

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
October 10, 2012**

<p><b>Drug Utilization Review Board</b> Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital Room Topeka, KS</p>	<p><b>Members Present:</b> Daniel Sutherland, RPh Judy McDaniel Dowd, PA-C Roger Unruh, D.O. Kevin Waite, Pharm.D. John Kollhoff, Pharm.D. <b>Member Absent:</b> Dennis Grauer, PhD Tim Heston, DO <b>DHCF Staff Present:</b> Kelley Melton, Pharm.D. Shelly Liby Shea Robinson <b>HP Enterprise Services Staff Present:</b> Karen Kluczykowski, RPh Nancy Perry, R.N. Deb Quintanilla, R.N. Lisa Todd, R.Ph. <b>HID Staff Present</b> Nicole Churchwell, Pharm.D. <b>ACS Staff Present</b> Larry Dent, Pharm.D.</p>	<p><b>Representatives:</b> Mike Ketcher, Novo Nordisk Jeff Himmelberg, GSK Sam Smothers, MedImmune Russ Wilson, J&amp;J Ann Corbin, Acorda Marissa Clark, Quantum PT Sumar Bieda, Purdue Leslie Saba, Amerigroup Jim Baumann, Pfizer Steve Granzkyk, Elan Phil King, Pfizer Terry McCurren, Otsuka America Jeff Wills, Acorda Chris Beal, Otsuka Carol A. Curtis, Astra-Zeneca</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Waite called the meeting to order at 10:02 a.m.	
II. Announcements	<p>Dr. Melton advised the attendees that the parking spaces in the front of the building (east side) are available for the Board members and that there is additional parking on the west side of the HP office for visitors. Dr. Melton announced that any members of the public should sign in and a public disclosure of interest forms will need to be completed and returned if they wish to speak on any particular agent during the meeting.</p> <p>Dr. Melton introduced Nancy Perry, RN, who is the head of the prior authorization unit at HP. Dr. Melton also announced that Dr. Grauer has decided to step down from the DUR Board. He has been involved with DUR for around 10 years, and the state greatly appreciates his time. Dr. Melton stated that Dr. Grauer's spot on the board is for a 'research pharmacist' chosen jointly by KU and PhRMA, and that the state plans to work with these groups to identify a replacement for Dr. Grauer.</p>	
III. Program Assessment	Dr. Nicole Ellermeier, HID RetroDUR pharmacist, presented the annual program assessment.	Dr. Kollhoff made a motion to select diabetes disease state

Dr. Ellermeier first presented the yearly totals from the past three state fiscal years for data including total claims, total members, etc. for fee-for-service utilization. Total expenditures were 2.5% higher in SFY 2012, with a less than 1% change in total claims. The trend has been an increase in cost in expenditures, while total numbers of claims has not changed as significantly. There was also a decrease in the number of fee-for-service members from SFY 2011 to SFY 2012, while the overall eligibility has not decreased.

Dr. Ellermeier next presented information on Drug Classification Reporting. The first level of reporting, Therapeutic Class, is the most broad. Dr. Ellermeier presented the top therapeutic classes for total number of pharmacy claims in SFY 2012, which has remained relatively unchanged from SFY 2011. She then presented the top therapeutic classes by claims cost in SFY 2012. This graphic shows that the top class, Antipsychotic agents, had a higher claims cost than the next six therapeutic classes combined. Antipsychotic agents accounted for 26% of the total claims cost, but only 6% of the total claims volume, while the antiretrovirals accounted for 7% of the total claims cost, and only 1% of the total claims volume.

Next, Dr. Ellermeier presented information at the generic ingredient level, which would include all generic and brand products of a given drug. The top 10 generic ingredients by number of claims were presented. Hydrocodone/Acetaminophen was highest on the list, which is a trend that the program has seen for many years. The top 10 generic ingredient by claims cost were then presented. Of these agents, the top five were all antipsychotic agents. In the future, the claims cost of some of the agents is expected to decrease as products become generically available. In SFY 2012, quetiapine and olanzapine had generic products released.

Dr. Ellermeier then presented information on reporting at a specific drug level. For this level of reporting, for example, Seroquel, generic Quetiapine, and Seroquel XR are reported separately. Even at this level of detail, hydrocodone/acetaminophen tablets are the most dispensed drug by total claims volume. For specific drugs by claims cost, the top drug is Abilify tablets, which has a total cost more than double than of the next closest product, Seroquel tablets.

Next, a Drug Trend Summary Analysis that reviewed some of the major trends of SFY 2012 was presented. The first trend reviewed was that seen in the anti-convulsant benzodiazepines. This class includes two agents, Klonopin (clonazepam) and Onfi (clobazam). There was an increase in claims cost in the 3<sup>rd</sup> & 4<sup>th</sup> quarters of SFY 2012. Looking at this at the specific drug level, the number of clonazepam claims has been fairly steady, while the number of Onfi claims increased in the 3<sup>rd</sup> and 4<sup>th</sup> quarters of SFY 2012. An increase in costs for this class of drugs corresponds with Onfi's entry in to the market.

management as the final RetroDUR intervention topic for SFY 2012.

Dr. Unruh seconded and the motion carried unanimously.

The increase in costs for the central alpha agonists class was reviewed. This class includes methyldopa, clonidine immediate release tablets, and Kapvay (extended-release clonidine). There has been a fairly steady increase in claims costs since the 3<sup>rd</sup> quarter of SFY 2011. Reviewing this information on a drug specific level, the increase in costs corresponds with the release of Kapvay in February of 2011.

The final class reviewed was the antipsychotics class. After a steady increase in claims cost, in SFY 2012, claims cost began to decrease. This is due to the release of generic drugs within the class. One example of this is the release of generic olanzapine products. Costs for these products began to decrease in conjunction with the release of generic olanzapine.

Dr. Ellermeier summarized the results of the annual report and asked for questions from the board. She then gave a quick overview of the DUR program from the past year. The board had folders available that included DUR newsletters from the past year, as well as the intervention topics. Dr. Ellermeier stated that the DUR program releases newsletters to providers quarterly, and topics this year included antipsychotics, poly-pharmacy, new Soma limitations, the American Academy of Pediatrics ADHD treatment guidelines, and Pradaxa storage.

In addition to DUR newsletters, Dr. Ellermeier's academic detailing focus this year was on updating prescribers on the AAP ADHD guidelines. Over 60 visits were made to prescribers that commonly prescribe these drugs in pediatrics.

The final order of business for the annual program assessment was the choice of remaining topics for RetroDUR intervention letters. In July, the board selected four topics: appropriate lab monitoring of atypical antipsychotics, risk of QT prolongation with quetiapine, non-adherence to antipsychotic medication, and long-term utilization of immediate release opioids. There were three new topics for the board to choose from. The first was appropriate Intuniv utilization, which would focus on use of Intuniv without a diagnosis of the FDA-approved indication of ADHD. The second was long-term effects of atypical antipsychotics in pediatrics, which would inform prescribers of the potential long-term effects of antipsychotics in pediatrics. The final proposed topic was diabetes state management, which would focus on common co-morbid conditions and complications of diabetes and their management. Dr. Ellermeier presented these topics to the board for discussion and selection.

Dr. Waite informed the board that their role was to select one more topic from the three proposed to complete this year's RetroDUR intervention topics. Dr. Waite suggested proposal number two may not be the best choice, as this is a topic that is already being hit with the other intervention topics. He mentioned the idea of 'alert fatigue' and that there could be a concern that we are diminishing the impact of letters sent to prescribers of antipsychotics if they continually receive these letters.

	Dr. Kollhoff mentioned that the diabetes topic hits the most number of people, and Dr. Waite stated that the board is looking at the claims cost for medications and may not consider the overall impact on healthcare costs. He agreed that this would be his choice as well. As a final comment, Ms. Dowd mentioned that diabetes has not been covered as a RetroDUR topic since 2010.	
IV. Old Business A. <b>Review and Approval of 4/11/12 Meeting Minutes</b>  B. <b>Review and Approval of 7/11/12 Meeting Minutes</b>	Dr. Melton mentioned that the April meeting minutes had been approved at the July DUR meeting. However, these minutes mis-stated testimony regarding Kalydeco given by Dr. Lisa Borland, Vertex, who asked for a re-review and correction of these minutes.  The minutes from the July DUR meeting were reviewed.	Dr. Waite moved to approve an amended version of the April DUR minutes.  Ms. Dowd seconded motion and it carried with a unanimous vote.  Dr. Unruh moved to approve the July DUR minutes.  Mr. Sutherland seconded and it carried with a unanimous vote.
V. New Business A. <b>Liraglutide (Victoza®)</b> i. Revised Prior Authorization Criteria ii. *Public Comment iii. Board Discussion	<u>Background</u> 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.  <u>Public Comments:</u> Mike Ketcher, Novonordisk, made himself available for any questions that the board might have regarding Victoza®. He also stated that they agree with the proposed changed and pointed out that there is a monotherapy indication for Victoza®, but not first-line.  <u>Board Discussion</u> Dr. Kollhoff asked if this reflects the package insert now. Dr. Melton explained that the package insert has not changed, but rather that the diabetes guidelines formerly had first line agents of metformin and sulfonylureas, but sulfonylureas are no longer one of the first line recommended agents.	Dr Unruh made a motion to approve amended Victoza® prior authorization criteria.  Dr. Kollhoff seconded the motion  The motion passed unanimously.
B. <b>Weight Loss Drugs: phentermine/topiramate ER (Qsymia®), lorcaserin (Belviq®), orlistat</b>	<u>Background</u> 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	Ms. Dowd made a motion to approve the revised Weight Loss Drugs criteria.

<p><b>(Xenical® and Alli®), &amp; phentermine (Adipex-P®)</b>  i. Revised Prior Authorization Criteria  ii. *Public Comment  iii. Board Discussion</p>	<p>diet and increased physical activity for chronic weight management in adults who are obese (initial BMI&gt;30 kg/m<sup>2</sup>) or overweight (initial BMI&gt;27 kg/ m<sup>2</sup>) 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.</p> <p><u>Public Comments:</u>  There was no public comment.</p> <p><u>Board Discussion</u>  Dr. Waite asked how the PA would work for MAO history, and where this piece of this criteria is addressed. Dr. Ellermeier stated that this is part of the automated SmartPA logic. Dr. Kollhoff mentioned that a list of MAOIs was attached of the criteria and Dr. Waite agreed that this seemed like a comprehensive list. Dr. Waite also mentioned that he felt the proposed quantity limits were also appropriate.</p>	<p>Mr. Sutherland seconded the motion.</p> <p>The motion passed unanimously.</p>
<p><b>C. Emtricitabine/tenofovir (Truvada®)</b>  i. Revised Prior Authorization Criteria  ii. *Public Comments  iii. Board Discussion</p>	<p><u>Background</u>  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.</p> <p><u>No Public Comments</u></p> <p><u>Board Discussion</u>  Dr. Melton mentioned that she had discussed this topic with Dr. Donna Sweet of KU Med in Wichita, who is an HIV/AIDS specialist that serves on the PDL Board. Dr. Sweet believes that the proposed criteria is a good idea, considering that the DUR Board has the public health opportunity to make sure that this is used appropriately. She was also reassured by the fact that the automated PA would allow those who are already HIV-positive to receive the drug.</p> <p>Dr. Waite stated that, as the program moves from fee-for-service to value-based purchasing, this is one that makes sense from a health-care cost perspective.</p>	<p>Dr. Kollhoff made a motion to accept Truvada® prior authorization criteria</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>

<p><b>D. Natalizumab (Tysabri®)</b></p> <p>i. Proposed Prior Authorization Criteria  ii. *Public Comments  iii. Board Discussion</p>	<p><u>Background</u>  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.</p> <p><u>No Public Comments</u></p> <p><u>Board Discussion</u>  Dr. Waite stated that this seemed to be a straight-forward change.</p>	<p>Dr. Kollhoff made a motion to approve Tysabri® PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>
<p><b>E. Multiple Sclerosis Interferons (interferon beta-1b (Betaseron® &amp; Extavia®) &amp; interferon beta-1a (Avonex® &amp; Rebif®)</b></p> <p>i. Proposed Prior Authorization Criteria  ii. *Public Comments  iii. Board Discussion</p>	<p><u>Background</u>  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.</p> <p><u>No Public Comment</u></p> <p><u>Board Discussion :</u>  Dr. Waite again stated that the criteria was straightforward, and complimented Dr. Ellermeier on how she had outlined quantity limits in the criteria to make them as easy to understand as possible.</p>	<p>Dr. Kollhoff made a motion to approve Multiple Sclerosis Interferons prior authorization criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>
<p><b>F. Glatiramer (Copaxone®)</b></p> <p>i. Proposed Prior Authorization Criteria  ii. *Public Comments  iii. Board Discussion</p>	<p><u>Background</u>  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.</p> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u>  Dr. Waite stated that the proposed prior authorization was consistent with the package insert.</p>	<p>Dr. Kollhoff made a motion to approve the criteria for Copaxone®.</p> <p>The motion was seconded by the Ms. Dowd.</p> <p>The motion passed unanimously.</p>
<p><b>G. Fingolimod (Gilenya®)</b></p> <p>i. Proposed Prior Authorization Criteria  ii. *Public Comments</p>	<p><u>Background</u>  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.</p>	<p>Ms. Dowd made a motion to approve the prior authorization criteria for Gilenya.</p> <p>Dr. Kollhoff seconded the</p>

<p>iii. Board Discussion</p>	<p><u>No Public Comments</u></p> <p><u>Board Discussion</u>  Dr. Waite pointed out to the board that the criteria is more stringent than some of the others, but this criteria is part of the REMS program associated with this product.</p> <p>Dr. Dowd asked about the ‘prescribed by or in consultation with a neurologist’ criteria. Dr. Dent stated that the criteria was based on claims data that could pick up a prescriber specialty from a script. Dr. Melton also added that because of all the contraindications, a PA would likely go to the call center regardless, at which point the call center could ask a prescriber for their specialty. Dr. Melton also provided more information on the Gilenya® REMS program.</p>	<p>motion.</p> <p>The motion passed unanimously.</p>
<p><b>H. Dalfampridine (Ampyra®)</b></p> <p>i. Proposed Quantity Limit and Prior Authorization Criteria  ii. *Public Comment  iii. Board Discussion</p>	<p><u>Background</u>  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.</p> <p><u>Public Comment</u>  Ann Corbin from Acorda Therapeutics thanked the committee for their time, and stated that they agree with the prior authorization. Marissa Clark, also from Acorda, agreed.</p> <p><u>Board Discussion</u>  Dr. Waite stated that the criteria is straightforward, although renal failure is a concern, and the seizure risk addresses the quantity limits is important to note.</p>	<p>Dr. Kollhoff made a motion to accept the Ampyra prior authorization criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>VI. KanCare Update</p>	<p>Dr. Melton presented a PowerPoint presentation regarding the upcoming KanCare managed care expansion and how it will affect the Medicaid pharmacy benefit. This included information on state statutes and regulations (Rules &amp; Regulations, step therapy, mental health statutes, etc.), the Preferred Drug List process, the DUR program, and prior authorization.</p>	
<p>VII. *Open Public Comment</p>	<p>Jim Baumann, Pfizer, asked a question regarding the mental health statute and which drugs the state considered to fall under this statute. Dr. Melton stated that the state has a list of therapeutic classes that they do not manage using either a PDL or PA criteria.</p> <p>Mr. Baumann asked if the state had done any research regarding other managed care Medicaid programs, such as Texas. Dr. Melton stated that Texas requires all of their 19</p>	

	<p>MCOs to follow the same PDL, but that they have different PA rules than Kansas. She also stated that the state has reviewed some of the negative experiences of other states such as Texas and Kentucky, and has tried to avoid some of the major issues.</p> <p>Russ Wilson, J&amp;J, asked what the timeline for PA criteria review and approval prior to KanCare GoLive is. Dr. Melton stated that the state plans to build a pharmacy hub that links to the various relevant sections at each MCO's sites, including PA information and phone contact information.</p> <p>Dr. Unruh asked if there was any effort among the three MCOs to have uniformity in their formularies. Dr. Melton explained that the MCOs are required to cover any federally-rebated medication, as well as following the PDL status of any drug that is on the PDL.</p> <p>Jim Baumann, Pfizer, mentioned that they use the KMAP NDC lookup to determine if drugs are covered, and asked if this will still be operational. Dr. Melton stated that this will still be operational, and that additionally, the eligibility lookup through KMAP will still work for providers.</p>	
<p>VIII. Adjourn</p>	<p>The meeting was adjourned at 12:35 p.m.</p> <p>The next meeting will be on Wednesday January 9, 2013. It will begin at 10:00 am at the HP Enterprises Services Office.</p> <p><b>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</b></p>	<p>Ms. Dowd made a motion to adjourn.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>