



**Drug Utilization Review Board
Meeting Agenda, Open Session
July 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

Tim Heston, DO	Daniel Sutherland, RPh
John Kollhoff, PharmD	Kevin Waite, PharmD
Judy McDaniel Dowd, PA-C	Roger Unruh, DO
Russell Scheffer, MD	

KDHE-DHCF Staff

F.E. Bustillo, III, MD	Kelley Melton, PharmD
------------------------	-----------------------

HP Enterprise Services/HID Staff

Nicole Ellermeier, 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 April 9, 2014 Meeting Minutes

III. NEW BUSINESS

A. Revised Prior Authorization (PA) Criteria

1. 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 ensure appropriate use.

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

2. 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 ensure appropriate use.

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

3. 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 ensure appropriate use.

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

4. 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 ensure appropriate use.

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

5. Buprenorphine Agents (Bunavail® (buprenorphine/naloxone buccal film))

Prior authorization criteria for Buprenorphine agents for opioid dependence were last revised in October 2013. Since the last revision, a new agent has been approved. Prior authorization criteria revisions are being proposed to include Bunavail.

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

6. Kalydeco® (ivacaftor)

Kalydeco is a treatment for cystic fibrosis indicated for patients age 6 years and older. Prior authorization criteria were initially approved in April 2012; since that time, the indication has been expanded to include additional genetic mutations. Prior authorization criteria are being revised to include all FDA-approved indications.

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

7. Xolair® (omalizumab)

Xolair is an anti-IgE antibody indicated for moderate to severe persistent asthma in patients with a positive skin test to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids, and chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite antihistamine treatment. Prior authorization criteria were initially approved in July 2005 and are being revised to include all FDA-approved indications and align more closely with the guidelines for the diagnosis and management of asthma.

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

8. **Promacta® (eltrombopag)**

Promacta is a thrombopoietin receptor antagonist indicated for the treatment of thrombocytopenia in patients with chronic ITP and patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Prior authorization criteria were last revised in July 2013, and are being revised to include all FDA-approved indications.

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

9. **Growth Hormones**

The prior authorization criteria for human growth hormones were last revised in September 2007. Prior authorization criteria are being revised to improve consistency in approval and denial determinations based on the FDA-approved indications.

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

10. **Testosterone Agents (Natesto® (testosterone nasal gel))**

Prior authorization criteria for testosterone agents were approved in July 2013. Since that time a new agent has been approved—Natesto nasal gel. Prior authorization criteria are being revised to include this new agent.

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

11. **Long-Acting Opioids**

Override criteria for the long-acting opioids were last revised in January 2014 to include a new agent. Override criteria are being revised to include a requirement that prescribers review the patient's K-TRACS profile.

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

B. New PA Criteria

1. **Xartemis XR® (oxycodone/acetaminophen)**

Xartemis XR is an extended-release formulation of oxycodone and acetaminophen indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. A limit of an initial 7 day supply and 4 tablets per day without an override is being proposed along with criteria for override above 7 days or 4 tablets per day.

- i. Override Criteria
- ii. *Public Comment
- iii. Board Discussion

2. **Demerol® (meperidine)**

Meperidine is indicated for the relief of moderate to severe pain. Meperidine should not be used for the treatment of chronic pain; it should only be used in the treatment of acute episodes of moderate to severe pain. Prolonged use may increase the risk of toxicity from the accumulation of the meperidine metabolite, normeperidine. A limit of 900mg per day for an initial 21 day supply is being proposed. Additional courses of therapy will require an override based on the proposed criteria.

- i. Override Criteria
- ii. *Public Comment
- iii. Board Discussion

3. Eylea® (aflibercept)

Eylea is an intravitreal injection indicated for the treatment of patients with neovascular (wet) age-related macular degeneration and macular edema following central retinal vein occlusion. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information and to remain consistent with other agents used for the approved indications.

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

4. Tanzeum® (albiglutide)

Tanzeum is a GLP-1 receptor agonist 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 FDA-approved labeling information and to remain consistent with other agents in this class.

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

5. Enzyme Replacement Therapy (Cerezyme® (imiglucerase), Eleyso® (taliglucerase alfa), & VPRIV® (velaglucerase alfa))

Cerezyme, Eleyso, and VPRIV are 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 indications.

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

6. Leukine® (sargramostim)

Leukine is a colony-stimulating factor; prior authorization criteria are being proposed to remain consistent with the other colony-stimulating factors based upon FDA-approved labeling information.

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

7. Neupogen® (filgrastim)

Neupogen is a colony-stimulating factor; prior authorization criteria are being proposed to remain consistent with the other colony-stimulating factors based upon FDA-approved labeling information.

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

8. Entyvio® (vedolizumab)

Entyvio is an integrin receptor antagonist indicated for the treatment of ulcerative colitis and Crohn's disease. Prior authorization criteria are being proposed to ensure appropriate utilization based upon FDA-approved labeling information.

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

9. Otezla® (apremilast)

Otezla is a PDE4 inhibitor indicated for the treatment of adult patients with active psoriatic arthritis. Prior authorization criteria are being proposed to ensure appropriate utilization based upon FDA-approved labeling information.

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

C. Miscellaneous Items

1. Fee-for-Service Retrospective Drug Utilization Review Topic Selections

The DUR Board will select topics for the five (5) RDUR intervention topics for State Fiscal Year 2015.

- i. Topic Presentations
- ii. 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 October 8, 2014.**

*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****