Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes February 7, 2024

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Jason Wilbur, M.D.; Holly Randleman, Pharm.D.; Rhea Hartley, M.D.; and Chuck Wadle, D.O.

Staff
Pam Smith, R.Ph.

Guests
Abby Cate, Iowa Department of Health and Human Services; Erin Halverson, R.Ph., Iowa Medicaid; Gina Kuebler, R.Ph., Iowa Medicaid; Melissa Biddle, Iowa Medicaid; Candace Jordan, Pharm.D., Molina Healthcare; Jordan Thoman, Pharm.D., Wellpoint Iowa; and Carroll Nelson, Pharm.D., Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the virtual meeting to order at 9:30 a.m. The minutes from the November 1, 2023, meeting were reviewed. Holly Randleman motioned to accept them, and Jason Wilbur seconded. All members were in favor. The recommendation letter sent to DHHS after the last DUR meeting was also reviewed.

Iowa Medicaid Pharmacy Update

Amerigroup changed their name to Wellpoint as of 1/1/24, part of a rebranding initiative. The cost of dispensing survey will be mailed out to pharmacy providers in May 2024 for a response due in August 2024. Iowa Medicaid recently got the approval to move forward with a rule change to allow 90 days-supply for prescriptions versus the current 31 days-supply limit. A 90 days-supply allowance was implemented during the public health emergency, and it had a positive impact on the pharmacy program and our members. During that period, the allowance was open to all medications on our PDL. Once the PHE ended, the 90 days-supply allowance ended. This Committee reviewed and recommended the re-implementation of the 90 days-supply limit last year with a reviewed drug list that would include select, cost effective, generic medications. There have been some bills introduced that would affect pharmacy since the legislative session has started. Pharmacy has reviewed them, but nothing has been finalized for movement forward at this time. The topics of the bills include regulation of pharmacy benefit managers, 340B drug purchases, pharmacist use of epinephrine, pharmacist prescribing of hormonal contraceptives, abortion drug certification, and pharmacist/practitioner judgment. If there is any movement on any pharmacy bills, Abby Cate will bring those updates to future meetings. Following up from a previous meeting, the buprenorphine age edit has been adjusted to allow usage for those 16 years of age or older, rather than 18, to match the FDA approval.

Prevalence Report Summaries

Wellpoint Iowa*:* Jordan Thoman provided an overview for Wellpoint's statistics from September 2023 through November 2023, including: total paid amount ($100,286,555); total prescriptions (883,580); and unique users (114,640). The greatest utilization of the pharmacy benefit was for the age group of 19-64. On the top 100 pharmacies by prescription count report, University of Iowa Healthcare, 3 Walgreens locations, and Hy-Vee Pharmacy #1092 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 Health Care, Caremark Kansas Specialty Pharmacy, CVS Specialty Pharmacy, Caremark Illinois Specialty Pharmacy, and Community Walgreens Pharmacy. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Dermatologicals; Analgesics – Anti-Inflammatory; and Antiasthmatic and Bronchodilator Agents. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vraylar, Ozempic, Trulicity, and Trikafta. Omeprazole had the highest prescription count, followed by: sertraline, atorvastatin, levothyroxine, and trazodone.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2023 through November 2023, including: total amount paid ($2,790,128), unique users (3,766); cost per user ($740.87), number of total prescriptions dispensed (22,606); and percent generic (89.7%). The top 5 therapeutic classes by paid amount were: Analgesics - Anti-Inflammatory; Antidiabetics; Antivirals; Antipsychotics/Antimanic Agents; and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. The highest prescription count was from the Antidepressants category, with Anticonvulsants in second place, followed by: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antiasthmatic and Bronchodilator Agents; and Antihypertensives. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Humira Pen, Biktarvy, Vijoice, Mavyret, and Evrysdi. The five drugs with the highest prescription counts were: albuterol, cetirizine, sertraline, atorvastatin, and trazodone.

Molina Healthcare*:* Candace Jordan provided an overview for Molina's statistics from September 2023 through November 2023, including: total paid amount ($45,267,181.95); total prescriptions (458,905); and unique users (71,770). 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, 3 Walgreens locations, and Broadlawns 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 Health Care, Caremark Specialty Pharmacy, Community Walgreens Pharmacy, Unity Point at Home, and CVS Specialty Pharmacy. The top 5 therapeutics classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-inflammatory; Dermatologicals; and Antiasthmatic and Bronchodilator Agents. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. Humira (CF) Pen was the most expensive

medication, followed by Vraylar, Ozempic, Trikafta, and Trulicity. Omeprazole had the highest prescription count, followed by: sertraline, atorvastatin, amoxicillin, and escitalopram.

Iowa Total Care: Carroll Nelson provided an overview for ITC's statistics from September 2023 through November 2023, including: total paid amount ($76,951,900.38); total prescriptions (721,436); and unique users (100,873). 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, 3 Walgreens locations, and Broadlawns 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, Caremark Kansas Specialty Pharmacy, Walgreens Community Pharmacy, Unity Point at Home, and Accredo Health Group. The top 5 therapeutic classes by paid amount were: Antidiabetics; Antipsychotics/Antimanic Agents; Analgesics – Anti-Inflammatory; Dermatologicals; and Antiasthmatic and Bronchodilator Agents. The top 5 classes by prescription count were: Antidepressants; Anticonvulsants; Antiasthmatic and Bronchodilator Agents; Antihypertensives; and Antidiabetics. The most expensive drugs were Humira Pen, Vraylar, Ozempic, Trikafta, and Trulicity, while atorvastatin, omeprazole, sertraline, levothyroxine, and lisinopril had the top 5 prescription counts.

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 $225,295,755 was spent in total for 2,086,527 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Humira Pen was the most expensive drug for FFS and all MCO plans. The top 25 drugs by prescription count were also similar across FFS and all MCO plans, with sertraline, omeprazole, and atorvastatin in the top 3 spots for all MCOs, and sertraline third for FFS. All four 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. Jason Kruse asked that DHHS review Vitiligo medication coverage, as it is currently not a covered diagnosis, categorized as cosmetic by Iowa Medicaid.

Name	Representing	Drug/Topic
Jennifer Meredith	Novartis	Cosentyx
Bradley Jones	Abbvie	Qulipta
Chase Williams	Gilead	Hepatitis C
Stacey Sandate	Ipsen	Bylvay
Hiten Patadia	Incyte	Opzelura
Nick Bianchini	Axsome	Auvelity

Written Provider Comments Received: Vitiligo, Hepatitis C direct-acting antivirals, Vitiligo

Written Manufacturer Comments Received: Opzelura

Retrospective DUR Data Presentations

Antidepressants in Children: The annual federal Drug Utilization Review (DUR) report (Sec. 1927. [42 U.S.C. 1396r–8]) issued by the Centers for Medicare and Medicaid Services (CMS) contains various survey questions relative to drug utilization and practice topics. The most recent survey includes the following questions:

- Does your state have a documented program in place to either manage or monitor the appropriate use of antidepressant drugs in children? If "yes", does your state either manage or monitor only children in foster care, all children, or other.
- Does your state have edits in place to monitor child's age, dosage, indication, polypharmacy, other.

As requested at the November meeting, Pam Smith brought back age band utilization data for each MCO and FFS. The Commission does not wish to take additional action through educational letters or age edits at this time. After reviewing the tables on duplicate therapy, the Commission decided to monitor usage for now and re-evaluate again in a year, removing trazadone from that future data set. No action will be taken regarding trazodone doses at the time, either.

Mood Stabilizers in Children: The annual federal Drug Utilization Review (DUR) report (Sec. 1927. [42 U.S.C. 1396r–8]) issued by the Centers for Medicare and Medicaid Services (CMS) contains various survey questions relative to drug utilization and practice topics. The most recent survey includes the following questions:

- Does your state have a documented program in place to either manage or monitor the appropriate use of mood stabilizing drugs in children? If "yes", does your state either manage or monitor only children in foster care, all children, or other.
- Does your state have edits in place to monitor child's age, dosage, indication, polypharmacy, other.
- CMS does not define mood stabilizers.

As requested at the November meeting, data was run to identify members on three or more concurrent medications (carbamazepine, divalproex, eslicarbazepine, gabapentin, lamotrigine, lithium, oxcarbazepine, pregabalin, topiramate, and valproic acid), and focus on the members less than 4 years of age. Data will be re-run to exclude those with a seizure diagnosis, with results brought back to the next meeting.

Low Dose Quetiapine: Currently there are no FDA approved indications for low-dose quetiapine (< 150 mg per day) in adults or pediatric/adolescents. Additionally, there is no compendia indication for the use of quetiapine in the pediatric/adolescent population and evidence is inconclusive for adults. Quetiapine doses less than 150 mg per day may be used for the off-label treatment of insomnia. At the November meeting, the Commission wanted to focus on members less than 18 years of age, so data was run to break those results into multiple age bands. Dr. Wadle asked how many members were also on trazadone, noting that letters would be worthwhile in that case. Pam Smith will run a new data set to identify members on more than one concurrent medication, including

quetiapine, trazadone, and other medications used for sedation, along with diphenhydramine. Results will be brought back to the next meeting.

Retrospective DUR Proposals

Diagnosis of Diabetes Mellitus without Statin Therapy:

- The American College of Cardiology and American Heart Association (ACC/AHA) recommend consideration of moderate-intensity statin therapy for primary prevention of atherosclerotic cardiovascular disease (ASCVD) in all individuals who are 40 to 75 years of age with diabetes mellitus given significant cardiovascular outcomes benefit.
- The American Diabetes Association (ADA) agrees with the recommendation of utilizing moderate-intensity statin in individuals 40 to 75 years of age with diabetes mellitus and encourages considering the use of high-intensity statin therapy in individuals with additional ASCVD risk factors.
- A meta-analysis of multiple randomized controlled trials found that moderate-intensity statin therapy was associated with a risk reduction of 25%, similar to people without diabetes and with no apparent difference in benefit between type 1 and type 2 diabetes.

Commission members noted that generally they have already had a discussion with patients about adding a statin, but many were resistant, and thus they felt educational letters to prescribers would have little impact.

Concurrent use of Levetiracetam and Clobazam:

- The U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication warning of a rare but serious drug reaction to the antiseizure medications levetiracetam and clobazam.
- Educational outreach to prescribers would bring attention to this serious drug reaction and assist prescribers in educating patients/care givers on the signs and symptoms of DRESS should the combination of levetiracetam and clobazam be prescribed to future patients.

Data will be run to identify members with concurrent claims for levetiracetam and clobazam for 30 days or more, with results brought back to the next meeting. Letters might be sent in the future depending on those findings.

Commission Recommendations for Retrospective DUR Agenda Topics

There were no additional recommendations.

The Commission took a short break and open session resumed at 11:23 a.m.

Prior Authorization

Biologicals for Arthritis: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling for requested drug and indication, including age,

dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of rheumatoid arthritis (RA); with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (hydroxycholoroquine, sulfasalazine, or leflunomide may be used if methotrexate is contraindicated); or*
2. *Patient has a diagnosis of moderate to severe psoriatic arthritis; with*
    a. *Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
3. *Patient has a diagnosis of juvenile idiopathic arthritis with oligoarthritis; with*
    a. *Documentation of a trial and inadequate response to intraarticular glucocorticoid injections and methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
4. *Patient has a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) with;*
    a. *Documentation of a trial and inadequate response to methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*
5. *Patient has a diagnosis of systemic juvenile idiopathic arthritis (sJIA).*

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

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

Biologicals for Hidradenitis Suppurativa: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals FDA approved or compendia indicated for the treatment of Hidradenitis Suppurativa (HS). Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred biologic agent.

Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and*
3. *Patient has at least three (3) abscesses or inflammatory nodules; and*

4. *Patient has documentation of adequate trials and therapy failures with the following:*
    a. *Daily treatment with topical clindamycin;*
    b. *Oral clindamycin plus rifampin;*
    c. *Maintenance therapy with a preferred tetracycline.*

If criteria for coverage are met, initial requests will be given for 4 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

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

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

Dupilumab (Dupixent): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient's current weight in kilograms (kg) is provided; and*
3. *Patient has a diagnosis of moderate-to-severe atopic dermatitis; and*
    a. *Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and*
    b. *Patient has failed to respond to good skin care and regular use of emollients; and*
    c. *Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
    d. *Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
    e. *Patient will continue with skin care regimen and regular use of emollients; and*
4. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) or with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or*

pulmonologist; and

b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and*
c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long-acting beta $_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
    i. *One (1) or more exacerbations in the previous year or*
    ii. *Require daily oral corticosteroids for at least 3 days; or*

5. *Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and*
    a. *Documentation dupilumab will be used as an add-on maintenance treatment; and*
    b. *Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:*
        i. *Nasal corticosteroid spray; and*
        ii. *Oral corticosteroid; or*
6. *Patient has a diagnosis of eosinophilic esophagitis (EoE); and*
    a. *Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and*
    b. *Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and*
    c. *Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and*
    d. *Documentation of previous trials and therapy failures with all of the following:*
        i. *High dose proton pump inhibitor (PPI) for at least 8 weeks; and*
        ii. *Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension): and*
        iii. *Dietary therapy; or*
7. *Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and*
    a. *Is prescribed by, or in consultation with an allergist, immunologist, or dermatologist; and*
    b. *Patient has experienced severe to very severe pruritits, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and*
    c. *Patient has ≥ 20 nodular lesions (attach documentation); and*
    d. *Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive*

days; and

8. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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

Rhea Hartley motioned to accept the criteria as amended, and Holly Randleman seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Febuxostat (Uloric) – Removal of Criteria: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for febuxostat (Uloric). Payment for febuxostat (Uloric) will only be considered for cases in which symptoms of gout still persist while currently using 300mg per day of a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.

Jason Wilbur motioned to remove the criteria above, and Holly Randleman seconded. All members were in favor. The recommendations will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

Select Preventative Migraine Treatments: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for select preventative migraine agents. Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent. Payment will be considered under the following conditions:

1. *Patient has one of the following diagnoses:*
    a. *Chronic Migraine, defined as:*
        i. *≥ 15 headache days per month for a minimum of 3 months; and*
        ii. *≥ 8 migraine headache days per month for a minimum of 3 months; or*
    b. *Episodic Migraine, defined as:*
        i. *4 to 14 migraine days per month for a minimum of 3 months; or*
    c. *Episodic Cluster Headache, defined as:*
        i. *Occurring with a frequency between one attack every other day and 8 attacks per day; and*

ii. *With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and*
iii. *Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and*

2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions and use in specific populations; and*
3. *The requested agent will not be used in combination with another CGRP inhibitor for the preventative treatment of migraine; and*
4. *Patient has been evaluated for and does not have medication overuse headache; and*
5. *For Episodic and Chronic Migraine, patient has documentation of two trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with ~~a~~ two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or*
6. *For Episodic Cluster Headache, patient has documentation of*
    a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*
    b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*
7. *Lost, stolen, or destroyed medication replacement requests will not be authorized.*

Initial requests will be approved for 3 months. Additional PAs will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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

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

Hepatitis C Treatment, Direct Acting Antivirals: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of chronic hepatitis C; and*
2. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
3. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
4. *Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and*
5. *DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines and patient's weight is provided; and*
6. *Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.*
7. *If patient is recently eligible for Iowa Medicaid and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.*
8. *The 72-hour emergency supply rule does not apply to DAAs.*

Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:

1. *Patient must meet all criteria for treatment approval above; and*
2. *The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and*
3. *HCV retreatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and*
4. *Patient has not been previously treated with and failed the requested DAA therapy; and*
5. *Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.*

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

Odevixibat (Bylvay): The Commission reviewed the proposed prior authorization criteria as follows:

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

1. *Request adheres to all FDA approved labeling including age, dosing, contraindications, warnings and precautions, and drug interactions; and*
2. *Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) type 1 or 2; and*
    a. *Genetic testing does not indicate PFIC type 2 with ABCB 11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and*
    b. *Patient has moderate to severe pruritis associated with PFIC; or*
3. *Patient has a diagnosis of Alagille Syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 mutation or deletion; and*
    a. *Patient has cholestasis with moderate to severe pruritis; and*
    b. *Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:*
        i. *Ursodeoxycholic acid (ursodiol)*
        ii. *Cholestyramine*
        iii. *Rifampin; and*
4. *Patient's current weight in kg is provided; and*
5. *Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in PFIC or ALGS.*

Initial authorizations will be approved for 3 months for initial treatment or after a dose increase. Additional authorizations will be considered when the following criteria are met:

1. *Patient's current weight in kg is provided; and*
2. *Documentation is provided the patient has responded to therapy and pruritis has improved. If there is no improvement in pruritis after 3 months of treatment with the maximum 120 mcg/kg/day dose, further approval of odevixibat will not be granted.*

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.

Oral Constipation Agents: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for oral constipation agents subject to clinical criteria. Payment for non-preferred oral constipation agents will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred oral constipation agent. Payment will be considered when patient has an

FDA approved or compendia indication for the requested drug when the following criteria are met:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. *Patient must have documentation of adequate trials and therapy failures with the following:*
    a. *Members 18 years of age or older:*
        i. *Stimulant laxative (senna) plus saline laxative (milk of magnesia); and*
        ii. *Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); or*
    b. *Members 17 years of age or younger:*
        i. *Polyethylene glycol; and*
        ii. *One other preferred generic laxative, such as lactulose or senna; and*
3. *Patient does not have a known or suspected mechanical gastrointestinal obstruction; and*
4. *Patient has one of the following diagnoses:*
    a. *A diagnosis of chronic idiopathic constipation (Amitiza, Linzess, Motegrity, Trulance)*
        i. *Patient has less than 3 spontaneous bowel movements (SBMs) per week; and*
        ii. *Patient has two or more of the following symptoms within the last 3 months:*
            1. *Straining during at least 25% of bowel movements;*
            2. *Lumpy or hard stools for at least 25% of bowel movements;*
            3. *Sensation of incomplete evacuation for at least 25% of bowel movements; and*
        iii. *Documentation the patient is not currently taking constipation causing therapies; or*
    b. *A diagnosis of irritable bowel syndrome with constipation (Amitiza, Ibsrela, Linzess, or Trulance)*
        i. *Patient is female (Amitiza only); and*
        ii. *Patient has recurrent abdominal pain on average at least 1 day per week in the last 3 months associated with two (2) or more of the following:*
            1. *Related to defecation;*
            2. *Associated with a change in stool frequency;*
            3. *Associated with a change in stool form; or*
    c. *A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza, Movantik, Relistor, or Symproic)*
        i. *Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and*
        ii. *Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:*
            1. *Hard to very hard stool consistency;*

2. *Moderate to very severe straining;*
3. *Having a sensation of incomplete evacuation; or*

d. *A diagnosis of functional constipation (Linzess)*
   i. *Patient has less than 3 SBMs per week; and 1 or more of the following criteria at least once per week for at least 2 months:*
      1. *History of stool withholding or excessive voluntary stool retention;*
      2. *History of painful or hard bowel movements;*
      3. *History of large diameter stools that may obstruct the toilet;*
      4. *Presence of a large fecal mass in the rectum;*
      5. *At least 1 episode of fecal incontinence per week.*

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment and patient continues to meet the age for indication.

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.

Oral Immunotherapy: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization is required for sublingual allergen immunotherapy. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations; and*
2. *Medication is prescribed by or in consultation with an allergist or immunologist; and*
3. *Patient has documentation of an adequate trial and therapy failure with an intranasal corticosteroid and oral or nasal antihistamine used concurrently; and*
4. *Patient has a documented intolerance to immunotherapy injections; and*
5. *The first dose has been administered under the supervision of a health care provider to observe for allergic reactions (date of administration and response required prior to consideration).*
6. *If patient receives other immunotherapy by subcutaneous allergen immunotherapy (SCIT), treatment of allergic rhinitis with sublingual allergen immunotherapy (SLIT) will not be approved.*

Short Ragweed Pollen (Ragwitek®) In addition to the above criteria being met:

1. *Patient is diagnosed with short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis; and*
2. *Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to short ragweed pollen.*

3. *If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of ragweed pollen season and continued throughout the season.*

Grass Pollen (Grastek® and Oralair®) In addition to the above criteria being met:

1. *Request is for Oralair®; and*
    a. *Patient is diagnosed with grass pollen-induced allergic rhinitis, with or without conjunctivitis; and*
    b. *Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to sweet vernal, orchard/cocksfoot, perennial rye, timothy, and Kentucky blue/June grass.*
    c. *If criteria for coverage are met, authorization will be considered at least 4 months prior to the expected onset of each grass pollen season and continued throughout the grass pollen season; or*
2. *Request is for Grastek®; and*
    a. *Patient is diagnosed with grass pollen-induced allergic rhinitis, with or without conjunctivitis; and*
    b. *Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to timothy grass (or cross reactive grasses such as sweet vernal, orchard/cocksfoot, perennial rye, Kentucky blue/June, meadow fescue, and redtop).*
    c. *If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of grass pollen season as follows:*
        - *Seasonally, through the end of the grass pollen season or*
        - *For sustained effectiveness, up to three consecutive years (including the intervals between grass pollen seasons) for one grass pollen season after cessation of treatment. Authorizations would be given in 12-month intervals up to three consecutive years with one grass pollen season.*

House Dust Mite (Odactra®) In addition to the above criteria being met:

1. *Patient is diagnosed with house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, and*
2. *Patient has a positive skin test to licensed house dust mite allergen extracts or in vitro testing for IgE antibodies to Dermatophagoides farina or Dermatophagoids pteronyssinus house dust mites; and*
3. *If criteria for coverage are met, authorization will be considered for 12 months.*

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 proposed 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 when the patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations; and*
2. *Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and*
3. *Prescribed by or in consultation with a neurologist, ~~or~~ psychiatrist, psychiatric nurse practitioner, or psychiatric physician assistant; and*

Tardive Dyskinesia (Ingrezza or Austedo)

1. *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*
2. *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*
3. *Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and*

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); or*

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

1. *Patient has a diagnosis of Huntington's disease with chorea symptoms; and*
2. *Patient is not suicidal, or does not have untreated or inadequately treated depression; and*
3. *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.*

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 DUR Digest Volume 36, Number 1.

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

At 12:03, Jason Wilbur motioned to adjourn, and Rhea Hartley seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for May 1, 2024, location to be determined.