to severe pain associated with endometriosis; and*
    b. *Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and*
    c. *Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.*

d. *Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.*
e. *Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose; or*

6. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) will be considered under the following conditions:*
   a. *Patient is premenopausal; and*
   b. *Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and*
   c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
   d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*
   e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
   f. *Requests will be considered for a maximum of 24 months treatment.*

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.

Select Anticonvulsants: The Commission reviewed the newly proposed prior authorization criteria as follows:

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

1. *Patient meets the FDA approved age for submitted diagnosis and drug; and*
2. *Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and*
3. *Is prescribed by or in consultation with a neurologist; and*
4. *Patient's current weight is provided; and*
5. *Follows FDA approved dosing for indication and drug. The total daily dose does not exceed the following:*
   a. *Cannabidiol*
      i. *Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day; or*
      ii. *Tuberous sclerosis complex: 25 mg/kg/day; or*
   b. *Fenfluramine*
      i. *With concomitant stiripentol (plus clobazam): 0.4 mg/kg/d with a maximum of 17 mg per day; or*

ii. *Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or*

c. *Stiripentol*
   i. *Prescribed concomitantly with clobazam; and*
   ii. *50 mg/kg/day with a maximum of 3,000 mg/day.*

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

Kellen Ludvigson 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.

Risdiplam (Evrysdi): The Commission reviewed the newly proposed 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*
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.

Jason Kruse motioned to accept the criteria as recommended, 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.

Satralizumab-mwge (Enspryng): The Commission reviewed the newly proposed prior authorization criteria as follows:

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

1. *Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and*
2. *Patient is anti-aquaporin 4 (AQP4) seropositive (attach documentation); and*
3. *Patient meets the FDA approved age and dosing; and*
4. *Patient has a history of at least 1 relapse in the previous 12 months prior to initiation of therapy; and*
5. *Patient has been tested for tuberculosis prior to the initiation of therapy and does not have active or untreated latent tuberculosis; and*
6. *Patient has been tested for hepatitis B virus (HBV) prior to the initiation of therapy and confirmed negative for active HBV; and*
7. *Prescribed by a neurologist.*

If criteria for coverage are met, initial requests will be given for 1 year. Additional authorizations will be considered upon documentation of clinical response to therapy (i.e. a reduction in the frequency of relapse).

Jason Wilbur 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.

Acute Migraine Treatments: The Commission reviewed the updated 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.

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

- 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

Pirfenidone (Esbriet)/Nintedanib (Ofev): The Commission reviewed the updated 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.*

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.

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors: The Commission reviewed the newly 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. *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.

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

Peanut Allergen Powder-dnfp: The Commission reviewed the newly proposed prior authorization criteria as follows:

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

1. *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 initial dose escalation is administered in the provider office and should be billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and*
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.

Clarification was provided for #8. Kellen Ludvigson motioned to accept the criteria as amended, and Jason Kruse seconded. As this was the second review of these criteria, the recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the first review of the draft DUR Digest Volume 33, Number 1.

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

At 12:59, Kellen Ludvigson motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for March 3, 2021, with location or virtual status to be determined.