

# Iowa Medicaid Drug Utilization Review Commission

## Meeting Minutes October 1, 2014

### Attendees:

#### Commission Members

Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Gregory Barclay, M.D.; Kellen Ludvigson, Pharm.D.; Larry Ambroson, R.Ph.; Brett Faine, Pharm.D.; Brian Couse, M.D.; Jason Wilbur, M.D.; and Susan Parker, Pharm.D.

#### Staff

Pam Smith, R.Ph.

#### Guests

Jason Kessler, M.D., IME; Erin Halverson, R.Ph., IME; Megan Smith, Pharm.D., IME; and Melissa Biddle, IME.

### 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 6, 2014 meeting were reviewed. Gregory Barclay motioned to accept them, and Kellen Ludvigson seconded simultaneously. All members were in favor. The recommendation letter sent to DHS after the last meeting, in addition to a letter sent to the DUR Commission from the P&T Committee requesting development of PA criteria for Hetlioz, Otezla, and Zykadia, were also reviewed.

### IME Updates

Medicaid Director Jennifer Vermeer left Iowa Medicaid for a position at the University of Iowa on August 21, 2014. Julie Lovelady is the interim director while a national search is conducted. Over 115,000 members are now enrolled in the Iowa Health and Wellness Plan (IHAWP). A new DHS website was launched in June, along with a new website featuring the latest information on IHAWP: <http://www.iahealthlink.gov>. Magellan and the IME are working together on the health homes for chronic conditions project. CMS approved the State Plan Amendment to increase the dispensing fee to \$11.73 on September 24, 2014. Claims will be adjusted retroactively back to August 1, 2014. Providers will be notified of this change via informational letter. Pam Smith will bring results from the annual Federal and State DUR reports to the next meeting.

### Prevalence Report Summary

Statistics from July through August 2014 were discussed, including: cost per user (\$299.24), number of total prescriptions dispensed (an increase of 4% compared to the previous reporting period), average cost per prescription (\$60.48), and generic utilization (83.6%). The total paid amount increased by 6.6% from the previous reporting period. There were 183,702 unique users, which is 2% more than the total for May and June. Lists of the top 20 therapeutic classes were provided. SSRIs had

the highest prescription count, and Anticonvulsants came in second. The top 100 drugs were also reviewed. The ten most expensive medications were: Abilify, Vyvanse, methylphenidate hcl er, Lantus, Advate, Cymbalta, Focalin XR, Adderall, Advair Diskus, and Strattera.

### **Case Studies**

Pam Smith presented 4 case studies. Recommendations by commissioners from these four examples resulted in annualized total savings of \$2,054.31 pre-rebate (state and federal).

### **Public Comment**

There were none, as both speakers chose to defer to the second public comment section.

### **ProDUR Edit**

***Antipsychotics – Age Edit and Duplicate Therapy Edit:*** The DUR Commission reviewed recommendations they initially made in April 2012 to implement ProDUR edits on antipsychotics in members less than 18 years of age. Specifically, the recommendation was to: 1) implement an age edit on risperidone for members less than five (5) years of age and an age edit on all other antipsychotics for members less than six (6) years of age; and 2) apply a duplicate therapy edit to all antipsychotics. After discussion, the Commission continues to support implementation of the aforementioned ProDUR edits, tentatively scheduled for implementation in the summer of 2015. Prior to initiation of these edits, an informational letter will be sent to all providers, to encourage changes to drug regimen or submission of a PA prior to implementation of the edits and prior to discharge. Soft edits will also be programmed into the Point of Sale (POS) system indicating the claim(s) will deny for a PA at the specific date indicated, which should prompt the pharmacy to notify the prescriber.

### **Focus Studies**

***Valproate Use for Migraine in Females:*** This was a follow-up discussion. Nineteen (19) of the 39 members identified changed therapy, for an annualized cost savings of \$2,998.62 (state and federal, pre-rebate) as a result of the 93 surveys sent out to prescribers and pharmacies. Forty-two (42), or 45%, of those surveys were returned.

***Ketoconazole Utilization:*** This was a follow-up discussion. Fifty-four (54) of the 66 members identified changed therapy, for an annualized cost savings of \$3,764.10 (state and federal, pre-rebate) as a result of the 132 surveys sent out to prescribers and pharmacies. Sixty-six (66), or 50%, of those surveys were returned.

***Overutilization of Opioids:*** This was a follow-up discussion. One-hundred twenty (120) of the 244 members identified changed therapy, for an annualized cost

savings of \$66,768.90 (state and federal, pre-rebate) as a result of the 941 surveys sent out to prescribers and pharmacies. Three-hundred eighty-one (381), or 40% of those surveys were returned.

***Opioid Utilization Potential Drug Seeking Behavior:*** This was a follow-up discussion. Twenty-two (22) of the 38 members identified changed therapy, for an annualized cost savings of \$5,445.06 (state and federal, pre-rebate) as a result of the 375 surveys sent out to prescribers and pharmacies. One-hundred thirty (130), or 35%, of those surveys were returned. The Commission was curious as to the algorithm used by the lock-in department to identify potential members, and Pam Smith will look into that.

***Valproate Use in Women of Childbearing Age without Seizure or Bipolar Diagnosis:*** This was a follow-up discussion. Twenty-six (26) of the 70 members identified changed therapy, for an annualized cost savings of \$4,856.64 (state and federal, pre-rebate) as a result of the 154 surveys sent out to prescribers and pharmacies. Sixty-four (64), or 42%, of those surveys were returned.

***Valproate Use in Women of Childbearing Age with Seizure or Bipolar Diagnosis:*** This was a follow-up discussion. Seventy-five (75) of the 270 members identified changed therapy, for an annualized cost savings of \$14,919.44 (state and federal, pre-rebate) as a result of the 592 surveys sent out to prescribers and pharmacies. Two-hundred fifty-six (256), or 43% of those surveys were returned.

***Long Term Use of Short-Acting Opioids:*** The Commission wants to lower the existing quantity limits to a quantity of 120 per 30 days, or 4 per day, across the entire drug class. Jason Wilbur motioned to implement this quantity limit, and Brett Faine seconded. All members were in favor. Soft POS edits will be put into place to notify providers of the changes prior to implementation of the quantity limits, and an information letter will also be sent out to prescribers and pharmacies.

***Duplicate Antipsychotics:*** Letters will be sent to those who will be affected by the ProDUR edits that were agreed upon at previous meetings for members 17 years of age and younger, as documented above. The Commission also wants to send letters to the prescribers of adults on 2 or more second generation antipsychotics concurrently for greater than 90 days to ask: 1) if the patient would be a candidate to taper to one agent, 2) if the patient is a candidate for clozapine therapy, and 3) if the patient has had three failed trials of monotherapy prior to using two or more antipsychotics.

***Duplicate Benzodiazepines:*** The Commission wants to review the quantity limits on all benzodiazepines, and also look at the numbers on combination therapy. This information will be brought to the December meeting. Additionally, letters will be sent to the prescribers of the members identified to ask if the patient could be adequately controlled on one agent.

**Niacin Utilization:** Letters will be sent to the prescribers of the members taking niacin with a statin to suggest dose optimization of the statin and discontinuation of niacin. Additionally, the DUR Commission made a recommendation that the P&T Committee make niacin non-preferred on the PDL, requiring use of a statin prior to use.

**Public Comment**

Name	Representing	Drug/Topic
Lisa Willshaw	MedImmune	Synagis
Christina Reimers	Merck	Zontivity, Grastek, and Ragwitek

**Prior Authorization**

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

PA Category	Recommend Changes
Alpha2 Agonists, Extended-Release	Define length of trial.
Amylino Mimetic (Symlin®)	Add requirement of 0.5% improvement in A1C
Anti-Acne	Waiting for American Academy of Dermatology to update guidelines, anticipated in November, 2014.
Apixaban (Eliquis)	Update criteria based on new FDA approved indications
Benzodiazepines	Require SSRI failure for GAD.
Biologic Immunomodulators	Add TB screening across all biologic immunomodulator PA forms.
Erythropoiesis Stimulating Agents	Require response to treatment.
Hepatitis C Antiviral Agents	Possibly allow other tests in addition to biopsy, as there have already been 33 appeals. Remove Incivek criteria.
Pulmonary Arterial Hypertension Agents	Limit access to responsive types, not smokers.
Testosterone Products	Update diagnosis for coverage based on recent FDA review.
Thrombopoietin Receptor Agonists	Update Promacta criteria for new indications.
Antiemetics	Look at increasing the number of ondansetron units allowed with out PA.
Topical corticosteroids (new)	Require multiple trials with preferred agents prior to a non-preferred agent.
Antineoplastics (new)	Universal PA form for oral agents - Check for diagnosis and dosing.
Immunoglobulin serums (new)	Look at utilization and determine if PA criteria is required.

**Vorapaxar (Zontivity):** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for vorapaxar (Zontivity™). Payment will be considered under the following conditions:*

- 1. Patient has a history of myocardial infarction (MI) or peripheral artery disease; and*
- 2. Patient does not have a history of stroke, transient ischemic attack (TIA), intracranial bleeding, or active peptic ulcer; and*
- 3. Patient has documentation of an adequate trial and therapy failure with aspirin plus clopidogrel; and*
- 4. Patient will use vorapaxar concurrently with aspirin and/or clopidogrel.*

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

Mark Graber commented that there is no active coagulation for stints, and suggested requiring a second trial with Brillinta. An age limit was also suggested as this is not effective over age 75. This will be brought back to the next meeting.

**Ceritinib (Zykadia):** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for ceritinib (Zykadia™). Payment will be considered under the following conditions:*

- 1. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test (attach copy of results); and*
- 2. Patient is 18 years of age or older; and*
- 3. Prescribed by a oncologist; and*
- 4. Patient has documentation of treatment with crizotinib and the disease has progressed while on treatment or is intolerant to treatment.*
- 5. Liver function tests (ALT, AST, and total bilirubin) will be monitored at least monthly while on ceritinib.*

*If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered with documentation patient has not experienced disease progression or unacceptable toxicity.*

Brett Faine motioned to accept the criteria, and Jason Wilbur seconded. All members were in favor.

**Chronic Pain Syndromes:** The Commission reviewed the prior authorization criteria as follows:

*A prior authorization is required for duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™). 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. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization. Payment will be considered under the following conditions:

1. A diagnosis of **fibromyalgia** (Cymbalta<sup>®</sup>, Lyrica<sup>®</sup>, and Savella<sup>™</sup>)
  - a. A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, SSRI, or SNRI, **WITH**
  - b. Documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.), **AND**
  - c. Documentation of a previous trial and therapy failure at a therapeutic dose with Savella<sup>™</sup> when Cymbalta<sup>®</sup> and Lyrica<sup>®</sup> are requested.
2. A diagnosis of **post-herpetic neuralgia** (Lyrica<sup>®</sup>)

A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, valproate, or carbamazepine.
3. A diagnosis of **diabetic peripheral neuropathy** (Cymbalta<sup>®</sup> and Lyrica<sup>®</sup>)

A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or topical lidocaine.
4. A diagnosis of **partial onset seizures**, as adjunct therapy (Lyrica<sup>®</sup>)
5. A diagnosis of **major depressive disorder or generalized anxiety disorder** (Cymbalta<sup>®</sup>)
6. A diagnosis of **chronic musculoskeletal pain** (Cymbalta<sup>®</sup>)

A trial and therapy failure at a therapeutic dose with at least two drugs from two distinct therapeutic classes from the following: NSAIDs, opioids, tramadol, or tricyclic antidepressants.

Requests for concomitant use of these agents for an indicated chronic pain diagnosis may only be considered once each agent has been tried at maximum tolerated dose separately. Duplicate use of drugs from the same therapeutic category will not be considered. Requests for doses above the manufacturer recommended dose will not be considered.

Kellen Ludvigson motioned to accept the criteria as amended (chronic musculoskeletal pain), and Brian Couse seconded. All members were in favor. The recommendation will be sent to the Department for consideration.

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

Prior authorization is required for sublingual allergen immunotherapy. Payment will be considered under the following conditions:

1. Medication is prescribed in consultation with an allergist; and

2. *Patient is diagnosed with pollen-induced allergic rhinitis with or without conjunctivitis; and*
3. *Patient has documented trials and therapy failures with allergen avoidance and pharmacotherapy (intranasal corticosteroids and antihistamines); and*
4. *Patient has a documented intolerance to immunotherapy injections; and*
5. *The first dose has been administered under the supervision of a health care provider to observe for allergic reactions (date of administration and response required prior to consideration).*
6. *If patient receives other immunotherapy by subcutaneous allergen immunotherapy (SCIT), treatment of allergic rhinitis with sublingual allergen immunotherapy (SLIT) will not be approved.*

*Short Ragweed Pollen (Ragwitek<sup>®</sup>) In addition to the above criteria being met:*

- *Patient is 18 through 65 years of age; and*
- *Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to short ragweed pollen.*
- *If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of ragweed pollen season and continued throughout the season.*

*Grass Pollen (Grastek<sup>®</sup> and Oralair<sup>®</sup>) In addition to the above criteria being met:*

*Grastek<sup>®</sup>*

- *Patient is 10 through 65 years of age (Oralair<sup>®</sup>); and*
- *Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to sweet vernal, orchard/cockfoot, perennial rye, timothy, and Kentucky blue/June grass.*
- *If criteria for coverage are met, authorization will be considered at least 4 months prior to the expected onset of each grass pollen season and continued throughout the grass pollen season; or*

*Oralair<sup>®</sup>*

- *Patient is 5 through 65 year of age (Grastek<sup>®</sup>); and*
- *Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to timothy grass (or cross reactive grasses such as sweet vernal, orchard/cockfoot, perennial rye, Kentucky blue/June, meadow fescue, and redtop).*
- *If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of each grass pollen season.*

Jason Wilbur motioned to accept the criteria as amended, and Larry Ambroson and Brian Couse seconded simultaneously. All members were in favor. The recommendation will be sent to the Department for consideration.

**Methotrexate Injection:** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for non-preferred methotrexate injection. Payment will be considered under the following conditions:*

1. *Diagnosis of severe, active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA) and ALL of the following:*
  - a. *Prescribed by a rheumatologist; and*
  - b. *Patient has a documented trial and intolerance with oral methotrexate; and*
  - c. *Patient has a documented trial and therapy failure or intolerance with at least one other non-biologic DMARD (hydroxychloroquine, leflunomide, minocycline or sulfasalazine); and*
  - d. *Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and*
  - e. *Patient does not reside in a long-term care facility.*
2. *Diagnosis of severe, recalcitrant, disabling psoriasis and ALL of the following:*
  - a. *Patient is 18 years of age or older; and*
  - b. *Prescribed by a dermatologist; and*
  - c. *Patient has documentation of an inadequate response to all other standard therapies (oral methotrexate, topical corticosteroids, vitamin D analogues, cyclosporine, systemic retinoids, tazarotene, and phototherapy).*
  - d. *Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and*
  - e. *Patient does not reside in a long-term care facility.*

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

**Tasimelteon (Hetlioz):** The Commission reviewed the prior authorization criteria as follows:

- Prior authorization is required for tasimelteon (Hetlioz) Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered under the following conditions:*
1. *Patient has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24) as confirmed by a sleep specialist; and*
  2. *Patient is 18 years of age or older; and*
  3. *Documentation the patient is totally blind with no perception of light is provided; and*
  4. *Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic – non-benzodiazepine agent; and*
  5. *Patient has a documented trial and therapy failure with ramelteon (Rozerem).*
- If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered when the patient has received 3 months of continuous therapy and patient has achieved adequate results with tasimelteon (Hetlioz), such as entrainment, significant increases in nighttime sleep, and/or significant decreases in daytime sleep.*

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

**Apremilast (Otezla):** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for apremilast (Otezla®). Payment will be considered under the following conditions:*

- 1. Patient is 18 years of age or older; and*
- 2. Patient has a diagnosis of active psoriatic arthritis ( $\geq 3$  swollen joints and  $\geq 3$  tender joints); and*
- 3. Prescribed by a rheumatologist or a dermatologist; and*
- 4. Patient does not have severe renal impairment ( $\text{CrCl} < 30 \text{ mL/min}$ ); and*
- 5. Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*
- 6. Patient has documentation of trials and therapy failures with two preferred biological agents used for psoriatic arthritis.*

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

**Palivizumab (Synagis):** The Commission reviewed the prior authorization criteria as follows:

*Prior authorization is required for therapy with palivizumab. Prior authorizations will be approved for administration during the RSV season for a maximum of five doses per patient. No allowances will be made for a sixth dose. Patients, who experience a breakthrough RSV hospitalization, should have their monthly prophylaxis discontinued, as there is an extremely low likelihood of a second RSV hospitalization in the same season. Payment for palivizumab will be considered for patients who meet one of the following criteria:*

*Chronic Lung Disease (CLD) of Prematurity*

- Patient is less than 12 months of age at start of therapy and develops CLD of prematurity (defined as gestational age less than 32 weeks and required greater than 21% oxygen for at least the first 28 days after birth).*
- Requests for patients during their second year of life (12 months to < 24 months) will be considered for patients meeting the CLD of prematurity definition above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.*

*Hemodynamically Significant Congenital Heart Disease (CHD)*

- Patient is less than 12 months of age at start of therapy and has hemodynamically significant CHD further defined by any of the following:*

- *Patient with acyanotic heart disease who is receiving medication to control congestive heart failure and will require cardiac surgical procedures or*
- *Patient with moderate to severe pulmonary hypertension.*
- *Requests for patients with cyanotic heart defects will be considered with documentation of consultation with a pediatric cardiologist that recommends patient receive palivizumab prophylaxis.*

*Premature Infants (without CLD of Prematurity or CHD)*

- *Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks.*

*Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder*

- *Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway due to an ineffective cough.*

*Immunocompromised Children*

- *Patient is less than 24 months of age at start of therapy and is profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy).*

Pam Smith consulted other states on their criteria for the upcoming RSV season; only a few who accepted the supplemental rebate offer, contingent upon not updating their criteria, would not be adopting the new AAP guidelines. Wellmark will also be adopting the new guidelines, and the Iowa AAP is also supports the new AAP guidelines. 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 27, Number 1.

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

***Off-label Pharmaceutical Marketing:*** The Commission members received copies of the information provided by CMS on this topic.

A unanimous roll call vote was made at 11:50 to adjourn the meeting and move to closed session (motion by Brian Couse, second by Jason Wilbur).

**The next meeting will be held at 9:30 a.m. on Wednesday, December 3, 2014, at the Learning Resource Center in West Des Moines.**