

**Drug Utilization Review Board  
Meeting Agenda, Open Session  
January 13, 2016 10:00 a.m. – 2:00 p.m.**

**Meeting Location**

HP Enterprise Services, Capital Room  
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619

**Board Members**

Russell Scheffer, MD	Roger Unruh, DO
James Backes, PharmD	Moneeshindra Mittal, MD
Tim Heston, DO	Lauren Morton, PharmD, BCPS
John Kollhoff, PharmD	LaTonyua Rice, PharmD, CGP
Judy McDaniel Dowd, PA-C	

**KDHE-DHCF Staff**

Liane Larson, PharmD      Carol Arace, Administrative Assistant

**HP Enterprise Services/HID Staff**

Ariane Casey, PharmD      Karen Kluczykowski, RPh  
Nancy Perry, RN

**MCO Staff**

Jonalan Smith, PharmD, FASCP, **Sunflower State Health Plan**  
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**  
Lisa Todd, RPh, **Amerigroup**

**I. CALL TO ORDER**

**A. Announcements**

**II. OLD BUSINESS**

**A. Review and Approval of October 14, 2015 Meeting Minutes**

**III. NEW BUSINESS**

**A. Mental Health Medication Advisory Committee (MHMAC)**

**1. Use of Multiple Concurrent Benzodiazepines**

At the October 2015 MHMAC meeting, the committee approved the benzodiazepine dosing limit criteria. Prior authorization criteria are being proposed to limit the number of individual benzodiazepines used concurrently within 30 days to a maximum of 2 medications before a prior authorization is required.

- i. MHMAC PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**2. Use of Concurrent Multiple Antipsychotics**

At the October 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent antipsychotics. Prior authorization criteria are being proposed to limit the number of individual antipsychotics used concurrently for greater than 60 days to a maximum of 2 oral/injectable medications or 1 injectable formulation in adults and 2 medications in the pediatric population before a prior authorization is required.

- i. MHMAC PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**3. Antipsychotics for Children Ages 13 and Younger**

At the October 2015 MHMAC meeting, the committee approved the age limit criteria for antipsychotics in children 13 years of age or younger. Prior authorization criteria are being proposed to limit the use to specific diagnoses and require appropriate monitoring.

- i. MHMAC PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**4. Antipsychotic Dosing Limits**

At the October and December 2015 MHMAC meetings, the committee approved the criteria for antipsychotic dosing limits. Prior authorization criteria are being proposed to limit the maximum daily dose allowed before a prior authorization is required.

- i. MHMAC PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**5. Use of Multiple Concurrent Selective Serotonin Reuptake Inhibitors (SSRIs)**

At the December 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent selective serotonin reuptake inhibitors (SSRIs). Prior authorization criteria are being proposed to limit the number of individual antipsychotics used concurrently for greater than 60 days to a maximum of 1 medication before a prior authorization is required.

- i. MHMAC PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**6. Use of Multiple Concurrent Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)**

At the December 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent serotonin-norepinephrine reuptake inhibitors (SNRIs). Prior authorization criteria are being proposed to limit the number of individual antipsychotics used concurrently for greater than 60 days to a maximum of 1 medication before a prior authorization is required.

- i. MHMAC PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**7. Use of Multiple Concurrent Antidepressants**

At the December 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent antidepressants. Prior authorization criteria are being proposed to limit the number of individual antipsychotics used concurrently for greater than 60 days to a maximum of 2 medications before a prior authorization is required.

- i. MHMAC PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

## B. Revised Prior Authorization (PA) Criteria

### 8. LABA-Anticholinergic Combinations (Utibron Neohaler [indacaterol/glycopyrrolate], Stiolto Respimat [tiotropium/olodaterol])

Prior authorization criteria for LABA-Anticholinergic Combinations (formerly named Anoro Ellipta, the only medication in the class at that time) were initially approved in October 2014. Since that time, two new agents have been approved. The prior authorization criteria is being revised to include the new agents, Utibron NeoHaler and Stiolto Respimat.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 9. Eylea® (aflibercept)

Eylea is an intravitreal injection indicated for the treatment of macular edema and macular degeneration. Prior authorization criteria were initially approved in July 2014. Since that time, two new indications have been approved, diabetic macular edema and diabetic retinopathy in patients with diabetic macular edema. The prior authorization criteria are being revised to ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 10. Hetlioz® (tasimelteon)

Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24 hour sleep-wake disorder. Prior authorization criteria were initially approved in January 2015. Efficacy of Hetlioz was only established in patients who were totally blind with no perception of light. The prior authorization criteria are being revised to ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 11. Humira® (adalimumab)

Humira is a tumor necrosis factor-alpha (TNF- $\alpha$ ) blocker indicated as a biologic treatment in several diagnoses. Prior authorization criteria were last revised in January 2015. Since that time, a new indication has been approved, hidradenitis suppurativa. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 12. Stelara® (ustekinumab)

Stelara is an immunomodulator indicated for biologic treatment of plaque psoriasis and psoriatic arthritis. Prior authorization criteria were last revised in January 2014. Recommended dosing begins at 45 mg per injection, only to be increased based on weight, efficacy, and coexistent conditions. The prior authorization criteria are being revised to ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**13. Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor Combinations (Invokamet [canagliflozin/metformin], Synjardy [empagliflozin/metformin], Xigduo XR [dapagliflozin/metformin])**

Prior authorization criteria for SGLT2 Inhibitor Combinations were initially approved in April 2015. Since that time, three new agents have been approved. The prior authorization criteria is being revised to include the new agents, Invokamet, Synjardy, and Xigduo XR.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**14. Topical Acne Medications**

Prior authorization criteria for Topical Acne Medications were last revised in October 2014. Since that time, a new agent has been approved and minimum ages have been established in several products. The prior authorization criteria is being revised to include the new agent, Epiduo Forte, and allow approval for appropriate ages based on medication. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**15. Zyvox® (linezolid)**

Zyvox is an anti-infective agent indicated for the treatment of gram positive bacteria. Prior authorization criteria were initially approved in May 2009. Dependent upon the infection, the recommended duration of treatment is typically 10-14 days and up to 28 days for certain infections. The prior authorization criteria are being revised to ensure appropriate use and to approve for a recommended duration of therapy.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**16. Berinert® (C1 esterase inhibitor, human)**

Berinert is a protein C1 inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in October 2010. Since that time, a new specification has been approved, laryngeal attack. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**17. Cinryze® (C1 esterase inhibitor, human)**

Cinryze is a protein C1 inhibitor indicated for the prophylaxis of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in July 2009. Since that time, the medication has been approved for ages 13 years and older. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to include ages 13-17 years for this indication, to be consistent with similar agents, and to ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**18. Ruconest® (C1 esterase inhibitor, recombinant)**

Beriner is a protein C1 inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in October 2014. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**19. Firazyr® (icatibant)**

Firazyr is a bradykinin inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in July 2012. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**20. Kalbitor® (ecallantide)**

Kalbitor is a kallikrein inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in July 2012. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**21. Harvoni® (ledipasvir/sofosbuvir)**

Harvoni is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection. Prior authorization criteria were last revised in October 2015. Since that time, Harvoni has become indicated for the treatment of genotypes 4, 5, and 6. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

**22. Viekira Pak® (ombitasvir/paritaprevir/ritonavir and dasabuvir)**

Viekira Pak is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection. Prior authorization criteria were last revised in October 2015. Since that time, a contraindication for use in patients with Child-Pugh class B has been added. This is due to the risk of serious liver injury in those with underlying advanced liver disease. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 23. **Technivie® (ombitasvir/paritaprevir/ritonavir)**

Technivie is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection. Prior authorization criteria were initially approved in October 2015. Since that time, a contraindication for use in patients with Child-Pugh class B has been added. This is due to the risk of serious liver injury in those with underlying advanced liver disease. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. \*Public Comment
- iii. Board Discussion

## **C. New Prior Authorization (PA) Criteria**

### 1. **Neurokinin 1 (NK<sub>1</sub>) Antagonists**

NK<sub>1</sub> inhibitors are indicated for the prevention of nausea and vomiting associated with cancer chemotherapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 2. **Emend® (aprepitant)**

Emend Oral is a neurokinin 1 (NK<sub>1</sub>) inhibitor indicated for the prevention of nausea and vomiting associated with cancer chemotherapy or for prevention of postoperative nausea and vomiting. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 3. **Ninlaro® (ixazomib)**

Ninlaro is a proteasome inhibitor indicated for the treatment of multiple myeloma, in combination with lenalidomide and dexamethasone, in adult patients who have received at least 1 prior therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

### 4. **Empliciti® (elotuzumab)**

Empliciti is an antineoplastic monoclonal antibody indicated for the treatment of multiple myeloma, in combination with lenalidomide and dexamethasone, in adult patients who have received 1-3 prior therapies. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

**5. Darzalex® (daratumumab)**

Darzalex is an antineoplastic monoclonal antibody indicated for the treatment of multiple myeloma in adult patients who have received at least 3 prior therapies, including a proteasome inhibitor and an immunomodulatory agent or who are double-refractory to a proteasome inhibitor and an immunomodulatory agent. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

**6. Tagrisso® (osimertinib)**

Tagrisso is a tyrosine kinase inhibitor indicated for the treatment of metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) in adult patients who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

**7. Onivyde® (irinotecan liposome)**

Onivyde is a DNA topoisomerase I inhibitor indicated for the treatment of metastatic adenocarcinoma of the pancreas, in combination with fluorouracil and leucovorin, after disease progression following gemcitabine-based therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

**8. Cotellic® (cobimetinib)**

Cotellic is a mitogen-activated extracellular kinase (MEK) inhibitor indicated for the treatment of unresectable or metastatic melanoma in adult patients with a BRAF V600E or V600K mutation, in combination with vemurafenib. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

**9. Nucala® (mepolizumab)**

Nucala is a respiratory monoclonal antibody indicated for add-on maintenance treatment of severe asthma with an eosinophilic phenotype in adults and children 12 years and older. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

#### **10. Belbuca® (buprenorphine)**

Belbuca is an opioid receptor agonist-antagonist analgesic indicated for the management of severe pain requiring daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

#### **11. Intravenous Immune Globulins (IVIGs)**

Intravenous immune globulins are used for several FDA indications and several off-label uses. Prior authorization criteria is being proposed to ensure appropriate use based upon the available prescribing information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. \*Public Comment
- iii. Board Discussion

#### **IV. OPEN PUBLIC COMMENT**

#### **V. ADJOURN**

**Lunch will be provided for the DUR Board members.  
The next DUR Board meeting is scheduled for April 13, 2016.**

\*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

**\*\*THIS AGENDA IS SUBJECT TO CHANGE\*\***