# Iowa Medicaid Drug Utilization Review Commission
# Meeting Minutes October 5, 2016

**Attendees:**

| Commission Members |
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| Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; and Susan Parker, Pharm.D. |

| Staff |
| --- |
| Pam Smith, R.Ph. |

| Guests |
| --- |
| Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley. |

## Welcome & Introductions

Mark Graber called the meeting to order at 9:33 a.m. at the Learning Resource Center in West Des Moines. The minutes from the August 3, 2016 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Brett Faine seconded. The decision was unanimous. Mark Graber nominated Brett Faine to take over as chairperson, but he declined. Laurie Pestel nominated Mark Graber to remain as chairperson, and Larry Ambroson seconded. All members were in favor. Kellen Ludvigson nominated Laurie Pestel to remain as vice-chairperson, and Brett Faine and Larry Ambroson both seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was also reviewed.

## IME Pharmacy Update/News Relevant to Medicaid

The P&T Committee will do its annual PDL review in November, and discuss 2017 supplemental rebate contracts at that time. The MCO representatives each provided a summary of their recent prior authorization and claim statistics similar to those provided in the fee-for-service prevalence report summary below. Kellen Ludvigson mentioned an issue he'd had where an MCO member claim required prior authorization when it shouldn't have. Susan Parker asked for more detail so that she could bring it to her monthly meeting, and offered that future similar issues could be sent to her or Pam Smith for follow-up and resolution.

## Prevalence Report Summary

Fee-for-service (FFS) statistics from July through August 2016 were discussed, including: cost per user ($210.45), number of total prescriptions dispensed (a decrease of 24.6% compared to the previous reporting period), average cost per prescription ($58.78), and generic utilization (86.0%). The total paid amount decreased by 31.7% from the previous reporting period. There were 10,253 unique users, which is 24.7% less than the total for May and June. Lists of the top 20 therapeutic classes were provided. The highest

prescription count continues to come from the SSRI category, with Anticonvulsants still in second place. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, methylphenidate hcl er, Abilify, Strattera, Synagis, Focalin XR, Humalog, Advair Diskus, Onfi, and Latuda.

**Public Comment**

| Name | Representing | Drug/Topic |
|---|---|---|
| Jan Foote, ARNP | Blank Children's Hospital | Lupron Depot Ped PA Criteria |
| Melanie Dumlao | Sanofi Genzyme | Abagio – MS Oral class |
| Alan Roloff | Biogen Inc. | Tedfidera |

**Focus Studies**

***Duplicate Inhaled Corticosteroids:*** This was a follow-up discussion. Seventeen (17) of the 23 members identified changed therapy, for an annualized cost savings of $56,392 (state and federal, pre-rebate) as a result of the 63 surveys sent out to prescribers and pharmacies. A total of 22 (34.92%) surveys were returned.

***Duplicate Long-Acting Beta-Agonists:*** This was a follow-up discussion. Seven of the 12 members identified changed therapy, for an annualized cost savings of $35,371.72 (state and federal, pre-rebate) as a result of the 36 surveys sent out to prescribers and pharmacies. A total of 7 (19.44%) surveys were returned.

**ProDUR Edits**

***Morphine Equivalent Dosing (MED) Limits:*** As requested at the August meeting, the Commission was provided with reports illustrating the impact to fee-for-service and MCO members if limits were implemented. Kellen Ludvigson motioned to set a limit for 90mg morphine milligram equivalents (MME) per day, for the entire opioid class. Daniel Gillette seconded, and all members in favor. Any claims greater than or equal to 90 MME per day will require a prior authorization. Prior authorization criteria need to be created, possibly 2-tiered in the long-term with differing criteria for 50mg versus 90mg, and potentially requiring a concurrent Narcan prescription for anything higher than 90mg. Pam Smith will look into other states' criteria and see if CMS will share the Medicare Part D PA criteria, and also evaluate the opioids to identify any existing quantity limits that would exceed the 90mg equivalent limit. Kellen Ludvigson also suggested that the PA form require a check of the PMP prior to the prescriber writing the prescription, and that any claim found to have been cashed out for anything greater than an emergency supply would negate the prior authorization.

***Narcan Nasal Spray:*** Kellen Ludvigson motioned to set a limit of one box (2 doses) per 365 days, and Daniel Gillette seconded. All members were in favor. Quantities greater than 1 box per 365 days will require a prior authorization (criteria to be developed by the DUR at a future meeting).

***EpiPen:*** Fee-for-service and MCO pharmacy claims from April through October 2016 will be checked for frequent fills, unique users, and number of fills and results brought to a future meeting. If necessary, this might be an educational initiative.

**Prior Authorization**

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

| PA Category | Recommended Changes |
|---|---|
| Alpha2 Agonists, Extended-Release | Remove Strattera trial. |
| Antidepressants | Check indications to make sure additional diagnoses don't need to be added to #1. |
| Anti-Diabetics, Non-Insulin Agents | Include language for Incretin Mimetics (reference American Diabetic Association guidelines) |
| Becaplermin (Regranex®) | Check indications. |
| Benzodiazepines | Add criteria for use with opioids. |
| Buprenorphine Transdermal System (Butrans) & Buccal Film (Belbuca) | Move to the Long-Acting Opioids criteria. |
| Buprenorphine/Naloxone | Reword #6 (Requests for buprenorphine will only be considered for pregnant patients). |
| Colchicine (Colcrys®) | Re-evaluate if still needed. Amerigroup only had 7 PAs in August and approved them all per Sandy Pranger. |
| CNS Stimulants and Atomoxetine | Remove all references to ADD as it's no longer a diagnosis and language indicating idiopathic hypersomnia is not a covered diagnosis. |
| Concurrent IM/PO Antipsychotic Use | Will no longer be needed due to POS duplicate therapy edits being put in place in 2017. Will remove/update once POS edits implemented. |
| Insulin, Pre-Filled Pens | Possibly change the trial criteria for products that don't have an equivalent preferred agent in a non-pen form or create separate criteria for those agents. |
| Long-Acting Opioids | Incorporate criteria for benzodiazepines and naloxone. |
| Lumacaftor/Ivacaftor (Orakmbi™) | Adjust age requirement as now indicated to 6 years of age. |
| Roflumilast (Daliresp™) | Revise #3 to require an inhaled anticholinergic in combination with an inhaled corticosteroid and long-acting bronchodilator for COPD. |

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

*Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:*

*Moderate to Severe Persistent Asthma*

1. *Patient has a diagnosis of moderate to severe persistent asthma for at*

*least one year; and*

2. *Patient is 6 years of age or older; and*
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
    b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
5. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
    b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and*
6. *History of positive skin or RAST test to a perennial aeroallergen; and*
7. *Prescriber is an allergist, immunologist, or pulmonologist; and*
8. *Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and*
9. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.*
10. *Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of Xolair®.*

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

*<u>Chronic Idiopathic Urticaria</u>*

1. *Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and*
2. *Patient is 12 years of age or older; and*
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. *Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
5. *Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and*

6. *Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
7. *Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

*If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.*

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

Brett Faine motioned to accept the criteria as amended, and Larry Ambroson and Daniel Gillette both seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

***Oral Constipation Agent:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for oral constipation agents. Payment will be considered under the following conditions:*

1. *Patient is 18 years of age or older; and*
2. *Patient must have documentation of adequate trials and therapy failures with both of the following:*
    a. *Stimulant laxative (senna) plus saline laxative (milk of magnesia); and*
    b. *Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose).*
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® or Linzess™)*
        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; and*
            3. *Sensation of incomplete evacuation for at least 25% of bowel movements; and*
        iii. *Documentation the patient is not currently taking constipation causing therapies*

b. *A diagnosis of irritable bowel syndrome with constipation (Amitiza® or Linzess™)*
    i. *Patient is female (Amitiza® only); and*
    ii. *Patient has abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two (2) or more of the following:*
        1. *Improvement with defecation;*
        2. *Onset associated with a change in stool frequency; and/or*
        3. *Onset associated with a change in stool form.*
c. *A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™ or Relistor®)*
    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; and/or*
        3. *Having a sensation of incomplete evacuation.*
    iii. *Patient has documentation of an adequate trial and therapy failure with Amitiza®, if prior authorization request is for a different oral constipation agent.*

*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.*

Daniel Gillette motioned to accept the criteria as amended, and Brett Faine and Kellen Ludvigson both seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

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

*Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:*

1. *A diagnosis of relapsing forms of multiple sclerosis; and*
2. *A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis; and*
3. *Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.*

*For patients initiating therapy with fingolimod (Gilenya™), 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. *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 III/IV heart failure.*
2. *Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.*
3. *Patient does not have a baseline QTc interval ≥ 500ms.*
4. *Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.*

*For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:*

1. *Patient does not have severe hepatic impairment.*
2. *A negative pregnancy test for females of childbearing age.*
3. *Use of a reliable form of contraception for females of childbearing age.*
4. *Patient is not taking leflunomide.*

*For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:*

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

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

Daniel Gillette motioned to accept the criteria as amended, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

***Lupron Depot Pediatric:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for Lupron Depot-Ped. Payment will be considered for patients when the following is met:*

1. *Patient has a diagnosis of central precocious puberty (CPP); and*
2. *Patient has documentation of onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males; and*
3. *Patient is currently < 11 years of age for females or < 12 years of age for males; and*

4. *Confirmation of diagnosis by a pubertal response to a gonadotropin-releasing hormone (GnRH) stimulation test is provided (attach results); and*
5. *Documentation of advanced bone age (defined as greater than or equal to two standard deviations above the gender/age related mean); and*
6. *Baseline evaluations including the following have been conducted and/or evaluated:*
    a. *Height and weight measurements; and*
    b. *Sex steroid (testosterone or estradiol) levels have been obtained; and*
    c. *Appropriate diagnostic imaging of the brain has been conducted to rule out an intracranial tumor; and*
    d. *Pelvic/testicular/adrenal ultrasound has been conducted to rule out steroid secreting tumors; and*
    e. *Human chorionic gonadotropin levels have been obtained to rule out a chorionic gonadotropin secreting tumor; and*
    f. *Adrenal steroid levels have been obtained to rule out congenital adrenal hyperplasia; and*
7. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.*

*When criteria for coverage are met, an initial authorization will be given for 6 months.*

*Additional approvals will be granted at 6 month intervals until the patient is ≥ 11 years of age for females and ≥ 12 years of age for males. If therapy beyond the aforementioned ages is required, documentation of medical necessity will be required.*

As this was the second review of these criteria, no motion was necessary. Susan Parker will ask the IME Provider Cost Audit unit to look at the fee schedule for Medical reimbursement of this medication due to the public comment provided. The recommendation will be sent to the Department for consideration.

***Lupron Depot Adult:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:*

1. *Patient is 18 years of age or older; and*
2. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
3. *Patient has a diagnosis of endometriosis for whom therapy with NSAIDs and at least one preferred 3 month course of a continuous hormonal contraceptive has failed; or*

4. *Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or*
5. *Patient has a diagnosis of advanced prostate cancer.*

*Therapy will be limited as follows:*

- *Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.*
- *Uterine leiomyomata – 3 month approval.*
- *Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).*

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

***Short-Acting Opioids:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for all non-preferred short acting opioids. Payment will be considered under the following conditions:*

1. *Patient has pain severe enough to require opioid treatment; and*
2. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen or NSAIDs); and*
4. *Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and*
5. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring program website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
6. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*

*If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:*

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a short-acting opioid is appropriate for this member.*

*The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.*

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

***Buprenorphine/Naloxone:*** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for oral buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids, tramadol and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:*

1. *Patient has a diagnosis of opioid dependence and is 16 years of age or older: AND*
2. *Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND*
3. *Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND*
4. *A projected treatment plan is provided, including:*
   - *Anticipated induction/stabilization dose,*
   - *Anticipated maintenance dose,*
   - *Expected frequency of office visits, and*
   - *Expected frequency of counseling/psychosocial therapy visits; AND*
5. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
6. *Requests for buprenorphine will only be considered for pregnant patients.*

*Requests for renewal must include:*

- *An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale,*
- *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request,*
- *Documentation of a current, negative drug screen,*
- *Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.*
- *Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.*

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 reviewed the draft for DUR Digest Volume 29, Number 1 a second time. The final version will be posted to the DUR website.

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

At 11:34, Larry Ambroson motioned to adjourn the meeting and Daniel Gillette seconded. (No closed session was needed due to lack of profile review post MCO transition.)

**The next meeting will be held at 9:30 a.m. on Wednesday, December 7, 2016, at the Learning Resource Center in West Des Moines.**