Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes August 4, 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.; Susan Parker, Pharm.D.; and Lisa Todd, Amerigroup.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Gina Kuebler, R.Ph., IME; Melissa Biddle, IME; and Emily Rogers, Iowa Total Care.

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:33 a.m. This meeting was purely virtual and done through WebEx teleconference due to the continued COVID-19 pandemic. The minutes from the May 5, 2021 meeting were reviewed. Jason Kruse motioned to accept them, and Chuck Wadle 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 requesting development of prior authorization criteria for Verquvo. Annual chair and vice-chair elections were conducted. Jason Wilbur motioned to retain Brett Faine as chairperson, and Kellen Ludvigson seconded. Brett Faine then motioned to retain Kellen Ludvigson as vice-chairperson, and Jason Kruse seconded. All members in attendance were in favor of both motions. Members were also asked to complete their annual conflict of interest disclosures.

IME Pharmacy Update

Tentatively effective November 1, 2021, the dispensing fee will be increased to $10.38, or the first day of the month following CMS approval of the State Plan Amendment just submitted, whichever is later. This is Brett Faine's last year on the DUR Commission, after which he will have served three 4-year terms. Lisa Todd from Amerigroup is now the MCO representative on the Commission, in a non-voting capacity. This position alternates between the MCO companies every two years.

Prevalence Report Summaries

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from March 2021 through May 2021, including: total amount paid ($2,227,364), unique users (3,799); cost per user ($586.30), number of total prescriptions dispensed (23,418); and percent generic (89.3%). The top 5 therapeutic classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Antipsychotics – Atypicals; 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, Vyvanse, Humira Pen, Sabril, and Sutent. The five drugs with the highest prescription counts were: clonidine hcl, trazodone hcl, sertraline hcl, omeprazole, and Vyvanse.

Iowa Total Care: Emily Rogers spoke and provided written summaries that included ITC's statistics from March 2021 through May 2021, including: total paid amount ($73,332,223.73); total prescriptions (782,408); and unique users (115,598). 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, Nucara Specialty, Walgreens, and CVS. The top 5 therapeutic classes by paid amount were: Insulin; Anti-TNF-alpha-Monoclonal Antibodies; Sympathomimetics; Antipsychotics – Misc.; and Antiretrovirals. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and NSAIDs. The most expensive drugs were Humira Pen, Vyvanse, Vraylar, Invega Sustenna, and Biktarvy, while albuterol, omeprazole, sertraline, atorvastatin, and trazodone had the top 5 prescription counts.

Amerigroup*:* Lisa Todd provided an overview for Amerigroup's statistics from March 2021 through May 2021, including: total paid amount ($112,246,474); unique users (162,733); total prescriptions (1,145,966); generic prescriptions (1,030,255 totaling $21,434,772); brand prescriptions (115,711 totaling $90,811,702). 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, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vyvanse, Vraylar, Latuda, and Invega Sustenna. Omeprazole had the highest prescription count, followed by: sertraline hcl, albuterol, trazodone hcl, and atorvastatin.

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 $187,806,062 was spent in total for 282,130 unique users who had 1,951,792 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 Vyvanse 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 4,815. 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
Mary Claire Wohletz	Merck	Verquvo

Written Provider Comments Received:
Buprenorphine

Written Manufacturer Comments Received: Verquvo, Xolair

Retrospective DUR Data Presentations

Concurrent Opioids and Benzodiazepines: This topic is included in the SUPPORT Act and required for CMS reporting, optional this year, but mandatory in 2 years. The Commission thought a hard POS edit preventing concurrent use and development of PA criteria would be the best course of action, but no vote was taken at this time. However, data will be run to see the top providers and number of claims involved and brought back to the next meeting, prior to any recommendationf for any ProDUR edits or PA criteria.

Montelukast without Asthma Diagnosis: The Commission would like to target the prescribers of members not also on a steroid inhaler, to potentially eliminate members with a asthma but not found to have an asthma diagnosis in their medical claims, pointing out the *Boxed Warning* due to the risk of serious neuropsychiatric events, asking if the patient had an inadequate response or intolerance to alternative therapies, and if therapy with montelukast outweighs the potential risks when used for indications other than asthma. Pam Smith will update the data and bring it back to the next meeting, prior to letters being sent.

PPI Therapy – New Start and High Dose: The Commission recommended tabelting this topic and monitor utilization and possibly revisit the topic in the future.

Retrospective DUR Proposals

Duplicate PPIs: Data will be brought to the next meeting identifying members with two or more chemically distinct PPIs with 60 or more days of overlap.

Chronic Use of Controlled Sedative/Hypnotic Agents: Data identifying members with claims for a controlled sedative/hypnotic agent for more than 90 days in a 120 day period will be examined and discussed at a future meeting.

Commission Recommendations for Retrospective DUR Agenda Topics
There were no additional topic suggestions.

Prospective DUR
Oral Benzodiazepine Quantity Limits: Data will be re-run to identify the number of unique members with 60-89 units, 90-119 units, and 120 or more units over a 3 month period. The Commission would like to focus on clonazepam, alprazolam, lorazepam, and diazepam, though Dr. Wadle suggested limits on all bendodiazepines to prevent possible drift to other agents if these four are further restricted.

Budesonide/Formoterol Inhalation Aerosol & Mometasone/Formoterol Inhalation Aerosol: As this was the second review, and the Commission had no additional changes, the recommended quantity limit, allowing 2 inhalers per 30 days, will be sent to DHS for consideration.

The Commission took a short break and open session resumed at 11:20 a.m.

Prior Authorization
Topical Acne and Rosacea Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is not required for preferred topical acne agents (topical antibiotics and topical retinoids) for members under 21 years of age. PA is required for preferred topical acne agents for members 21 years or older, non-preferred topical acne agents and all topical rosacea agents. Payment will be considered under the following conditions:

1. *Documentation of diagnosis; and*
2. *For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid; and*
3. *Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid); and*
4. *Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent; and*
5. *Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products; and*
6. *Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis; and*

7. *Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

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

Jason Wilbur 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.

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

Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe. Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit. Payment for omalizumab (Xolair) prefilled syringe will be considered for FDA approved and compendia indications under the following conditions:

1. *Patient meets the FDA approved age; and*
2. *Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and*
3. *The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and*
4. *Dose follows the FDA approved dosing for indication; and*
5. *Prescriber is an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist; and*
6. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and*
7. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

<u>Moderate to Severe Persistent Asthma</u>

1. *Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
    b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
3. *Patient's weight is within the following range:*

   a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
   b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and*
4. *History of positive skin or RAST test to a perennial aeroallergen; and*
5. *Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

<u>Chronic Idiopathic Urticaria</u>

1. *Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and*
2. *Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
3. *Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and*
4. *Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
5. *Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

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

<u>Nasal Polyps</u>

1. *Patient has a diagnosis of nasal polyps; and*
2. *Pretreatment IgE level is within the following range:*

a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 1500 IU/mL; and*

3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; and*
4. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
5. *Will be used concurrently with a nasal corticosteroid; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

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

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 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.

Vericiguat (Verquvo): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for vericiguat (Verquvo). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and*
2. *Patient meets one of the following:*
    a. *Recent hospitalization for heart failure (within the last 6 months); or*
    b. *Recent need for outpatient intravenous diuretics (within the last 3 months); and*
3. *Patient is within the FDA labeled age for indication; and*
4. *Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and*
5. *Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and*

6. *Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:*
    a. *Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and*
    b. *Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and*
7. *Is dosed based on FDA approved dosing; and*
8. *Initial requests for Verquvo 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.*

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

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.

Viloxazine (Qelbree): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for viloxazine (Qelbree). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and*
2. *Patient is between 6 and 17 years of age; and*
3. *Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and*
5. *Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and*
6. *Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and*
7. *Is dosed based on FDA approved dosing, and dose does not exceed 400 mg per day; and*
8. *Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.*

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

Chuck Wadle motioned to accept the criteria as recommended, and John Ellis 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.

Non-Biologic Agents for Ulcerative Colitis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for select non-biologicals for ulcerative colitis (UC). Payment for non-preferred select non-biologics for UC may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of moderately to severely active ulcerative colitis (UC) and*
2. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and*
3. *A documented trial and inadequate response to two preferred conventional therapies (immunomodulators) including aminosalicylates and azathioprine/6-mercaptopurine; and*
4. *A documented trial and inadequate response with a preferred biological DMARD; and*
5. *Will not be taken concomitantly with immunomodulators or biologic therapies.*

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 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.

Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for oral gonadotropin-releasing hormone (GnRH) antagonists. Payment for non-preferred oral GnRH antagonists may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent. 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. *Request adheres to all FDA approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

4. *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*
5. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) or relugolix, estradiol, norethindrone acetate (Myfembree) 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

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

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.

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 DUR Commission reviewed information regarding a newly expanded indication for valsartan/sacubitril (Entesto), to reduce the risk of cardiovascular death and hospitalization for heart failure. The DUR Commission also reviewed The 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment. Guideline-directed therapy for heart failure with reduced ejection fraction (HFrEF) includes angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs) as initial treatment, with an ARNI being preferred regardless of prior treatment with an ACEI or ARB. After review of the new information and discussion, the DUR Commission determined removal of PA criteria would be in the best interest of Iowa Medicaid members given the proven efficacy of valsartan/sacubitril (Entresto) in the treatment of heart failure.

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 lV) 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.

At the prior meeting review, the Commission also voted to implement a quantity limit of 60 for 30 for all strengths. No further changes were recommended. As this was the second review of these criteria, no motion was necessary. The recommendation for PA removal will be sent to the Department for consideration.

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*

4. *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.*

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.

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.*

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.

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).*

<u>Chorea associated with Huntington's disease</u> (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.*

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 DUR Digest Volume 33, Number 2. No additional recommendations were made. The DUR Digest will be posted to the DUR website.

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

At 12:11, Chuck Wadle motioned to adjourn, and Jason Wilbur seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for November 3, 2021, location to be determined.