



**Drug Utilization Review Board
Meeting Agenda, Open Session
April 9, 2014 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
Daniel Sutherland, RPh
Kevin Waite, PharmD
Roger Unruh, DO
Tim Heston, DO
John Kollhoff, PharmD
Judy McDaniel Dowd, PA-C

KDHE-DHCF Staff

Kelley Melton, PharmD

HP Enterprise Services/HID Staff

Nicole Ellermeier, PharmD
Nancy Perry, RN
Karen Kluczykowski, RPh

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 January 8, 2014 Meeting Minutes

III. NEW BUSINESS

A. New Preferred Drug List (PDL) Classes

1. Oral Mesalamine Products for Inflammatory Bowel Disease

At the March 2014 PDL Meeting, the committee approved the addition of the Oral Mesalamine Products for Inflammatory Bowel Disease to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.

- i. PDL Non-Preferred PA Criteria
- ii. *Public Comment
- iii. Board Discussion

2. **Carbonic Anhydrase Inhibitors**

At the March 2014 PDL Meeting, the committee approved the addition of the Carbonic Anhydrase Inhibitors to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.

- i. PDL Non-Preferred PA Criteria
- ii. *Public Comment
- iii. Board Discussion

3. **Hypertriglyceridemia Agents**

At the March 2014 PDL Meeting, the committee approved the addition of the Hypertriglyceridemia Agents to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.

- i. PDL Non-Preferred PA Criteria
- ii. *Public Comment
- iii. Board Discussion

4. **Homozygous Familial Hypercholesterolemia (HoFH) Agents**

At the March 2014 PDL Meeting, the committee approved the addition of the HoFH agents to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.

- i. PDL Non-Preferred PA Criteria
- ii. *Public Comment
- iii. Board Discussion

5. **Inhaled Tobramycin Products**

At the March 2014 PDL Meeting, the committee approved the addition of the Inhaled Tobramycin Products to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.

- i. PDL Non-Preferred PA Criteria
- ii. *Public Comment
- iii. Board Discussion

6. **COX II Inhibitors**

At the March 2014 PDL Meeting, the committee approved the addition of the COX II Inhibitors to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.

- i. PDL Non-Preferred PA Criteria
- ii. *Public Comment
- iii. Board Discussion

B. Revised Prior Authorization (PA) Criteria

1. **Pulmonary Hypertension Agents (Adempas® (riociguat) & Orenitram® (treprostinil))**

Prior authorization criteria for pulmonary arterial hypertension agents were initially approved in April 2013. Since the last revision in January 2014, two new agents have been approved. Prior authorization criteria revisions are being proposed to include Adempas and Orenitram.

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

2. Mekinist® (trametinib)

Mekinist is a kinase inhibitor indicated as a single agent or in combination with dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Prior authorization criteria were initially approved in October 2013 and in January 2014 Mekinist received approval for use in combination with dabrafenib. Prior authorization criteria are being revised to include all FDA-approved indications.

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

3. Tafinlar® (dabrafenib)

Tafinlar is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or in combination with trametinib for patients with BRAF V600E or V600K mutations. Prior authorization criteria were initially approved in October 2013 and in January 2014 Tafinlar received approval for use in combination with trametinib. Prior authorization criteria are being revised to include all FDA-approved indications.

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

4. Weight Loss Drugs

Weight loss drugs prior authorization criteria were initially approved in September 2007 and were last revised in October 2012. Xenical® (orlistat) recently received approval to reduce the risk for weight gain after prior weight loss. Prior authorization criteria are being revised to include all FDA-approved indications.

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

5. Incivek® (telaprevir)

Incivek is a hepatitis C protease inhibitor indicated for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria were initially approved in 2013. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.

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

6. Olysio® (simeprevir)

Olysio is a hepatitis C protease inhibitor indicated for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria were initially approved in January 2014. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.

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

7. Victrelis® (boceprevir)

Victrelis is a hepatitis C protease inhibitor indicated for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria were initially approved in 2013. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.

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

8. Sovaldi® (sofosbuvir)

Sovaldi is a hepatitis C virus nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C. Prior authorization criteria were initially approved in January 2014. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.

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

9. Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors (Farxiga® (dapagliflozin) & Invokana® (canagliflozin))

Farxiga and Invokana are SGLT2 Inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.

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

10. Sensipar® (cinacalcet)

Sensipar is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in patient with chronic kidney disease on dialysis, hypercalcemia in patients with parathyroid carcinoma, and severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy. Prior authorization criteria are being proposed to ensure use based upon FDA-approved indications.

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

11. Constipation Agents (Amitiza® (lubiprostone) & Linzess® (linaclotide))

Amitiza and Linzess are both indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. Additionally, Amitiza is indicated for the treatment of opioid-induced constipation in adults with chronic, non-cancer pain. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.

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

12. Lucentis® (ranibizumab)

Lucentis is an intravitreal injection indicated for the treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and diabetic macular edema. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.

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

13. Jetrea® (ocriplasmin)

Jetrea is an intravitreal injection indicated for the treatment of symptomatic vitreomacular adhesion. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.

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

14. **Elelyso® (taliglucerase alfa)**

Elelyso is indicated for long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type 1 Gaucher disease. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indication.

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

15. **Xofigo® (radium Ra 223 dichloride)**

Xofigo is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.

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

16. **Provenge® (sipuleucel-T)**

Provenge is indicated for the treatment of asymptomatic or minimally symptomatic metastatic castration-resistant (hormone refractory) prostate cancer. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.

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

C. Miscellaneous Items

1. **Managed Care Organization Annual Reports**

Amerigroup, United Healthcare, and Sunflower will present reports detailing utilization trends and provider education efforts for 2013.

- i. Overall MCO Utilization Data – Nicole Ellermeier, PharmD
- ii. Amerigroup Individual Report – Lisa Todd, RPh
- iii. United Healthcare Individual Report – Jennifer Murff, RPh
- iv. Sunflower Individual Report – Jonalan Smith, PharmD
- v. *Public Comment
- vi. 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 July 9, 2014.**