



**Drug Utilization Review Board Meeting
Meeting Agenda, Open Session
October 10, 2012 10:00 a.m.**

HP Enterprise Services ~ Capital Room
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, Kansas 66619

Board Members

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

KDHE-DHCF Staff

Shelly Liby	Kelley Melton, PharmD
Shea Robinson	

HP Enterprise Services / HID Staff

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

Xerox Staff

Larry Dent, PharmD, BCPS	Bethany Noble, CPHT
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- I. Call to Order
- II. Announcements
- III. Old Business
 - A. Revision of April 11, 2012 Meeting Minutes**
 - B. Review and Approval of July 11, 2011 Meeting Minutes**
- IV. New Business
 - A. Liraglutide (Victoza®)**

Liraglutide is 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. Current criteria require documentation of pretreatment of inadequate glycemic control (HbA1c \geq 6.5%) of therapy with maximum tolerated doses of metformin and/or sulfonylurea, unless contraindicated. Due to recent changes in the American Diabetes Association treatment guidelines, sulfonylureas are no longer required as first-line therapy over liraglutide. The recommendation is to revise the current prior authorization criteria to remove pretreatment with a sulfonylurea.

*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.**

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

B. Weight Loss Drugs (phentermine/topiramate ER (Qsymia®), lorcaserin (Belviq®), orlistat (Xenical® & Alli®), phentermine (Adipex-P®))

Phentermine/topiramate ER is a combination product containing a sympathomimetic amine anorectic and an anticonvulsant. Lorcaserin is a serotonin 2C receptor agonist. Both are new agents recently approved for weight loss and are indicated as adjuncts to a reduced-calorie diet and increased physical activity for chronic weight management in adults who are obese (initial BMI ≥ 30 kg/m²) or overweight (initial BMI ≥ 27 kg/m²) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. Currently, all other weight loss medications require prior authorization.

Phentermine/topiramate ER is supplied as 3.75mg/23mg, 7.5mg/46mg, 11.25mg/69mg, and 15mg/92mg capsules and is dosed once daily. Further, the 3.75mg/23mg and 11.25mg/69mg capsules are for titration purposes only and should be limited to 14 days. The recommended dose for lorcaserin is 10 mg twice daily with a caution not exceed the recommended dose. Thus, it is recommended that these new agents be added to the weight loss drugs prior authorization criteria along with quantity limits.

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

C. Emtricitabine/tenofovir (Truvada®)

Emtricitabine/tenofovir is a combination product containing two nucleoside analog HIV-1 reverse transcriptase inhibitors, which include emtricitabine (Emtriva®) and tenofovir (Viread®). It is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. Emtricitabine/tenofovir is also indicated in HIV-negative adults along with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. To ensure that Truvada is used for PrEP in high risk individuals with HIV-negative status, it is recommended that prior authorization criteria be approved.

- i. New Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

D. Natalizumab (Tysabri®)

Natalizumab is an integrin receptor antagonist indicated for the treatment of multiple sclerosis (MS) and Crohn's disease. Natalizumab is currently on prior authorization and was last reviewed in April 2012. It is recommended that the natalizumab criteria be updated for better consistency among the MS agents' criteria.

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

E. Multiple Sclerosis Interferons (interferon beta-1b (Betaseron® & Extavia®) & interferon beta-1a (Avonex® & Rebif®))

Interferons beta-1b and beta-1a are indicated for relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with MS. To ensure safe and appropriate use, it is recommended that prior authorization criteria be approved for these agents.

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- i. New Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

F. Glatiramer (Copaxone®)

Glatiramer is an immunomodulator agent indicated for reduction of the frequency of relapses in patients with relapsing-remitting MS including patients who have experienced a first clinical episode and have MRI features consistent with MS. To ensure safe and appropriate use, it is recommended that prior authorization criteria be approved for glatiramer.

- i. New Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

G. Fingolimod (Gilenya®)

Fingolimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. To ensure safe and appropriate use, it is recommended that prior authorization criteria be approved for fingolimod.

- i. New Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

H. Dalfampridine (Ampyra®)

Dalfampridine is a potassium channel blocker indicated to improve walking in patients with MS. In clinical studies, this was demonstrated by an increase in walking speed. This drug is not indicated to decrease relapse rate or prevent the accumulation of disability. Off-label uses include treating fatigue in MS patients and in spinal cord injury patients to enhance nerve transmission to affected muscles. The recommended dose is 10 mg twice daily with a caution not to exceed 20 mg/day due to increased risk of seizures. To ensure safe and appropriate use and to limit off-label prescribing, it is recommended that prior authorization criteria be approved for dalfampridine.

- i. New Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

I. Kansas Medical Assistance Program (KMAP) State Fiscal Year (SFY) 2012 Program Assessment

Health Information Designs (HID) will present the SFY 2012 annual program assessment for KMAP.

- i. Program Assessment Presentation
- ii. Board Discussion

V. *Open Public Comment

VI. KanCare DUR Information

VII. Adjourn

Lunch will be provided for DUR Board Members.

NEXT MEETING: January 9, 2013

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