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Susan Mosier, MD, Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
July 26, 2017 10:00 a.m. – 2:00 p.m.

Meeting Location
DXC Technology, Building #283, Capital Room
6511 SE Forbes Ave, Topeka, KS 66619

Board Members

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

KDHE-DHCF Staff

Annette Grant, RPh
Robert Handke, PharmD
Carol Arace, Administrative Assistant

DXC Technology/HID Staff

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

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 April 12, 2017 Meeting Minutes

B. Selzentry® (maraviroc)

At the April 2017 DUR meeting, a question regarding the "HIV specialist" arose. According to American Academy of HIV Medicine (AAHIVM), an HIV specialist is a MD, DO, PA, or NP who provides direct, ongoing care to HIV patients to at least 20 patients over 24 months.

III. NEW BUSINESS

A. New Preferred Drug List (PDL) Classes

1. **5 Alpha-Reductase Inhibitors**
   At the June 2017 PDL meeting, the committee approved the addition of the 5 Alpha-Reductase Inhibitors to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Gastrointestinal Motility - Anti-Constipation Agents**
   At the June 2017 PDL meeting, the committee approved the addition of the Gastrointestinal Motility - Anti-Constipation to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Gastrointestinal Motility - Anti-Diarrheal Agents**
   At the June 2017 PDL meeting, the committee approved the addition of the Gastrointestinal Motility - Anti-Diarrheal Agents to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Injectable Hereditary Angioedema Agents**
   At the June 2017 PDL meeting, the committee approved the addition of the Injectable Hereditary Angioedema Agents to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

B. Revised Prior Authorization (PA) Criteria

1. **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 April 2017. Sovaldi has been approved down to the age of 12 years old or weighing at least 35 kg for genotypes 2 and 3. 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. **Harvoni® (ledipasvir/sofosbuvir)**
   Harvoni is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. Harvoni has been approved down to the age of 12 years old or weighing at least 35 kg for genotypes 1, 4, 5, and 6. 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

3. **CFTR Modulators (Kalydeco® [ivacaftor], Orkambi® [lumacaftor/ivacaftor])**
   Kalydeco and Orkambi are cystic fibrosis transmembrane conductance regulator (CFTR) potentiators indicated for the treatment of cystic fibrosis (CF). Prior authorization criteria was initially approved in October 2015. Since that time, Orkambi has been approved down to the age of 6 years. Kalydeco has been approved for any CFTR gene mutation that is responsive to ivacaftor based on clinical and/or in vitro assay data. 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

4. **Remicade® (Renflexis® [infliximab-abda])**
   Renflexis is the second biosimilar available for Remicade. Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Prior authorization criteria for this agent were last revised in July 2016. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Renflexis.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Opioid Induced Constipation Agents (Symproic® [naldemedine])**
   Symproic is an opioid antagonist indicated for the treatment of opioid induced constipation in adults with chronic non-cancer pain. Symproic is an addition to the Opioid Induced 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

6. **Actemra® (tocilizumab)**
   Actemra is an interleukin-6 (IL-6) receptor antagonist. Prior authorization criteria were last revised in April 2016. Since that time, the medication has become indicated for the treatment of giant cell arteritis (GCA). 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

7. **Keytruda® (pembrolizumab)**
   Keytruda is a programmed death receptor-1 (PD-1) blocking antibody. Prior authorization criteria were last revised in January 2017. Since that time, the medication has become indicated for the treatment of classical Hodgkin lymphoma (cHL), urothelial carcinoma, and microsatellite instability-high cancer (MSI-H). Additionally, usage for non-small cell lung cancer (NSCLC) has been amended. 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. **Neupogen® (filgrastim)**
   Neupogen is a granulocyte colony stimulating factor (G-CSF). Prior authorization criteria was initially approved in July 2014. Since that time, the medication has become indicated for the treatment of severe chronic neutropenia. It was not initially approved for chemotherapy induced neutropenia in criteria. 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. **Zykadia® (ceritinib)**
   Zykadia is a tyrosine kinase inhibitor indicated for the treatment of non-small cell lung cancer (NSCLC). Prior authorization criteria was initially approved in October 2014. Since that time, the medication has become indicated as first line therapy. It was not initially approved for chemotherapy induced neutropenia in criteria. 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. **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. Prior authorization criteria was initially approved in April 2017. 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

11. **Growth Hormone**
    Growth hormone agents are used for several indications in both children and adults. Prior authorization criteria were last revised in July 2015. 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

12. **Rituxan® (Rituxan Hycela® [rituximab with hyaluronidase])**
    Rituxan Hycela is a combination of rituximab, a CD20-directed cytolytic antibody, and hyaluronidase human, an endoglycosidase, indicated for the treatment of adult patients with Follicular Lymphoma (FL), Diffuse Large B-cell Lymphoma (DLBCL), and Chronic Lymphocytic Leukemia (CLL). Prior authorization criteria were last revised in April 2012. The prior authorization criteria are being revised to add the new agent and 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

C. New Prior Authorization (PA) Criteria

1. **Dupixent® (dupilumab)**
   Dupixent is an interleukin-4 receptor alpha antagonist indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. 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. **Kevzara® (sarilumab)**
   Kevzara is indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs). 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. **Radicava® (edaravone)**
   Radicava is indicated for the treatment of amyotrophic lateral sclerosis. 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. **Tramadol Products**
   Tramadol is FDA-approved only for use in adults, and should consider recommending OTC or other FDA-approved prescription medicines for pain management in children younger than 12 years and in adolescents younger than 18 years. 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. **Codeine Products**
   Single-ingredient codeine medicines are FDA-approved only for use in adults, and should consider recommending OTC or other FDA-approved prescription medicines for cough and pain management in children younger than 12 years and in adolescents younger than 18 years. 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. **Daraprim® (Pyrimethamine)**
   Daraprim is an antiparasitic compound indicated for treatment and prophylaxis of toxoplasmosis. It is FDA indicated for the treatment and chemoprophylaxis of malaria, however, current Centers for Disease Control and Prevention recommendations for malaria prophylaxis and treatment do not include the use of pyrimethamine; resistance to pyrimethamine is prevalent worldwide. 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. **Xermelo® (telotristat ethyl)**
   Xermelo is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA 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

8. **Long-Acting Hemophilia Agents (Adynovate®, Alprolix®, Eloctate®, Idelvio®)**
   Long-acting hemophilia agents are indicated for the treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding. 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

9. **Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)**
   Vosevi is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, and is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have 1) genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor or 2) genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. 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

10. **Alunbrig® (brigatinib)**
    Alunbrig is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. 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

11. **Bavencio® (avelumab)**
    Bavencio is a programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).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. **Imfinzi® (durvalumab)**
    Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who either 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 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

13. **Kisqali® (ribociclib)**
    Kisqali is a kinase inhibitor indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. 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

14. **Lartruvo® (olaratumab)**
    Lartruvo is a platelet-derived growth factor receptor alpha (PDGFR-α) blocking antibody indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery. 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

15. **Lynparza® (olaparib)**
    Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy in patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. 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

16. **Revlimid® (lenalidomide)**
    Revlimid is a thalidomide analogue indicated for multiple myeloma (MM), mantle cell lymphoma (MCL), and transfusion-dependent anemia. 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

17. **Stivarga® (regorafenib)**
    Stivarga is a kinase inhibitor indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy; Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate; and Hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. 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

18. **Xalkori® (regorafenib)**
    Xalkori is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test or metastatic NSCLC whose tumors are ROS1-positive. 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

19. **Zejula® (niraparib)**
    Zejula is a poly(ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. 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

D. Mental Health Medication Advisory Committee (MHMAC)

1. **Antipsychotics in Children and Adolescents < 18 years of Age**
    At the February 2017 MHMAC meeting, the criteria was amended and dosing limits were added. The new title is “Antipsychotics in Children and Adolescents < 18 years of Age”.
        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 October 11, 2017.

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The next DUR Board meeting is scheduled for October 11, 2017.

*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****