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Susan Mosier, MD, Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
April 12, 2017 10:00 a.m. – 2:00 p.m.

Meeting Location
HP Enterprise Services, Building #283, Capital Room
6511 SE Forbes Ave, Topeka, KS 66619

Board Members

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

KDHE-DHCF Staff

Annette Grant, RPh	Carol Arace, Administrative Assistant

HP Enterprise Services/HID Staff

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

MCO Staff

Angie Zhou, PharmD, **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 11, 2017 Meeting Minutes

B. Use of Multiple Concurrent Tricyclic Antidepressants

At the November 2016 MHMAC meeting, the committee approved the criteria for the concurrent use of two or more different TCAs used concurrently for greater than sixty days. During the January 2017 DUR meeting, the DUR board members wanted more data information before approval.

i. Additional information
ii. *Public Comment
iii. Board Discussion

III. NEW BUSINESS

A. New Preferred Drug List (PDL) Classes

1. **Attention-deficit hyperactivity disorder (ADHD) Stimulants – Amphetamine-type**
   At the March 2017 PDL meeting, the committee approved the addition of the ADHD Stimulants – Amphetamine-type 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. **Attention-deficit hyperactivity disorder (ADHD) Stimulants – Methylphenidate-type**
   At the March 2017 PDL meeting, the committee approved the addition of the ADHD Stimulants – Methylphenidate -type 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. **Attention-deficit hyperactivity disorder (ADHD) Stimulants – Miscellaneous-type**
   At the March 2017 PDL meeting, the committee approved the addition of the ADHD Stimulants – Miscellaneous -type 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. **Insulin-Glucagonlike Peptide 1 (GLP-1) Receptor Agonists**
   At the March 2017 PDL meeting, the committee approved the addition of the Insulin-Glucagonlike Peptide 1 (GLP-1) Receptor 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

5. **Narcotic Antagonists**
   At the March 2017 PDL meeting, the committee approved the addition of the Narcotic Antagonists 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. **Pulmonary Hypertension Agents**
   At the March 2017 PDL meeting, the committee approved the addition of the Pulmonary Hypertension 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

7. **Selective Serotonin Reuptake Inhibitors (SSRIs)**
   At the March 2017 PDL meeting, the committee approved the addition of the SSRIs 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

8. **Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)**
   At the March 2017 PDL meeting, the committee approved the addition of the SNRIs 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

9. **Statin Combinations**
   At the March 2017 PDL meeting, the committee approved the addition of the Statin 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

10. **Tricyclic Antidepressants (TCAs)**
    At the March 2017 PDL meeting, the committee approved the addition of the TCAs 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. **Selzentry® (maraviroc)**
   Selzentry is an antiretroviral agent used in the treatment of human immunodeficiency virus (HIV). Selzentry has been approved down to the age of 2 years old and weighing at least 10 kg. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Ilaris® (canakinumab)**
   Ilaris is a biologic immunomodulator. Prior authorization criteria for this agent was last revised in January 2017. At that DUR meeting, there was a typographical error for the diagnosis of Familial Mediterranean Fever (FMF) in adult and pediatric patients. The prior authorization criteria are being revised to correct that error.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Xiidra® (lifitegrast)**
   At the January 2017 DUR meeting, the criteria was proposed to update the Xiidra criteria to include the prescriber to also be an optometrist. Due to regulations, this must be on the agenda to make a change.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Sovaldi® (sofosbuvir)**
   Sovaldi is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. The previous requirements for Daklinza plus Sovaldi included a METAVIR score of F2; Daklinza was updated to F3. The Sovaldi was not updated in the section of use with Daklinza. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Zepatier® (elbasvir/grazoprevir)**
   Zepatier is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. NS5A polymorphism testing is indicated for genotype 1a only. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Humira® (adalimumab)**
   Humira is an immunomodulator indicated for the treatment of several disorders. Prior authorization criteria were last revised in October 2016. For the treatment of rheumatoid arthritis (RA), some patients not able to take concomitant methotrexate (MTX) may derive additional benefit from increasing the dosing frequency to adalimumab 40 mg every week.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Darzalex® (daratumumab)**
   Darzalex is an antineoplastic monoclonal antibody indicated for the treatment of multiple myeloma (MM). Prior authorization criteria for this agent was initially approved in January 2017. Since that time, the medication has been approved as combination therapy with either lenalidomide and dexamethasone or bortezomib and dexamethasone in patients who have received at least 1 prior therapy. For the initial indication, Darzalex is approved for use as monotherapy after 3 lines of prior therapy. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Lucentis® (ranibizumab)**
   Lucentis is an intravitreal injection. Prior authorization criteria were last revised in April 2014. Since that time, the medication has been approved for the treatment of patients with myopic choroidal neovascularization (mCNV). The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment

iii. Board Discussion

9. **Opdivo® (nivolumab)**
   Opdivo is an antineoplastic monoclonal antibody. Prior authorization criteria were last revised in October 2016. Since that time, Opdivo has become indicated for the treatment of: a) recurrent or metastatic squamous cell carcinoma of the head and neck (HNSCC) with disease progression on or after platinum-based chemotherapy, and b) locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

10. **Imbruvica® (ibrutinib)**
    Imbruvica is a tyrosine kinase inhibitor. Prior authorization criteria were last revised in July 2016. Since that time, the medication has become indicated for the treatment of marginal zone lymphoma (MZL) after systemic therapy and receiving at least 1 prior anti-CD20-based therapy. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

11. **Constipation Agents (Trulance® [plecanatide])**
    Trulance is a guanylate cyclase-C (GC-C) agonist indicated for the treatment of chronic idiopathic constipation in adults. Trulance is an addition to the Constipation Agents PA Criteria. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

12. **Rosacea Agents (Rhofade® [oxymetazoline], Finacea® [azelaic acid], Soolantra® [ivermectin], MetroCream®, Metrogel®, MetroLotion®, Noritate®, Rosadan® [metronidazole topical])**
    The newly added agents are an addition to the Mirvaso PA Criteria and is to be renamed. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

13. **SGLT2 Inhibitor Combination (Qtern® [dapagliflozin/saxagliptin])**
    Qtern is a SGLT2 inhibitor/DPP4 inhibitor combination. Qtern is an addition to the SGLT2 inhibitor Combination PA Criteria. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

14. **Topical Immunomodulators (Eucrisa® [crisaborole])**
    Eucrisa is a phosphodiesterase 4 inhibitor indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older. Eucrisa is an addition to the Topical Immunomodulator PA Criteria. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

15. **Long-Acting Opioids (Arymo ER® [morphine sulfate ER], Vantrela® [hydrocodone ER])**
    Arymo ER and Vantrela ER are additions to the Long-Acting Opioids PA Criteria. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

16. **Opana ER® (oxymorphone ER)**
    Opana ER is an opiate agonist indicated for the treatment of pain. Prior authorization criteria were last revised in October 2015. The quantities in the Long-Acting Opioids PA criteria was updated. The Opana ER was not updated individually. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

17. **Exondys 51® (eteplirsen)**
    Exondys 51 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. Prior authorization criteria were last revised in January 2017. Conformational studies have shown benefit of DMD to oral glucocorticoids, including prednisone, prednisolone, and deflazacort. 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

C. New Prior Authorization (PA) Criteria

1. **Emflaza® (deflazacort)**
    Emflaza is a corticosteroid (oxazolone derivative of prednisolone, the active metabolite of prednisone) indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

2. **Siliq® (brodalumab)**
   Siliq is a humanized interleukin-17A antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and who have failed to respond or have lost response to other systemic therapies. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Rubraca® (rucaparib)**
   Rubraca is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Long-Acting Insulin/GLP-1 Agonist Combinations® (Soliqua [insulin glargine-lixisenatide], Xultophy [insulin degludec-liraglutide])**
   These combination agents contain a long-acting human insulin analog with a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin or the GLP-1. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Spinraza® (nusinersen)**
   Spinraza is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Ibrance® (palbociclib)**
   Ibrance is a cyclin-dependent kinas inhibitor indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER-2)-negative advanced or metastatic breast cancer, in either a) combination with letrozole in postmenopausal women as initial endocrine-based therapy, or b) combination with fulvestrant in women with disease progression following endocrine therapy. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **New-to-Market-Drug**
   The proposed criteria will allow for new drugs to be manually reviewed using advanced medical hold criteria until the PDL Committee and/or the DUR Board has an opportunity to give clinical review of the new drug.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

D. Mental Health Medication Advisory Committee (MHMAC)

1. **Use of Concurrent Multiple Antipsychotics/16 and Older Antipsychotic Dosing Limits**
   At the February 2017 MHMAC meeting, the criteria was amended for a title change from "Antipsychotic Dosing Limits" to "16 and Older Antipsychotic Dosing Limits".
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Opioid Dependence Agents**
   At the February 2017 MHMAC meeting, the criteria was amended, at the request of the DUR board. If a beneficiary is prescribed both a benzodiazepine and buprenorphine, the benzodiazepine claim will deny unless it is in consultation with the buprenorphine prescriber.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

E. Miscellaneous Items

1. **Managed Care Organization Annual Reports**
   Amerigroup, United Healthcare, and Sunflower will present reports detailing utilization trends and provider education efforts for 2016.
   i. Overall MCO Utilization Data – Annette Grant, RPh
   ii. Sunflower Individual Report – Angie Zhou, PharmD
   iii. United Healthcare Individual Report – Jennifer Murff, RPh
   iv. Amerigroup Individual Report – Lisa Todd, RPh
   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 12, 2017.