Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes November 1, 2023

Attendees:

Commission Members
Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; John Ellis, Pharm.D.; 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., Amerigroup.; and Carroll Nelson, Pharm.D., Iowa Total Care.

Welcome & Introductions

Chairperson Melissa Klotz called the virtual meeting to order at 9:32 a.m. The minutes from the August 2, 2023, meeting were reviewed. Chuck Wadle motioned to accept them, and Holly Randleman seconded. All members were in favor. The recommendation letter sent to DHHS after the last DUR meeting was also reviewed.

Iowa Medicaid Pharmacy Update

Point of care testing for influenza and streptococcus A has been implemented for MCO Medicaid members, allowing pharmacists to test for those at pharmacies and also prescribe medications based on test results. Options for members with fee-for-service Medicaid coverage are still being discussed. Informational Letter 2510 was sent out to providers detailing the implementation. This is the last meeting for John Ellis who has been on the Committee for four and a half years.

Prevalence Report Summaries

Iowa Total Care: Carroll Nelson provided an overview for ITC's statistics from June 2023 through August 2023, including: total paid amount ($85,325,411.42); total prescriptions (785,573); and unique users (124,164). 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, 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, Caremark Kansas Specialty Pharmacy, Walgreens Community Pharmacy, Unity Point at Home, and Nucara Specialty. 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, Trulicity, and Trikafta, while sertraline, omeprazole, atorvastatin, levothyroxine, and lisinopril had the top 5 prescription counts.

***Amerigroup**:* Jordan Thoman provided an overview for Amerigroup's statistics from June 2023 through August 2023, including: total paid amount ($110,618,579); total prescriptions (958,675); and unique users (147,387). 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, Drilling 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 Health Care, Caremark Kansas Specialty Pharmacy, CVS Specialty Pharmacy, Unity Point at Home, 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 ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, and Antihypertensives. Humira (CF) Pen was the most expensive medication, followed by Vraylar, Vyvanse, Ozempic, and Trulicity. Omeprazole had the highest prescription count, followed by: sertraline, atorvastatin, trazodone, and levothyroxine.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from June 2023 through August 2023, including: total amount paid ($2,925,207), unique users (3,654); cost per user ($800.55), number of total prescriptions dispensed (21,959); and percent generic (88.3%). The top 5 therapeutic classes by paid amount were: Analgesics-Anti-Inflammatory; Antidiabetics; Antipsychotics/Antimanic Agents; Antivirals, 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; Evrysdi, Vijoice; and Revlimid. The five drugs with the highest prescription counts were: sertraline, clonidine, trazodone, escitalopram, and cetirizine.

***Molina Healthcare**:* Candace Jordan provided an overview for Molina's statistics from July 2023 through August 2023, including: total paid amount ($35,826,892.18); total prescriptions (333,313); and unique users (65,914). 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 a Hy-Vee Pharmacy 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 Nucara Specialty Pharmacy. The top 5 therapeutics classes by paid amount were: Antipsychotics; Antirheumatic; Incretin Mimetic; Skin and Mucous; and Amphetamines. These were the top five classes by prescription count: Antidepressants, Miscellaneous Anticonvulsants, Antipsychotics, PPI, and Anxiolytics.

Humira (CF) Pen was the most expensive medication, followed by Vraylar, Trikafta, Vyvanse, and Trulicity. Omeprazole had the highest prescription count, followed by: sertraline, atorvastatin, escitalopram, 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 $234,696,090 was spent in total for 2,099,520 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 and omeprazole in the top 2 spots for all MCOs, and sertraline first 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.

Name	Representing	Drug/Topic
Bradley Jones	Abbvie	Ubrelvy, Vraylar
James Matthew Baker	Axsome	Avelity
Mark Golick	Neurocrine Biosciences	Ingrezza
Sarah Sanders	Novartis	Cosentyx, Ilaris
Chad Sanders	Ipsen Biopharmaceuticals	Abilify

Written Provider Comments Received: Dupixent, Hepatitis C treatments, Dupixent

Written Manufacturer Comments Received: none

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 August meeting, additional research tables showing utilization by age band, duplicate therapy, and daily trazodone usage were reviewed. After discussion, data will be broken down further to clarify utilization by age band, duplicate therapy with 3 or more chemically distinct drugs, duplicate therapy within antidepressant class and trazodone dose broken out by age bands. The Commission would like

compare data to national data, if available. Findings will be brought back to a future meeting.

Antianxiety/Sedatives 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 antianxiety/sedative 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 antianxiety/sedative drugs.

As requested at the August meeting, claim inquiries were run to target drugs where the safety and effectiveness have not been established in pediatric patients less than 18 years old, also looking at duplicate prescribing. After reviewing the results, the Commission would like to target data for members less than 6 years old and compare it to national data, if available. They also requested data on duplicate therapy with 3 or more chemically distinct agents, duplicate benzodiazepines. Z-drug plus benzodiazepine, and chronic use of a benzodiazepine. Findings will be brought back to a future meeting.

Retrospective DUR Proposals

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 August meeting, data was run to identify any members with two or more chemically distinct mood stabilizers, also looking for utilization for patients less than 4 years of age, excluding those with a seizure diagnosis. In addition, Pam Smith researched how other states are addressing this CMS survey request. The Commission recommended using the MassHealth Pediatric Behavioral Medication Initiative definition for mood stabilizers that includes: carbamazepine, divalproex, eslicarbazepine, gabapentin, lamotrigine, lithium, oxcarbazepine, pregabalin, topiramate, and valproic acid. Data will be run to identify duplicate thearpy with 3 or more chemically distinct agents and utilization in members 0 through 3 years of age.

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. The Commission would like to focus on members less than 18 years of age, and break those results into multiple age bands. Findings will be brought back to a future meeting.

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

Prospective DUR
Seizure Rescue Treatment, Nasal Spray – Quantity Limit: Recent review of monthly paid pharmacy claims found an instance where Valtoco (diazepam nasal spray) was being dispensed in large quantities to one member (receiving a quantity greater than the maximum dosage and treatment frequency, as stated in the FDA approved label, in a 30-day period). Valtoco is preferred on the Preferred Drug List (PDL) with no current quantity limit. After further review of preferred rescue medications indicated for the acute treatment of seizures, the quantity limits below are being recommended for Valtoco and Nayzilam (midazolam nasal spray) to ensure appropriate use.

Medication Name & Strength	**Quantity Limit Per 30 Days**
Nayzilam (midazolam) 5 mg	5 boxes (10 nasal spray units)
Valtoco (diazepam) 5 mg, 10 mg	5 cartons (10 blister packs)
Valtoco (diazepam) 15 mg, 20 mg	10 cartons (20 blister packs)

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.

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

Prior Authorization

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

PA Category	**Recommended Changes**
Biologicals for Arthritis	Molina Healthcare requested criteria for juvenile idiopathic arthritis be reviewed and updated to account for systemic juvenile idiopathic arthritis
Febuxostate (Uloric)	Removal of criteria now that generic is available and recommended to be preferred
Hepatitis C Treatments, Direct Acting Antivirals	Recommend the requirement for a specialist to prescribe or consult be removed

Odevixibat (Bylvay): The Commission reviewed the proposed changes to 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*

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.

Rhea Hartley motioned to accept the criteria as amended, and Holly Randleman 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.

Oral Constipation Agents: The Commission reviewed the proposed changes to 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.

Jason Wilbur motioned to accept the criteria as amended, and John Ellis 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.

Oral Immunotherapy: The Commission reviewed the proposed changes to 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®)

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 farinae or Dermatophagoides pteronyssinus house dust mites; and*

If criteria for coverage are met, authorization will be considered for 12 months.

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.

Vesicular Monoamine Transporter (VMAT) 2 Inhibitors: The Commission reviewed the proposed changes to 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 (VMAT) 2 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).*

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.*

Rhea Hartley motioned to accept the criteria as amended, and Chuck Wadle 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.

Antidepressants: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for non-preferred antidepressants subject to clinical criteria. 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. *Documentation of a previous trial and therapy failure at a therapeutic dose with two preferred generic SSRIs; and*
3. *Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SNRI; and*
4. *Documentation of a previous trial and therapy failure at a therapeutic dose with one non-SSRI/SNRI generic antidepressant; and*
5. *Documentation of a previous trial and therapy failure at a therapeutic dose with vilazodone; and*
6. *Documentation of a previous trial and therapy failure at a therapeutic dose with vortioxetine; and*
7. *Documentation of a previous trial and therapy failure at a therapeutic dose with an antidepressant plus adjunct; and*
8. *If the request is for dextromethorphan and bupropion extended-release tablet (Auvelity), one of the trials must include a previous trial and inadequate response at a therapeutic dose with an extended-release bupropion agent; and*
9. *If the request is for an isomer, prodrug or metabolite of the requested medication, one of the trials must be with the preferred parent drug of the same chemical entity that resulted in a partial response with a documented intolerance.*

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

The Commission also recommended a quantity limit for Auvelity of 60 tablets per 30 days and an age edit for Auvelity for members 18 years of age and older. No further changes were recommended. As this was the second review of these criteria and ProDUR edits, no motion was necessary. The recommendation will be sent to the Department for consideration.

Deucravacitinib (Sotyktu): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for deucravacitinib (Sotyktu). 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 has a diagnosis of plaque psoriasis; and*
    a. *Documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine is provided; and*

b. *Documentation of a trial and inadequate response to the preferred adalimumab agent; and*
c. *Will not be combined with any of the following systemic agents: biologic DMARD, Janus kinase inhibitor, phosphodiesterase 4 (PDE4) inhibitor, or potent immunosuppressant.*

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

The Commission also recommended a quantity limit for Sotyktu 6 mg tablet of 30 tablets per 30 days. No further changes were recommended. As this was the second review of these criteria quantity limit, no motion was necessary. The recommendation will be sent to the Department for consideration.

Tezepelumab (Tezspire): The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for tezepelumab-ekko (Tezspire) prefilled pen. Requests for tezepelumab-ekko (Tezspire) single dose vial or prefilled syringe will not be considered through the pharmacy benefit. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions 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 has a diagnosis of severe asthma; and*
    a. *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 beta2 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*
    b. *Patient must have of one of the following, in addition to the regular maintenance medications defined above:*
        i. *Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months, or*
        ii. *One or more asthma exacerbations resulting in hospitalization in the previous 12 months; and*
    c. *This medication will be used as an add-on maintenance treatment; and*
    d. *Patient/caregiver will administer medication in patient's home; and*
    e. *Is not prescribed in combination with other biologics indicated for asthma.*

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Requests 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.

The Commission also recommended a quantity limit for Tezspire 210mg/1.91 mL prefilled pen of one (1) prefilled pen per 28 days. No further changes were recommended. As this was the second review of these criteria and quantity limit, no motion was necessary. The recommendation will be sent to the Department for consideration.

Janus Kinase Inhibitors: The Commission reviewed the proposed prior authorization criteria as follows:

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved indication of alopecia areata, vitiligo, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules when the following conditions are met:

1. *Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); 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. *Patient has a diagnosis of:*
    a. *Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and*
        ii. *A documented trial and inadequate response to one preferred TNF inhibitor; OR*
    b. *Psoriatic arthritis (tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
        ii. *Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR*
    c. *Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and*
        ii. *A documented trial and inadequate response with a preferred TNF inhibitor; and*

iii. *If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR*

d. *Moderately to severely active Crohn's disease (upadacitinib); with*
   i. *A documented trial and inadequate response to two preferred conventional therapies including aminosalicylates (sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; and*
   ii. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
e. *Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with*
   i. *A documented trial and inadequate response to intraarticular glucocorticoid injections; and*
   ii. *A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
   iii. *A documented trial and inadequate response with a preferred TNF inhibitor; OR*
f. *Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis) (tofacitinib, upadacitinib); with*
   i. *A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and*
   ii. *A documented trial and inadequate response with at least one preferred TNF inhibitor; OR*
g. *Atopic dermatitis; with*
   i. *Documentation patient has failed to respond to good skin care and regular use of emollients; and*
   ii. *A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
   iii. *A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
   iv. *For mild to moderate atopic dermatitis (ruxolitinib)*
      a. *A documented trial and therapy failure with crisaborole; and*
      b. *Affected area is less than 20% of body surface area (BSA); and*
      c. *Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or*
   v. *For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):*
      a. *A documented trial and therapy failure with cyclosporine or azathioprine; and*

b. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.*

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

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

Miscellaneous

DUR Digest: The Commission members conducted the first review of DUR Digest Volume 36, Number 1.

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

At 12:06, Jason Wilbur motioned to adjourn, and Rhea Hartley seconded. All in attendance agreed.

The next scheduled meeting is tentatively set for February 7, 2024, location to be determined.