



**Drug Utilization Review Board
Meeting Agenda, Open Session
April 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 January 13, 2016 Meeting Minutes

III. NEW BUSINESS

A. New Preferred Drug List (PDL) Classes

1. Topical Testosterone Agents

At the March 2016 PDL meeting, the committee approved the addition of the Topical Testosterone Agents to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

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

iii. Board Discussion

2. **Cannabinoid Antiemetics**

At the March 2016 PDL meeting, the committee approved the addition of the Cannabinoid Antiemetics to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

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

3. **Ophthalmic Anti-Infective/Steroid Combinations**

At the March 2016 PDL meeting, the committee approved the addition of the Ophthalmic Anti-Infective/Steroid Combinations to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

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

4. **Ophthalmic Beta-Blockers**

At the March 2016 PDL meeting, the committee approved the addition of the Ophthalmic Beta Blockers to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

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

5. **Ophthalmic Alpha Adrenergic Agonists**

At the March 2016 PDL meeting, the committee approved the addition of the Ophthalmic Alpha Adrenergic Agonists to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

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

6. **Platelet Aggregation Inhibitors (Stroke)**

At the March 2016 PDL meeting, the committee approved the addition of the Platelet Aggregation Inhibitors for Stroke to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

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

7. **Platelet Aggregation Inhibitors (Secondary Cardiac Prevention)**

At the March 2016 PDL meeting, the committee approved the addition of the Platelet Aggregation Inhibitors for Secondary Cardiac Prevention to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

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

B. Revised Prior Authorization (PA) Criteria

1. Actemra® (tocilizumab)

Actemra is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

2. Cimzia® (certolizumab)

Cimzia is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

3. Enbrel® (etanercept)

Enbrel is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

4. Entyvio® (vedolizumab)

Entyvio is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

5. Humira® (adalimumab)

Humira is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

6. Ilaris® (canakinumab)

Ilaris is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

7. Kineret® (anakinra)

Kineret is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

8. **Orencia® (abatacept)**

Orencia is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

9. **Remicade® (infliximab)**

Remicade is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

10. **Simponi® (golimumab)**

Simponi is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

11. **Stelara® (ustekinumab)**

Stelara is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.

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

12. **Cosentyx® (secukinumab)**

Cosentyx is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months. Prior authorization criteria were initially approved in April 2015. Since that time, two new FDA indications have been approved: psoriatic arthritis and ankylosing spondylitis. 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

13. **Xeljanz® (tofacitinib)**

Xeljanz is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months. Prior authorization criteria were initially approved in July 2013. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Xeljanz XR.

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

14. **Botox® (onabotulinumtoxinA)**

Botox is a botulinum toxin. Prior authorization criteria were last revised in October 2015. Since that time, Botox has become indicated for the treatment of lower limb spasticity in adults. 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. Opdivo® (nivolumab)

Opdivo is a monoclonal antibody (antineoplastic) indicated for the treatment of melanoma. Prior authorization criteria were initially approved in October 2015. Since that time, the BRAF V600 mutations have become approved as a single agent or in combination with ipilimumab for either mutation; also a new indication of renal cell carcinoma has been added. 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

16. Pulmonary Hypertension Agents (Uptravi® [selexipag])

Uptravi is a prostacyclin IP receptor agonist indicated for the treatment of pulmonary arterial hypertension (PAH). Prior authorization criteria for PAH agents were last revised in April 2014. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Uptravi.

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

17. Intravenous Immune Globulins (IVIGs)

Intravenous immune globulins are used for several FDA indications and several off-label uses. Prior authorization criteria were initially approved in January 2016. At the January 2016 DUR meeting, it was suggested by the DUR board members to extend the duration of approval. Since all indications were included, the diagnoses were separated into chronic and acute indications. The length of approval for chronic conditions requiring long-term IVIGs are 12 months and acute conditions requiring temporary use of IVIGs are 1 month.

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

18. Afinitor® (everolimus)

Afinitor is a kinase inhibitor indicated for the treatment of several FDA indications. Prior authorization criteria were initially approved in January 2014. Since that time, a new FDA indication has been approved. 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. Gilenya® (fingolimod)

Gilenya is an immunomodulatory agent indicated for the treatment of multiple sclerosis (MS). Prior authorization criteria were initially approved in October 2012. Since that time, there have been post-marketing reports of progressive multifocal leukoencephalopathy (PML) due to the JC virus. 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. Tecfidera® (dimethyl fumarate)

Tecfidera is an immunomodulatory agent indicated for the treatment of multiple sclerosis (MS). Prior authorization criteria were initially approved in July 2013. Since that time, there have been post-marketing reports of progressive multifocal leukoencephalopathy (PML) due to the JC virus. 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. Imbruvica® (ibrutinib)

Imbruvica is a tyrosine kinase inhibitor indicated for the treatment of chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), and Waldenström macroglobulinemia. Prior authorization criteria were initially approved in October 2015. Since that time, use in CLL is approved regardless of the patient's treatment history. 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. 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 January 2016. The Hepatitis C guidelines recommend holding treatment in pregnancy due to a lack of evidence supporting safety. 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 last revised in January 2016. 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

24. Daklinza® (daclatasvir)

Daklinza 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, Daklinza has been approved for genotype 1; also, it has been established to be safe and effective in the decompensated cirrhosis and post liver transplant populations. 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. Zepatier® (elbasvir/grazoprevir)

Zepatier is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection in genotype 1 and 4. 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. Zurampic® (lesinurad)

Zurampic is a uric acid transporter 1 inhibitor indicated for the treatment of hyperuricemia associated with gout (in combination with a xanthine oxidase inhibitor) in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. 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. Kanuma® (sebelipase alfa)

Kanuma is indicated for the treatment of patients with lysosomal acid lipase (LAL) deficiency. 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. Strensiq® (asfotase alfa)

Strensiq is indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP). 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

D. Mental Health Medication Advisory Committee (MHMAC)

1. Use of Concurrent Multiple Antipsychotics

At the October 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent antipsychotics. Then at the February 2016 meeting, the criteria was amended, at the request of the DUR board members. 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 greater than 120 days to a maximum of 2 medications in the pediatric population before a prior authorization is required.

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

E. Miscellaneous Items

1. Managed Care Organization Annual Reports

Amerigroup, United Healthcare, and Sunflower will present their annual reports at the July 2016 DUR meeting.

IV. OPEN PUBLIC COMMENT

V. ADJOURN

**Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for July 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****