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Robert Moser, MD, Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
April 10, 2013, 10:00am-2:00pm

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

KDHE-DHCF Staff

Kelley Melton, PharmD

HP Enterprise Services/HID Staff

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

MCO Staff

Thomas Kaye, RPh, **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 October 10, 2012 Meeting Minutes

III. NEW BUSINESS

A. KanCare Prior Authorization Criteria and Limitation Overview

1. AmeriGroup
2. Sunflower
3. UnitedHealthcare

B. Fee-for-Service Criteria

1. **Botulinum Toxins (Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), Myobloc® (rimabotulinumtoxinB), Xeomin® (incobotulinumtoxinA))**
   In January 2013 the Food and Drug Administration (FDA) expanded the labeled indications for Botox to include the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or are intolerant of an anticholinergic medication. Revised prior authorization criteria are being proposed to include this new indication.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Prolia® (denosumab)**
   In September 2012 the FDA expanded the labeled indications for Prolia to include treatment to increase bone mass in men with osteoporosis at high risk for fracture or for patients who have failed or are intolerant to other available osteoporosis therapy. Revised prior authorization criteria are being proposed to include this new indication.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Actemra® (tocilizumab)**
   In October 2012 the indication for rheumatoid arthritis was revised. Actemra is currently indicated for adult patients with moderate to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs. Revised prior authorization criteria are being proposed to include this new indication.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Humira® (adalimumab)**
   In November 2012 the FDA expanded the labeled indications for Humira to include inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants. Revised prior authorization criteria are being proposed to include this new indication.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Kineret® (anakinra)**
   In December 2012 the FDA expanded the labeled indications for Kineret to include the treatment of neonatal-onset multisystem inflammatory disease. Revised prior authorization criteria are being proposed to include this new indication.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

C. Managed Care Organization Criteria

1. **Restasis® (cyclosporine)**
   Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Zetia® (ezetimibe)**
   Zetia inhibits the absorption of intestinal cholesterol and related phytosterol. It is indicated in patients with primary hyperlipidemia, mixed hyperlipidemia, homozygous familial hypercholesterolemia, or homozygous sitosterolemia. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. ~~**Xifaxan® (rifaximin)**~~
   ~~Xifaxan is a rifamycin antibacterial indicated for the treatment of travelers' diarrhea, in patients 12 years of age and older, caused by noninvasive strains of *Escherichia coli* and to reduce the risk of overt hepatic encephalopathy recurrence in patients 18 years of age and older. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.~~
   ~~i. Prior Authorization Criteria~~
   ~~ii. *Public Comment~~
   ~~iii. Board Discussion~~

4. **Syprine® (trientine)**
   Syprine is a chelating compound for removal of excess copper from the body. It is indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Ferriprox® (deferiprone)**
   Ferriprox is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Exjade® (deferasirox)**
   Exjade is an iron chelating agent indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older and for patients 10 years of age or older with non-transfusion dependent thalassemia syndromes. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Pulmonary Arterial Hypertension Agents (Adcirca® (tadalafil), Flolan® (epoprostenol), Letairis® (ambrisentan), Remodulin® (treprostinil), Revatio® (sildenafil), Tracleer® (bosentan), Tyvaso® (treprostinil), Veletri® (epoprostenol), and Ventavis® (iloprost))**
   Pulmonary hypertension agents are used to improve exercise ability and delay clinical worsening in patients with pulmonary arterial hypertension. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

~~8. **Topical & Buccal Testosterone Agents (Androderm® Transdermal, AndroGel®, Axiron® Topical Solution, Fortesta® Gel, Striant® Buccal, and Testim® Gel)**~~
   ~~The topical and buccal testosterone agents are indicated for androgen replacement therapy in males with primary hypogonadism and hypogonadotropic hypogonadism. Due to the risk of off-label utilization, prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.~~
   ~~i. Prior Authorization Criteria~~
   ~~ii. *Public Comment~~
   ~~iii. Board Discussion~~

~~9. **Delatestryl® (testosterone enanthnate injection)**~~
   ~~Delatestryl is indicated for androgen replacement therapy in males with primary hypogonadism and hypogonadotropic hypogonadism, to stimulate puberty in males with clearly delayed puberty, and for females with advancing inoperable metastatic breast cancer. Due to the risk of off-label utilization, prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.~~
   ~~i. Prior Authorization Criteria~~
   ~~ii. *Public Comment~~
   ~~iii. Board Discussion~~

~~10. **Testopel® Pellets (testosterone)**~~
   ~~Testopel is indicated for androgen replacement therapy in males with primary hypogonadism and hypogonadotropic hypogonadism, and to stimulate puberty in males with clearly delayed puberty. Due to the risk of off-label utilization, prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.~~
   ~~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 July 10, 2013.

*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****