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Robert Moser, MD, Secretary  
Andrew Allison, PhD, Director

Sam Brownback, Governor

**Drug Utilization Review Board Meeting  
Meeting Agenda, Open Session  
October 12, 2011, 10:00 a.m.**

**Meeting Location**

HP Enterprise Services ~ Capital and Cedar Crest Rooms  
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, Kansas 66619

**Board Members**

Michael Burke, MD, PhD	Dennis Grauer, PhD
John Kollhoff, PharmD	Judy McDaniel Dowd, PA-C
Daniel Sutherland, RPh	Roger Unruh, DO
Kevin Waite, PharmD	

**KDHE Staff**

Margaret Smith, MD	Shea Robinson
Shelly Liby	Kelley Melton, PharmD

**HP Enterprise Services / HID Staff**

Karen Kluczykowski, RPh	Debra Quintanilla, RN
Lisa Todd, RPh	Nicole Churchwell, PharmD

**ACS Staff**

Bethany Noble, CPhT	Larry Dent, PharmD, BCPS
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I. Call to Order

II. Announcements

III. Old Business

**A. Review and Approval of June 15, 2011 Meeting Minutes**

IV. New Business

**A. Short-Acting Transmucosal Fentanyl Products (Actiq®, Fentora®, Onsolis®, Abstral® and Lazanda®)**

The short-acting transmucosal fentanyl products have required prior authorization since 2006. This group of products was last reviewed in April 2011 when Abstral was added to the current criteria; since that time a new agent has been approved, Lazanda nasal spray. It is recommended that Lazanda be added to the current criteria and that the criteria be revised to reflect changes in the package inserts for several products regarding new REMS programs.

- i. Revised Clinical PA Criteria
- ii. \*Public Comment
- iii. Board Discussion/Action

**B. High-Dose Short-Acting Opioids**

The high-dose short-acting opioids criteria was last reviewed in April 2011 when Abstral was added to the criteria; since that time a new agent has been approved, Lazanda nasal spray. It is recommended that Lazanda be added to the current criteria.

- i. Revised Clinical PA Criteria
- ii. \*Public Comment
- iii. Board Discussion/Action

**C. Nuedexta® (dextromethorphan/quinidine)**

Nuedexta is a combination product for the treatment of pseudobulbar affect (PBA). Dextromethorphan stimulates sigma-1 receptors and inhibits NMDA receptors, and quinidine inhibits dextromethorphan metabolism increasing bioavailability. Studies to support the effectiveness of Nuedexta were conducted in patients with underlying amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS); however, effectiveness can be extrapolated to PBA that occurs in other neurologic conditions. It is recommended that the current criteria be revised to remove the “secondary to ALS or MS” portion of the criteria.

- i. Revised Clinical PA Criteria
- ii. \*Public Comment
- iii. Board Discussion/Action

**D. Long-Acting Beta-Agonists (Brovana® (arformoterol), Foradil® and Perforomist® (formoterol), Arcapta® (indacaterol) and Serevent® Diskus (salmeterol))**

In March 2009 the DUR Board approved prior authorization criteria for Foradil and Serevent Diskus due to the FDA warning regarding the risk of asthma related deaths associated with the utilization of long-acting beta-agonists alone. Other long-acting beta-agonists have entered the market since this time, and it is proposed that these agents be added to this prior authorization criteria.

- i. Revised Clinical PA Criteria
- ii. \*Public Comment
- iii. Board Discussion/Action

**E. Xarelto® (rivaroxaban)**

Xarelto is an anticoagulant indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism (PE) in patients undergoing knee or hip replacement surgery. For patients undergoing hip replacement surgery, treatment duration of 35 days is recommended and for patients undergoing knee replacement surgery, treatment duration of 12 days is recommended. It is proposed that a limit be placed on Xarelto for a total of 35 days per year. Additional courses of therapy will require prior authorization.

- i. Days Supply Limit, Override PA criteria, Diagnosis Restrictions
- ii. \*Public Comment
- iii. Board Discussion/Action

**F. Flexeril®, Fexmid® and Amrix® (cyclobenzaprine)**

Cyclobenzaprine is a skeletal muscle relaxant indicated as an adjunct to rest and physical therapy for relief of muscle spasms associated with acute, painful musculoskeletal conditions. Cyclobenzaprine should only be used for short periods of (up to two or three weeks); the recommended maximum dose is 30 mg per day. The DEA recently issued a warning stating that cyclobenzaprine may be subject to intentional misuse and abuse. A review of Kansas Medical Assistance Programs utilization data shows beneficiaries using cyclobenzaprine at higher doses and durations longer than recommended by the package insert. The proposed limit is 30 mg per day for 21 days. Additional courses of therapy will require prior authorization. These limits are similar to what was approved for Soma in October 2010.

- i. Days Supply Limit, Dose Per Day Limit, Override Criteria
- ii. \*Public Comment
- iii. Board Discussion/Action

\*Public Comment is limited to five minutes per product; additional time will be allowed at the 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.**

**G. Supprelin® LA (histrelin acetate)**

Supprelin LA is a gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of children with central precocious puberty (CPP). Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also show a significantly advanced bone age that can result in diminished adult height attainment. Supprelin LA is similar to Lupron, which had prior authorization criteria approved in April 2011 due to the off-label utilization in autism and short stature. Prior authorization criteria are being proposed for Supprelin LA to prevent patients from switching from Lupron to Supprelin LA once the prior authorization is implemented for Lupron.

- i. New Clinical PA Criteria
- ii. \*Public Comment
- iii. Board Discussion/Action

**H. Krystexxa® (pegloticase)**

Krystexxa is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Currently there are no off-label uses in DrugDex for Krystexxa but there have been reports that similar medications are used for preventing high uric acid due to cancer treatments and preventing recurring kidney stones in patients with high uric acid levels and Krystexxa could possibly be used off-label for this. Prior authorization criteria are being proposed to ensure appropriate use in adult patients with chronic gout who are refractory to conventional therapy and to prevent off-label utilization for unapproved indications.

- i. New Clinical PA Criteria
- ii. \*Public Comment
- iii. Board Discussion/Action

**I. Program Assessment and Intervention Topic Selection**

Each year the DUR Board is presented with the program assessment, which includes analysis of utilization trends from the previous state fiscal year. Following the program assessment, the DUR Board will be asked to choose the remaining intervention topics; each year five topics are chosen for review. In June 2011 the DUR Board chose the first two topics: cardiometabolic side effects of antipsychotic agents and drug interactions in patients with seizure disorders.

- i. Program Assessment, Intervention Topic Selection
- ii. \*Public Comment
- iii. Board Discussion/Action

V. Public Comment

VI. Adjourn

**Lunch will be provided for DUR Board Members  
NEXT MEETING: January 11, 2012**

\*Public Comment is limited to five minutes per product; additional time will be allowed at the 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.**