# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes November 6, 2019

**Attendees:**

| Commission Members |
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| 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 |
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| Pam Smith, R.Ph. |

| Guests |
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| Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Emily Rogers, Pharm.D., Iowa Total Care; and Jeannine Murray, Amerigroup. |

## Welcome & Introductions

Chairperson Brett Faine called the meeting to order at 9:33 a.m. in Capitol Room 116 in Des Moines. The minutes from the August 7, 2019 meeting were reviewed. Jason Kruse motioned to accept them, and Mark Graber seconded. All members were in favor. The recommendation letter sent to DHS after the last meeting and a recommendation letter to the DUR Commission from the P&T Committee requesting creation of PA criteria for Mavenclad, Mayzent, and Osphena were also reviewed.

## Commission Recommendations for Retrospective DUR Agenda Topics

The Commission did not have any new recommendations.

## IME Pharmacy Update

House File 623 removed prior authorization requirements for Medication Assisted Treatment (MAT); DHS is currently in the process of creating rules to allow at least one form of MAT medication without PA, effective February 1, 2020. The new rules also address dispensing fees for maintenance drugs, encouraging pharmacies to dispense a 30 day supply for maintenance drugs. An informational letter will go out shortly regarding pharmacist enrollment for ordering and dispensing of naloxone, nicotine replacement, and the immunization process, corresponding to rules going into effect July 1, 2020. A second informational letter, likely sent early next spring, will address the billing for immunizations. There will soon be an opening for a doctor on the DUR Commission, as Mark Graber is in the last year of his 3 allowable terms. This is the first meeting for the newest Commission member, John Ellis, Pharm.D.

## Prevalence Report Summaries

***Fee-for-Service:*** Pam Smith provided an overview of fee-for-service statistics from June 2019 through August 2019, including: total amount paid ($2,743,177), cost per user ($391.88), and number of total prescriptions dispensed (32,000). There were 7,000

unique users, which is 34.5% less than the total for March through May, likely due to newly eligible members being immediately assigned an MCO rather than temporarily going to FFS as they had previously. The top 5 therapeutic classes by paid amount were: Glucocorticoids – Corticotropin; Anti-Inflammatories, Non-NSAID; Anticonvulsants; Antiretroviral Combinations; and Antipsychotics – Atypicals. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Antipsychotics – Atypicals; Antihypertensives - Central; and Narcotics – Miscellaneous. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Acthar, Humira Pen, Vyvanse, Concerta, ProAir HFA, Sutent, Invega Systenna, Enbrel Sureclick, Latuda, and Emflaza. The five drugs with the highest prescription counts were: hydrocodone/acetaminophen, trazodone hcl, omeprazole, lisinopril, and ProAir HFA.

***Amerigroup:*** Jeannine Murray provided an overview for Amerigroup's statistics from June 2019 through August 2019, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. The Bi-Monthly Statistics report reflected that expenditures totaled $93,693,230, a 44% increase from the total for March through May due to members previously on United Healthcare changing to Amerigroup. 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. These were the top five classes by prescription count: Antidepressants, Anticonvulsants, Antiasthmatic and Bronchodilator Agents, Antihypertensives, and Ulcer Drugs/Antispasmodics/ Anticholinergics. Vyvanse was the most expensive medication, followed by Concerta, Latuda, Humira Pen, and Humalog. Omeprazole had the highest prescription count, followed by: lisinopril, atorvastatin calcium, levothyroxine sodium, and sertraline hcl. Kellen Ludvigson noted that some of the prescription counts per prescriber seemed a little high, especially when combined with the other plans. Pam Smith will look at the prescribers with the highest counts on each plan report and research the issue. Erin Halverson added that IME was working with the data warehouse on a report that combines information from all MCO and FFS plans that could better clarify questions on these prevalence reports in the future.

***Iowa Total Care:*** Emily Rogers spoke and provided written summaries that included ITC's statistics from July through August 2019, including: total paid amount ($38,628,854.94), unique users (91,173), and cost per user ($423.69). There was also a handout showing utilization by age and gender; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, 4 Walgreens locations and the University of Iowa Ambulatory Care Pharmacy made up the top 5. University of Iowa Ambulatory Care Pharmacy was also the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulin; Sympathomimetics; Anti-TNF-alpha – Monoclonal Antibodies; Antiretrovirals; and Amphetamines. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Sympathomimetics; Proton-Pump Inhibitors; and HMG CoA Reductase Inhibitors. The most expensive drugs were Humira

Pen, Vyvanse, Latuda, Invega Sustenna, and Humalog, while omeprazole, lisinopril, atorvastatin, sertraline, and levothyroxine sodium 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 (including the last month of United Healthcare utilization). Its side-by-side statistics showed that $163,155,301 was spent in total for 357,236 unique users who had 1,931,692 prescriptions.

**Public Comment**

In addition to the written public comments provided to Commission members as a part of their meeting materials, they heard oral public comment from the speakers listed below.

| Name | Representing | Drug/Topic |
|---|---|---|
| Jim Baumann | Pfizer | Eucrisa |
| Kevin Duhrkopf | Sanofi Genzyme | Dupixent |
| Jenna Gianninoto | Abbvie | Mavyret |
| Christina Brandmeyer | Amgen | Amovig, Enbrel, Corlanor |

**ProDUR Edits**

***Review of Current and Proposed Opioid Quantity Limits:*** The DUR Commission unanimously recommended implementing ProDUR quantity limits on opioids as below. Given this was the first review, the recommendation will be sent to the medical/pharmacy associations for comment and brought back to the next meeting for further discussion.

- 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. See Current Opioid Quantity Limits table below (drugs stricken to be removed from current list). Motion by Mark Graber, and second by Kellen Ludvigson.
- 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. See Current Opioid Quantity Limits table below, current quantities stricken and newly recommended quantity limit listed. Motion by Jason Kruse, and second by Kellen Ludvigson.
- Establish quantity limits for long- and short-acting 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. See Proposed New Opioid Quantity Limits table below. Long-acting opioids - motion by Jason Kruse, and second by Brett Faine; Short-acting opioids - motion by Jason Kruse, and second by Mark Graber.

## Current Opioid Quantity Limits – Proposed Changes (changes stricken)

| Drug Product | Quantity | Days Supply | Comments |
|---|---|---|---|
| AVINZA 30MG (morphine er) | 30 | 30 | |
| AVINZA 45MG (morphine er) | 30 | 30 | |
| AVINZA 60MG (morphine er) | 30 | 30 | |
| AVINZA 75MG (morphine er) | 30 | 30 | |
| ~~AVINZA 90MG (morphine er)~~ | ~~30~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~AVINZA 120MG (morphine er)~~ | ~~150~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| CODEINE SULFATE 15MG | 180 | 30 | 6 tablets per day |
| CODEINE SULFATE 30MG | 180 | 30 | 6 tablets per day |
| CODEINE SULFATE 60MG | 180 | 30 | 6 tablets per day |
| COMBUNOX (oxycodone/ibuprofen) | 28 | 30 | |
| DURAGESIC 25MCG (fentanyl) | 10 | 30 | |
| ~~DURAGESIC 50MCG (fentanyl)~~ | ~~10~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~DURAGESIC 75MCG (fentanyl)~~ | ~~10~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~DURAGESIC 100MCG (fentanyl)~~ | ~~10~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~EMBEDA 20-0.8MG (morphine/naltrexone)~~ | ~~60~~ | ~~30~~ | Removed from market |
| ~~EMBEDA 30-1.2MG (morphine/naltrexone)~~ | ~~60~~ | ~~30~~ | Removed from market |
| ~~EMBEDA 50-2MG (morphine/naltrexone)~~ | ~~60~~ | ~~30~~ | Removed from market |
| ~~EMBEDA 60-2.4MG (morphine/naltrexone)~~ | ~~60~~ | ~~30~~ | Removed from market |
| ~~EMBEDA 80-3.2MG (morphine/naltrexone)~~ | ~~60~~ | ~~30~~ | Removed from market |
| ~~EMBEDA 100-4MG (morphine/naltrexone)~~ | ~~60~~ | ~~30~~ | Removed from market |
| FIORICET/CODEINE 50-300-40-30MG (butalbital-apap-caffeine w/ codeine) | 60 | 30 | |
| FIORICET/CODEINE 50-325-40-30MG (butalbital-apap-caffeine w/ codeine) | 60 | 30 | |
| FIORINAL/CODEINE 50-325-40-30MG(butalbital-asa-caffeine-codeine) | 60 | 30 | |
| HYCET SOL (hydrocodone/apap) | 3600ML | 30 | 120ML per day |
| KADIAN 10MG (morphine sulfate er capsule) | 60 | 30 | |
| KADIAN 20MG (morphine sulfate er capsule) | 60 | 30 | |
| KADIAN 30MG (morphine sulfate er capsule) | 60 | 30 | |
| KADIAN 40MG (morphine sulfate er capsule) | 60 | 30 | |
| ~~KADIAN 50MG (morphine sulfate er capsule)~~ | ~~60~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~KADIAN 60MG (morphine sulfate er capsule)~~ | ~~60~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~KADIAN 80MG (morphine sulfate er capsule)~~ | ~~60~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~KADIAN 100MG (morphine sulfate er capsule)~~ | ~~60~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| MSCONTIN 15MG (morphine sulfate sa) | 90 | 30 | |
| ~~MSCONTIN 30MG (morphine sulfate sa)~~ | ~~90~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~MSCONTIN 60MG (morphine sulfate sa)~~ | ~~90~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~MSCONTIN 100MG (morphine sulfate sa)~~ | ~~300~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| NORCO 5-325MG (hydrocodone/apap) | 180 (~~360~~) | 30 | 6 tablets per day |
| NORCO 7.5-325MG (hydrocodone/apap) | 180 (~~240~~) | 30 | 6 tablets per day |
| NORCO 10-325MG (hydrocodone/apap) | 180 | 30 | 6 tablets per day |
| ~~NUCYNTA 50MG (tapentadol)~~ | ~~180~~ | ~~30~~ | Exceeds 90 MME/day; Remove |

| | | | |
|---|---|---|---|
| ~~NUCYNTA 75MG (tapentadol)~~ | ~~180~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~NUCYNTA 100MG (tapentadol)~~ | ~~180~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| OPANA ER 5MG (oxymorphone) | 60 | 30 | |
| OPANA ER 7.5MG (oxymorphone) | 60 | 30 | |
| OPANA ER 10MG (oxymorphone) | 60 | 30 | |
| ~~OPANA ER 15MG (oxymorphone)~~ | ~~60~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~OPANA ER 20MG (oxymorphone)~~ | ~~60~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| ~~OPANA ER 30MG (oxymorphone)~~ | ~~60~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| PERCOCET 5-325MG (oxycodone w/ apap) | 180 (~~360~~) | 30 | 6 tablets per day |
| PERCOCET 7.5-325MG (oxycodone w/ apap) | 180 (~~240~~) | 30 | 6 tablets per day |
| ~~PERCOCET 10-325MG (oxycodone w/ apap)~~ | ~~180~~ | ~~30~~ | Exceeds 90 MME/day; Remove |
| TYLENOL W/ CODEINE ELIXIR (apap w/ codeine) | 2700ML | 30 | 90ML per day |
| TYLENOL W/ CODEINE NO. 2 (apap w/ codeine) | 180 (~~390~~) | 30 | 6 tablets per day |
| TYLENOL W/ CODEINE NO. 3 (apap w/ codeine) | 180 (~~390~~) | 30 | 6 tablets per day |
| TYLENOL W/ CODEINE NO. 4 (apap w/ codeine) | 180 (~~390~~) | 30 | 6 tablets per day |
| ULTRACET (tramadol/apap) | 180 (~~240~~) | 30 | 6 tablets per day |
| ULTRAM 50MG (tramadol) | 180 (~~240~~) | 30 | 6 tablets per day |
| ULTRAM ER 100MG (tramadol er) | 30 | 30 | |
| ULTRAM ER 200MG (tramadol er) | 30 | 30 | |
| ULTRAM ER 300MG (tramadol er) | 30 | 30 | |
| VICODIN ES 7.5-300MG(hydrocodone/apap) | 150 | 30 | 5 tablets per day |
| VICODIN HP 10-300MG (hydrocodone/apap) | 180 | 30 | 6 tablets per day |
| XODOL 5-300MG (hydrocodone/apap) | 180 (~~360~~) | 30 | 6 tablets per day |
| XODOL 7.5-300MG (hydrocodone/apap) | 180 | 30 | 6 tablets per day |
| XODOL 10-300MG (hydrocodone/apap) | 180 | 30 | 6 tablets per day |
| ZAMICET (hydrocodone/apap) | 2700ML | 30 | 90ML per day |

## Proposed New Opioid Quantity Limits

| Drug Product | Quantity | Days Supply | Comments |
|---|---|---|---|
| ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE CAP 320.5-30-16 MG | 180 | 30 | 6 capsules per day |
| ACETAMINOPHEN-CAFFEINE-DIHYDROCODEINE TAB 325-30-16 MG | 180 | 30 | 6 tablets per day |
| BENZHYDROCODONE HCL-ACETAMINOPHEN TAB 4.08-325 MG (APADAZ) | 180 | 30 | 6 tablets per day |
| BUPRENORPHINE TD PATCH WEEKLY 5 MCG/HR (BUTRANS) | 4 | 28 | 1 patch per week |
| HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 10 MG (ZOHYDRO ER) | 60 | 30 | 2 capsules per day |
| HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 15 MG | 60 | 30 | 2 capsules per day |
| HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 20 MG | 60 | 30 | 2 capsules per day |

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|---|---|---|---|
| HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 30 MG | 60 | 30 | 2 capsules per day |
| HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 40 MG | 60 | 30 | 2 capsules per day |
| HYDROCODONE BITARTRATE CAP ER 12HR ABUSE-DETERRENT 50 MG | 60 | 30 | 2 capsules per day |
| HYDROCODONE BITARTRATE TAB ER 24HR DETER 100 MG (HYSLINGA) | 30 | 30 | |
| HYDROCODONE BITARTRATE TAB ER 24HR DETER 120 MG | 30 | 30 | |
| HYDROCODONE BITARTRATE TAB ER 24HR DETER 20 MG | 30 | 30 | |
| HYDROCODONE BITARTRATE TAB ER 24HR DETER 30 MG | 30 | 30 | |
| HYDROCODONE BITARTRATE TAB ER 24HR DETER 40 MG | 30 | 30 | |
| HYDROCODONE BITARTRATE TAB ER 24HR DETER 60 MG | 30 | 30 | |
| HYDROCODONE BITARTRATE TAB ER 24HR DETER 80 MG | 30 | 30 | |
| HYDROCODONE-ACETAMINOPHEN SOLN 10-300 MG/15ML (LORTAB ELIXIR) | 2700 | 30 | 90 ml per day |
| HYDROCODONE-ACETAMINOPHEN TAB 10-300 MG (VICODIN HP) | 180 | 30 | 6 tablets per day |
| HYDROCODONE-ACETAMINOPHEN TAB 2.5-325 MG | 180 | 30 | 6 tablets per day |
| HYDROCODONE-ACETAMINOPHEN TAB 5-300 MG (VICODIN) | 180 | 30 | 6 tablets per day |
| HYDROCODONE-IBUPROFEN TAB 10-200 MG | 150 | 30 | 5 tablets per day |
| HYDROCODONE-IBUPROFEN TAB 5-200 MG | 150 | 30 | 5 tablets per day |
| HYDROCODONE-IBUPROFEN TAB 7.5-200 MG | 150 | 30 | 5 tablets per day |
| HYDROMORPHONE HCL SUPPOS 3 MG | 120 | 30 | 4 supp. per day |
| HYDROMORPHONE HCL TAB ER 24HR DETER 12 MG (EXALGO) | 30 | 30 | |
| HYDROMORPHONE HCL TAB ER 24HR DETER 16 MG | 30 | 30 | |
| HYDROMORPHONE HCL TAB ER 24HR DETER 8 MG | 30 | 30 | |
| LEVORPHANOL TARTRATE TAB 2 MG | 120 | 30 | 4 tablets per day |
| MEPERIDINE HCL TAB 100 MG | 180 | 30 | 6 tablets per day |
| MEPERIDINE HCL TAB 50 MG | 180 | 30 | 6 tablets per day |
| MORPHINE SULFATE SUPPOS 10 MG | 180 | 30 | 6 supp. per day |
| MORPHINE SULFATE SUPPOS 5 MG | 180 | 30 | 6 supp. per day |
| MORPHINE SULFATE TAB ER 12HR DETER 15 MG (MORPHABOND) | 90 | 30 | 3 tablets per day |
| MORPHINE SULFATE TAB ER ABUSE-DETERRENT 15 MG (ARYMO ER) | 90 | 30 | 3 tablets per day |
| OXYCODONE CAP ER 12HR ABUSE-DETERRENT 13.5 MG (XTAMPZA ER) | 60 | 30 | 2 capsules per day |
| OXYCODONE CAP ER 12HR ABUSE-DETERRENT 18 MG | 60 | 30 | 2 capsules per day |
| OXYCODONE CAP ER 12HR ABUSE-DETERRENT 27 MG | 60 | 30 | 2 capsules per day |
| OXYCODONE CAP ER 12HR ABUSE-DETERRENT 9 MG | 60 | 30 | 2 capsules per day |
| OXYCODONE HCL CAP 5 MG | 180 | 30 | 6 capsules per day |
| OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML) | 87 | 30 | 2.9 ml per day |
| OXYCODONE HCL SOLN 5 MG/5ML | 1770 | 30 | 59 ml per day |
| OXYCODONE HCL TAB 5 MG | 180 | 30 | 6 tablets per day |
| OXYCODONE HCL TAB ABUSE DETER 5 MG (ROXYBOND OR OXAYDO) | 180 | 30 | 6 tablets per day |
| OXYCODONE HCL TAB ABUSE DETER 7.5 MG (OXAYDO) | 180 | 30 | 6 tablets per day |

| | | | |
|---|---|---|---|
| OXYCODONE HCL TAB ER 12HR DETER 10 MG (OXYCONTIN) | 60 | 30 | 2 tablets per day |
| OXYCODONE HCL TAB ER 12HR DETER 15 MG | 60 | 30 | 2 tablets per day |
| OXYCODONE HCL TAB ER 12HR DETER 20 MG | 60 | 30 | 2 tablets per day |
| OXYCODONE W/ ACETAMINOPHEN TAB 2.5-300 MG | 180 | 30 | 6 tablets per day |
| OXYCODONE W/ ACETAMINOPHEN TAB 2.5-325 MG | 180 | 30 | 6 tablets per day |
| OXYCODONE-ASPIRIN TAB 4.8355-325 MG | 180 | 30 | 6 tablets per day |
| OXYCODONE-IBUPROFEN TAB 5-400 MG | 120 | 30 | 4 tablets per day |
| TAPENTADOL HCL TAB ER 12HR 50 MG (NUCYNTA ER) | 60 | 30 | 2 tablets per day |

***Gabapentinoid Quantity Limit:*** The DUR Commission recommended implementing a ProDUR quantity limit on gabapentin (see table below). Additionally, the DUR Commission recommended implementing a maximum milligram per day edit on gabapentin (3600 mg) and pregabalin immediate release (600 mg), limiting each medication to the maximum milligram per day across all strengths. As this was the second review, the recommendations will be sent to the Department for consideration.

| **Recommended Quantity Limits for Gabapentin** | | |
|---|---|---|
| **Strength** | **Daily Quantity Limit** | **Monthly Quantity Limit** |
| 100 mg | 6 capsules | 180 capsules |
| 300 mg | 9 capsules | 270 capsules |
| 400 mg | 9 capsules/tablets | 270 capsules/tablets |
| 600 mg | 6 tablets | 180 capsules |
| 800 mg | 4.5 tablets | 135 tablets |
| 50 mg/mL | 72 mL | 2160 mL |

## Retrospective DUR Proposals

The DUR Commission reviewed the retrospective DUR proposals below and requested claims data for each proposal be brought back to a future meeting.

***High Dose Gabapentin:*** To identify members exceeding the maximum recommended daily dose of 3,600 mg gabapentin. The MCOs and FFS will bring back the number of members exceeding 3,600 mg gabapentin per day. Additionally, it was suggested once pregabalin moves to a preferred status, claims will be reviewed to see how many members are using pregabalin and gabapentin concurrently.

***Duplicate SSRIs:*** To identify member with concurrent claims of SSRIs. The MCOs and FFS will bring back the number of members identified as having claims for two or more chemically distinct SSRIs. Mark Graber suggested looking at concurrent SSRI and SNRI usage as a possible retrospective study.

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

## Prior Authorization

***Annual Review of Prior Authorization Criteria:*** Changes were suggested for the following categories, to be discussed at upcoming meetings. The Commission requested that PA statistics per category as had been previously provided during the annual review (prior to Managed Care) be brought back (for both MCOs and FFS), as they found the numbers helpful in determining any necessary PA criteria changes. IME staff will work with the MCOs to develop this reporting.

| **PA Category** | **Recommended Changes** |
|---|---|
| Alpha1-Proteinase Inhibitor Enzymes | Change wording on #5 to say patient is actively attempting smoking cessation. |
| Amylino Mimetic (Symlin) | Potentially add to Anti-Diabetics, Non-Insulin Agents PA form. Utilization for each plan will be brought back to a future meeting to determine if change is needed. |
| Cannabidiol (Epidiolex) | Specify that LFTs that are contraindicated. |
| CNS Stimulants and Atomoxetine | Allow physician assistants working under a psychiatrist to prescribe for Binge Eating Disorder. |
| Crisaborole (Eucrisa) | Possibly create separate criteria for adults and children due to differences in standards of care in pediatric patients. PA stats will be researched by all entities, including reason for denials, and brought back for review. |
| Hematopoietics/ Chronic ITP | On #1 rather than say insufficient response to a corticosteroid, require a platelet goal of 50,000 to define failure of steroids. |
| Hepatitis C Treatments | Strike #6 which requires a Metavir score of 2 or greater fibrosis. |
| Idiopathic Pulmonary Fibrosis | Require that patient is actively attempting smoking cessation vs being a nonsmoker or abstinent for at least 6 weeks. |
| Lesinurad (Zurampic) | May no longer be commercially available. |
| PCSK9 Inhibitors | Allow consultation with specialists rather than requiring they prescribe. |
| Potassium Binders | Review due to new agents and suggest the P&T Committee consider making one of the newer agents preferred based on lack of efficacy and side effects. SPS can cause GI necrosis, especially when used in combination with a laxative. |
| Pulmonary Arterial Hypertension Agents | Specify that it's a primary disease and not secondary to COPD. |
| Roflumilast (Daliresp) | Update criteria to use new GOLD criteria definitions (very severe stage D COPD, require CAT score or MMRC score). |
| Valsartan/Sacubitril (Entresto) | Strike #11 requiring consultation with or prescribed by cardiologist. Pam Smith said this was slated for review at a future meeting due to the new indications. |

***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.

Jason Kruse motioned to accept the criteria as amended, 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. Linezolid utilization reports, for each plan, will be brought back as Kellen Ludvigson requested.

***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.

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

***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 lV 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.

Mark Graber motioned to accept the criteria as amended, and Jason Kruse and Chuck Wadle both 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.

***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.

Mark Graber 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.

***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)

Jason Kruse motioned to remove the criteria, contingent on action from the P&T Committee making generic Lyrica preferred, 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.

***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).

Mark Graber 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.

***Multiple Sclerosis Agents, Oral:*** The Commission reviewed the prior authorization criteria as follows:

For patients initiating therapy with a preferred oral medication, a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. A diagnosis of relapsing forms of multiple sclerosis; and
2. Patient meets the FDA approved age; and
3. Request is for FDA approved dosing; and
4. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.
5. Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

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

For patients initiating therapy with fingolimod (Gilenya):

1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class lll/IV heart failure; and
2. Patient does not have a history or presence of Mobitz Type ll 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker; and
3. Patient does not have a baseline QTc interval ≥ 500ms; and
4. Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio):

1. Patient does not have severe hepatic impairment; and
2. A negative pregnancy test for females of childbearing age; and

3. Use of a reliable form of contraception for females of childbearing age; and
4. Patient is not taking leflunomide.

For patients initiating therapy with dimethyl fumarate (Tecfidera):

1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy; and
2. Upon renewal, documentation of an updated CBC.

For patients initiating therapy with cladribine (Mavenclad):

1. Patient's current weight is provided; and
2. Patient does not have a current malignancy and patient is up to date on all age appropriate malignancy screening; and
3. Pregnancy has been excluded in females of reproductive potential; and
4. Women and men of reproductive potential must use effective contraception during treatment and for 6 months after the last dose in each treatment course; and
5. Women must not intend to breastfeed while being treated and for 10 days after the last dose; and
6. Patient does not have HIV infection; and
7. Patient does not have active chronic infection (e.g. hepatitis or tuberculosis); and
8. No more than two yearly treatment courses (i.e. two treatment courses consisting of two treatment cycles) will be considered.

For patients initiating therapy on siponimod (Mayzent):

1. Patient does not have a CYP2C9*3/*3 genotype; and
2. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; and
3. Patient does not have a presence of Mobitz Type II 2nd degree, 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker.

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.

***Ospemifene (Osphena):*** The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for ospemifene (Osphena). Requests for a diagnosis of moderate to severe dyspareunia are considered not medically necessary and will be denied. Payment will be considered under the following conditions:

1. Patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; and
2. Patient has documentation of an adequate trial and therapy failure with a preferred vaginal estrogen agent; and
3. Patient does not have any contraindications to ospemifene as listed in the FDA approved label; and
4. Will not be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; and
5. Patient does not have severe hepatic impairment (Child-Pugh Class C); and
6. Patient will be evaluated periodically as clinically appropriate to determine if treatment is still necessary as ospemifene should be used for the shortest duration consistent with treatment goals and risks for the individual woman; and
7. Dose does not exceed the FDA approved dose.

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

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy.

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

***Abilify MyCite:*** The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for aripiprazole tablets with sensor (Abilify MyCite). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder; and
2. Patient meets the FDA approved age for use of the Abilify MyCite device; and
3. Dosing follows the FDA approved dose for the submitted diagnosis; and
4. Documentation of patient adherence to generic aripiprazole tablets is less than 80% within the past 6 months (prescriber must provide documentation of the previous 6 months' worth of pharmacy claims for aripiprazole documenting non-adherence); and
5. Documentation all the following strategies to improve patient adherence have been tried without success:
    a. Utilization of a pill box
    b. Utilization of a reminder device (e.g. alarm, application, or text reminder)
    c. Involving family members or friends to assist

d. Coordinating timing of dose with dosing of another daily medication; and

6. Documentation of a trial and intolerance to a preferred long-acting aripiprazole injectable agent; and
7. Prescriber agrees to track and document adherence of Abilify MyCite through the web-based portal for health care providers and transition member to generic aripiprazole tablets after a maximum of 4 months use of Abilify MyCite. Initial approvals will be given for one month. Prescriber must review member adherence in the web-based portal and document adherence for additional consideration. If non-adherence continues, prescriber must document a plan to improve adherence. If adherence is improved, consideration to switch member to generic aripiprazole tablets must be considered. Note, the ability of the Abilify MyCite to improve patient compliance has not been established.
8. Requests will not be considered for patients in long-term care facilities.
9. A once per lifetime approval will be allowed.

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.

***CGRP Inhibitors:*** The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for CGRP Inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis 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 headaches 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 of ≥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. Patient meets the FDA approved age for submitted diagnosis; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or
5. 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 480 mg to 960 mg). 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.
6. The requested dose does not exceed the maximum FDA labeled dose for the submitted diagnosis; and
7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional prior authorizations 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.

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

**Miscellaneous**

***DUR Digest:*** The Commission members conducted the second review of the draft DUR Digest Volume 32, Number 1. The DUR Digest will be posted to the DUR website.

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

At 12:17, Chuck Wadle and Mark Graber simultaneously motioned to adjourn, and Melissa Klotz seconded. All in attendance agreed.

**The next meeting will be held at 9:30 a.m. on Wednesday, March 4, 2020, at a location to be determined.**