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

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Melissa Klotz, Pharm.D.; Jason Kruse, D.O.; Chuck Wadle, D.O.; John Ellis, Pharm.D.; and Susan Parker, Pharm.D.
Staff
Pam Smith, R.Ph.
Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Dawn Grittman, Pharm.D., Iowa Total Care; and Sandy Pranger, R.Ph., Amerigroup.

Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:31 a.m. at the Learning Resource Center in West Des Moines. The minutes from the November 6, 2019 meeting were reviewed. Jason Kruse motioned to accept them, and Melissa Klotz seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting was also reviewed. Pam Smith provided follow-up information from previous meetings regarding claims data for linezolid, Symlin, and Eucrisa, as well as prior authorization data for Eucrisa. The MCOs will look further into the data results for Eucrisa to provide more detail on the PA denials and reasoning behind them as Jason Kruse requested.

Commission Recommendations for Retrospective DUR Agenda Topics

The Commission did not have any new recommendations.

IME Pharmacy Update

Commission members were emailed links to four recent informational letters. Informational Letter 2086-MC-FFS explained changes effective March 18, 2020, including dispensing fees for maintenance drugs and Medication Assisted Treatment (MAT). Informational Letter 2109-MC-FFS provided a pharmacy claim submission update effective April 6, 2020. Informational Letter 2105-MC-FFS provided a clarification on information regarding the new provider type for pharmacists and associated enrollment. Informational Letter 2095-MC-FFS gave pharmacies directions for participation in the cost of dispensing survey. There is still an opening for a doctor on the DUR Commission, as Mark Graber is in the last year of his 3 allowable terms.

Prevalence Report Summaries

Amerigroup: Sandy Pranger provided an overview for Amerigroup's statistics from September 2019 through December 2019, including: number of enrolled eligible members (380,000); total paid amount ($98,097,014); unique users (163,015); total prescriptions

(1,193,791); generic prescriptions (1,047,977 totaling $24,666,600); brand prescriptions (145,814 totaling $73,430,414). She noted that the specialty drugs keep increasing. The breakdown of utilization by age shows that ages 19-64 continue to have the highest utilization, with 62% female and 38% male utilization across all age groups. The top 100 pharmacies by prescription count had 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy making up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, CVS Specialty, Hy-Vee Pharmacy Solutions, Accredo Health Group, and Nucara Specialty. On the top 100 prescribing providers by prescription count report, Roy Overton (Geriatrics) took the top spot due to the large volume of recent flu vaccines, followed by: Thomas Earwood, Jeffrey Wilham, Charles Tilley, and Bobbita Nag. Also noted was the fact that #36 Stephen Mandler did average 10 prescriptions per member, but this was just due to the billing as he does long term care. Three of the top five prescribers on the top 100 prescribing providers by paid amount practice at the University of Iowa: Janice Staber, Michael Ciliberto, and Laura Ramsey. There was nothing out of the ordinary on that report. Similar to previous reports, the top 5 therapeutics classes by paid amount were: Antidiabetics; ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants; Antipsychotics/Antimanic Agents; Antiasthmatic and Bronchodilator Agents; and Analgesics – Anti-Imflammatory. Opioid utilization continues to trend downward, though Chuck Wadle wondered if Suboxone utilization had gone up with the removal of the PA criteria. Sandy Pranger confirmed that was correct and said she would bring the analysis back to the next meeting. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Concerta, Humira (CF) Pen, Latuda, and Invega Sustenna. Sandy Pranger noted the shift to the CF Pen for members using Humira, as well as an increase in expenditures for antibiotics and flu vaccines. Omeprazole had the highest prescription count, followed by: atorvastatin calcium, lisinopril, sertraline hcl, and ProAir HFA. This report also showed an increase in prescriptions for antibiotics and flu vaccines. Melissa Klotz noted that 7 of the top 10 drugs by prescription count had experienced an increase in prescription count but decrease in paid amount since the previous reporting period. Sandy Pranger said she would look into this.

Iowa Total Care: Dawn Grittman spoke and provided written summaries that included ITC's statistics from September through December 2019, including: number of enrolled eligible members (approximately 262,000); total paid amount ($55,376,369.40); total prescriptions (739,251); and unique users (108,642). The greatest utilization of the pharmacy benefit was for the age group of 19-64, with females in that age group getting about 1.8 prescriptions per every male in the same age group. On the top 100 pharmacies by prescription count report, the University of Iowa Ambulatory Care Pharmacy, Broadlawns Outpatient Pharmacy, and 3 Walgreens locations made up the top 5. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs, the top 5 pharmacies being: University of Iowa Ambulatory Care, Nucara Specialty, Optum Pharmacy, Hy-Vee Pharmacy Solutions, and Accredo Health Group. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Stimulants – Misc.;

Amphetamines, and Antiretrovirals. The top 5 classes by prescription count were: SSRIs; Sympathomimetics; Anticonvulsants; Proton-Pump Inhibitors; and HMG CoA Reductase Inhibitors. The most expensive drugs were Vyvanse, Humira Pen, Concerta, Latuda, and Invega Sustenna, while omeprazole, lisinopril, atorvastatin, sertraline, and levothyroxine sodium had the top 5 prescription counts.

Fee-for-Service: Pam Smith provided an overview of fee-for-service statistics from September 2019 through December 2019, including: total amount paid ($2,072,620), unique users (4,875); cost per user ($425.15), number of total prescriptions dispensed (25,705); percent generic (86.7%); and number of enrolled eligible members (approximately 10,000). Pam Smith noted that there were a lot of pharmacies from Sioux City at the top of the top 100 pharmacies by prescription count report; there were also several increases in ranking due to vaccines. She also added that since the FFS population is so small, a pharmacy can easily experience a rank shift just from adding one new member. The top 100 pharmacies by paid amount report was largely influenced by specialty drugs. Meskwaki, which was #1 on the list, gets an encounter rate of the same flat rate for each drug; encounter claims do not qualify for dispensing fees. The top 5 prescribing providers by prescription count were: Leighton Frost, Shawn Salmen, Molly Earleywine, Joada Jean Best, and Michael Ciliberto. Pam Smith also looked at other providers that had a high average script per member number; long term care billing at 7 days per prescription often skews the averages. The top prescribing providers by paid amount were largely specialists, tending toward oncology, neurology, and hematology, with the big rank changes mainly due to no claims being submitted under those NPI numbers in the previous reporting period. There were some family medicine physicians toward the bottom of the list as they saw an increase in cough and cold medications. The top 5 therapeutic classes by paid amount were: Anticonvulsants; Anti-Inflammatories, Non-NSAID; Antipsychotics – Atypicals; Antiretroviral Combinations; and Stimulants – Amphetamines – Long Acting. NSAIDs and ACE Inhibitors did move into the top 20. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Antiasthmatic – Beta - Adrenergics. There was a rank change from 22 to 19 for the Stimulants – Methylphenidate – Long Acting, possibly due to the new requirement that adults use the long-acting formulations rather than the short-acting. The top 100 drugs were also reviewed, by paid amount and prescription count. The five most expensive medications were: Vyvanse, Humira Pen, Concerta, Invega Systenna, and ProAir HFA. The report reflects the seasonal changes, with increased utilization on multiple antibiotics, TamiFlu, and albuterol. The Chantix starter pack also entered the top 100, when it didn't before when PA criteria was in place. The five drugs with the highest prescription counts were: ProAir HFA, trazodone hcl, lisinopril, omeprazole, and montelukast sodium. Hydrocodone/acetaminophen fell from 1 to 13. Pam Smith also noted that the prescriptions for several medications including ibuprofen were down while the cost went up, likely due to the encounter claims.

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 $155,556,003 was spent in total for 276,532 unique

users who had 1,958,747 prescriptions. While there were similarities among the plans in the top therapeutic classes, FFS did vary because of the difference in the population. Vyvanse was the most expensive drug for all 3 plans, with Humira and Concerta also appearing in the top 3 for all. The top 25 drugs by prescription count were also similar across FFS and both MCO plans. When all three plans were combined, Roy Overton had the overall highest prescription count at 5,469.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comment from the speakers listed below.

Name	Representing	Drug/Topic
Syed Mahmud	Global Blood Therapeutics	Oxbryta
Peter Zoob	Vertex	Trikafta
Jim Baumann	Pfizer	Eucrisa
Nisha Rizvi	Novartis	Entresto
Christina Brandmeyer	Amgen	Enbrel
Alicia Duyvejonck	Genesis Health Group	Acute Migraine Medications

ProDUR Edits

Review of Current and Proposed Opioid Quantity Limits: The DUR Commission previously unanimously recommended implementing ProDUR quantity limits on opioids as detailed below, and had no additional changes. As this was the second review, no motion was necessary. The recommendations will be sent to the Department for consideration. See the 11/06/19 meeting minutes for a complete listing of current and proposed quantity limit changes.

- Remove opioids from the current Iowa Medicaid Quantity Limit list that total ≥ 90 morphine milligram eqivalents (MME) per day, leaving current quantity limits in place for liquid agents.
- Current short-acting opioid quantity limits – six (6) units per day on all solid oral dosage forms where the quantity exceeds 6 units per day on the current Iowa Medicaid Quantity Limit list.
- Establish quantity limits for opioids that fall below 90 MME per day, that do not have current quantity limits, including a maximum limit of six (6) units per day on all short-acting solid oral doage forms.

Retrospective DUR

Claims Data Review

Duplicate SSRIs: Letters will be sent to the prescribers and pharmacies of members with claims for two or more chemically distinct SSRIs. Mark Graber suggested looking at concurrent SSRI and SNRI usage as a possible retrospective study.

High Dose Gabapentin: Letters will be sent to the providers of members with claims for gabapentin exceeding 3600 mg per day, also warning them about the POS edit that will soon be implemented as well.

Proposals

Duplicate SNRIs: 60 days of claims data will be reviewed to check for members with fills of 2 or more concurrent SNRIs in that timeframe.

Baclofen Utilization: 30 and 60 days of claims data will be reviewed identify members with 1.) baclofen claims, 2.) those exceeding 80 mg baclofen per day, and 3.) those with concurrent use of baclofen and an opioid (regardless of baclofen dose). Mark Graber asked that both a 30-day 60-day claim report be run for comparison.

The Commission took a short break and open session resumed at 10:55.

Prior Authorization

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

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

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of cystic fibrosis (CF); and*
3. *Patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test (attach test results) for which the requested drug is indicated; and*
4. *Prescriber is a CF specialist or pulmonologist; and*
5. *Baseline liver function tests (AST, ALT, and bilirubin) are provided; and*
6. *Requests for Trikafta will not be considered for patients with severe hepatic impairment (Child-Pugh Class C); and*
7. *Will not be used with other CFTR modulator therapies.*

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

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

Jason Kruse motioned to accept the criteria as recommended, and Mark Graber 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.

Valsartan/Sacubitril (Entresto): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for valsartan/sacubitril (Entresto). Requests

above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and*
    a. *Patient has a left ventricular ejection fraction (LVEF) ≤40%; and*
    b. *Patient is currently tolerating treatment with an ACE inhibitor or angiotensin II receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and*
    c. *Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); or*
3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class II to IV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤ 40%; and*
4. *Will not be used in combination with an ACE inhibitor or ARB; and*
5. *Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and*
6. *Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and*
7. *Patient is not pregnant; and*
8. *Patient does not have severe hepatic impairment (Child Pugh Class C).*

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

Jason Kruse motioned to accept the criteria as recommended, 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.

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

Prior authorization (PA) is not required for preferred novel oral anticoagulants (NOACs). PA is required for non-preferred NOACs. Requests will be considered for FDA approved dosing and length of therapy for submitted diagnosis Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications for the requested drug under the following conditions:

1. *Patient is within the FDA labeled age for indication; and*
2. *Patient does not have a mechanical heart valve; and*
3. *Patient does not have active bleeding; and*
4. *For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1; and*
5. *A recent creatinine clearance (CrCl) is provided; and*

6. *A recent Child-Pugh score is provided; and*
7. *Patient's current body weight is provided; and*
8. *Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs; and*
9. *For requests for edoxaban, when prescribed for the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE), documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin) is provided.*

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

Mark Graber motioned to accept the criteria as recommended, and Kellen Ludvigson seconded. All members were in favor. The recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

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

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

1. *Patient meets the FDA approved age; and*
2. *Patient has a diagnosis of sickle cell disease (SCD); and*
3. *Requested dose is within the FDA approved dosing; and*
4. *Patient has experienced at least two sickle cell-related vasoocclusive crises within the past 12 months (documentation required); and*
5. *Patient has documentation of an adequate trial and therapy failure with hydroxyurea; and*
6. *Baseline hemoglobin (Hb) range is ≥5.5 to ≤10.5 g/dL; and*
7. *Is prescribed by or in consultation with a hematologist; and*
8. *Patient is not receiving concomitant blood transfusion therapy.*

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

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

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

Jason Kruse motioned to accept the criteria as recommended (with the caveat that utilization data be reviewed after six months to see if any changes to criteria are needed

or if guidelines have been updated), and Mark Graber 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.

IL-5 Antagonists: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment will be considered under the following conditions:

1. *Patient meets the FDA approved age for submitted diagnosis; and*
2. *Is dosed within FDA approved dosing for submitted diagnosis and age; and*
3. *Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and*
    a. *Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells per mcL within 12 months prior to initiation of therapy; and*
    b. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and*
    c. *Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and*
    d. *A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted in adults and < 90% in adolescents; or*
4. *Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and*
    a. *Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and*
    b. *One of the following:*
        i. *Eosinophil count greater than 1000 cells/mcL; or*
        ii. *Eosinophil count greater than 10% of the total leukocyte count; and*
5. *Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.*

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered when the following criteria are met:

Severe Asthma with an Eosinophilic Phenotype:

1. *Patient continues to receive therapy with an ICS, LABA and LTRA; and*

2. *Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or*
3. *Patient has experienced a decrease in administration of rescue medication (albuterol); or*
4. *Patient has experienced a decrease in exacerbation frequency; or*
5. *Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline.*

Eosinophilic Granulomatosis with Polyangiitis:

1. *Patient has demonstrated a positive clinical response to therapy (increase in remission time).*

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

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

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

Prior authorization (PA) is required for preferred acute migraine treatments for quantities exceeding 12 unit doses of tablets, syringes or sprays per 30 days. Payment for acute migraine treatments beyond this limit will be considered on an individual basis after review of submitted documentation. PA will be required for all non-preferred acute migraine treatments as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred acute migraine treatments will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for non-preferred combination products may only be considered after documented separate trials and therapy failures with the individual ingredients. For consideration, the following information must be supplied:

1. *The diagnosis requiring therapy; and*
2. *Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.*

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

Jason Kruse and Kellen Ludvigson both motioned simultaneously 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.

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

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

1. *The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and*
2. *There is no caregiver available to provide assistance, and*
3. *Patient does not reside in a long-term care facility, and*
4. *For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).*

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

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

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

Kellen Ludvigson motioned to remove the criteria as recommended, and Chuck Wadle 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.

Linezolid (Zyvox): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for linezolid. Payment for linezolid will be authorized when there is documentation that:

1. *The patient has one of the following diagnostic criteria:*
    a. *Vancomycin-resistant Enterococcus (VRE); or*
    b. *Methicillin-resistant Staph aureus (MRSA); or*
    c. *Methicillin-resistant Staph epidermis (MRSE); or*
    d. *Other multiply resistant gram positive infection (e.g. penicillin resistant Streptococcus spp); and*
2. *Patient meets ONE of the following criteria:*
    a. *Patient is severely intolerant to vancomycin with no alternative regimens with documented efficacy available*, or*
    b. *VRE in a part of body other than lower urinary tract**, or*
    c. *Patient discharged on linezolid and requires additional quantity (up*

to 10 days oral therapy will be allowed).

3. *A current culture and sensitivity report is provided documenting sensitivity to linezolid.*

**Severe intolerance to vancomycin is defined as:*

1. *Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration*
2. *Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine)*

***VRE in lower urinary tract, considered to be pathogenic, may be treated with linezolid if severe renal insufficiency exists and/or patient is receiving hemodialysis or has known hypersensitivity to nitrofurantoin.*

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.

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

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

1. *Patient is within the FDA labeled age for indication; and*
2. *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 has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and*
    f. *Patient will continue with skin care regimen and regular use of emollients; or*
3. *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; 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. *Two (2) or more exacerbations in the previous year or*
    ii. *Require daily oral corticosteroids for at least 3 days; and*

4. *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; and*
5. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 16 weeks 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.

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.

Biologicals for Axial Spondyloarthritis: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for biologicals used for axial spondyloarthritis conditions. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of:*
    - *ankylosing spondylitis (AS) or*
    - *nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and*
2. *The requested dose does not exceed the maximum FDA labeled or compendia recommended dose for the submitted diagnosis; and*
3. *Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
4. *Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and*
5. *Patient has documentation of an inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at maximum*

therapeutic doses, unless there are documented adverse responses or contraindications to NSAID use. These trials should be at least one month in duration; and

6. *Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include sulfasalazine and methotrexate; and*
7. *Requests for non-preferred biologicals for axial spondyloarthritis conditions will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents that are FDA approved or compendia indicated for the submitted diagnosis, when applicable.*

In addition to the above:
Requests for TNF Inhibitors:

1. *Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
2. *Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or IV and with an ejection fraction of 50% or less.*

Requests for Interleukins:

1. *Medication will not be given concurrently with live vaccines.*

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.

Ivabradine (Corlanor): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for ivabradine. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and*
    a. *Patient is 18 years of age or older; and*
    b. *Patient has documentation of a left ventricular ejection fraction ≤35%; and*
    c. *Patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; and*
    d. *Patient has documentation of blood pressure ≥90/50 mmHg; or*
2. *Patient has a diagnosis of stable symptomatic heart failure (NYHA/Ross class II to IV) due to dilated cardiomyopathy, and*

a. *Pediatric patient age 6 months and less than 18 years old; and*
b. *Patient has documentation of a left ventricular ejection fraction ≤45%; and*
c. *Patient is in sinus rhythm with a resting heart rate (HR) defined below;*
    i. *6 to 12 months - HR ≥ 105 bpm*
    ii. *1 to 3 years - HR ≥ 95 bpm*
    iii. *3 to 5 years - HR ≥ 75 bpm*
    iv. *5 to 18 years - HR ≥ 70 bpm; and*

3. *Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily) or weight appropriate dosing for pediatric patients, or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and*
4. *Patient has documentation of a trial and continued use with a preferred angiotensin system blocker at a maximally tolerated dose.*

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

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

Chronic Pain Syndromes: The Commission reviewed the prior authorization criteria below, and made a recommendation to remove it.

A prior authorization (PA) is required for pregabalin (Lyrica) and milnacipran (Savella). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life. Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions:

1. *A diagnosis of fibromyalgia (Lyrica and Savella)*
    a. *a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following preferred generic agents: tricyclic antidepressant or SNRI* ***WITH***
    b. *documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.)*

2. *A diagnosis of post-herpetic neuralgia (Lyrica)*
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. *A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica)*
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine.
4. *A diagnosis of partial onset seizures, as adjunct therapy (Lyrica)*
5. *A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica)*

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.

Anti-Diabetic Non-Insulin Agents: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for preferred anti-diabetic, non-insulin agents subject to clinical criteria. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indicated diagnosis, and*
2. *Patient meets the FDA approved or compendia indicated age, and*
3. *For the treatment of Type 2 Diabetes Mellitus, the patient has not achieved HgbA1C goals after a minimum three month trial with metformin at maximally tolerated dose.*
4. *Requests for non-preferred anti-diabetic, non-insulin agents, subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. Requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with metformin, a preferred DPP-4 Inhibitor or DPP-4 Inhibitor Combination, a preferred Incretin Mimetic, and a preferred SGLT2 Inhibitor at maximally tolerated doses.*

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

Initial authorizations will be approved for six months. Additional PAs will be considered on an individual basis after review of medical necessity and documented continued improvement in symptoms (such as HgbA1C for Type 2 Diabetes).

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 the draft DUR

Digest Volume 32, Number 2. No recommended changes were made.

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

At 11:47, Kellen Ludvigson motioned to adjourn, and Jason Kruse seconded. All in attendance agreed.

The next meeting will be held at 9:30 a.m. on Wednesday, May 6, 2020, at the Department for the Blind in Des Moines.