

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
April 11, 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> Dennis Grauer, PhD Judy McDaniel Dowd, PA-C Roger Unruh, D.O. Kevin Waite, Pharm.D. John Kollhoff, Pharm.D. <b>Member Absent</b> Daniel Sutherland, R.Ph. Tim Heston, D.O. <b>DHCF Staff Present:</b> Kelley Melton, Pharm.D. Shea Robinson Shelly Liby <b>HP Enterprise Services Staff Present:</b> Deb Quintanilla, R.N. Lisa Todd, R.Ph. Karen Kluczykowski, RPh Pam Girard, R.N. <b>HID Staff Present</b> Nicole Churchwell, Pharm.D. <b>ACS Staff Present</b> Bethany Noble, C.Ph.T Larry Dent, Pharm.D.</p>	<p><b>Representatives:</b> Julie McDavitt, Boehringer- Ingelheim Scott Maurice, Boehringer- Ingelheim Phil King, Pfizer Jim Bauman, Pfizer Teresa Blair, Amgen Risa Reuscher, Amgen Terry Rehmus, Janssen Kathleen Karnik, Janssen Mark Weizs, Otsuka Jerry McCurren, Otsuka Matthew Stafford, Merck Berend Koops, Merck Brian Rose, Savient Steve Granzzyk, Elan Jeff Himmelberg, GSK Jim Russell, GSK Eric Gardner, Vertex Lisa Borland, Vertex Russ Wilson, J &amp; J Susan Zalenski, J &amp; J Jeff Knappen, Allergan Jen Dalroush, Allergan Don Larson, Forest</p>
<b>TOPIC</b>	<b>DISCUSSION</b>	<b>DECISION AND/OR ACTION</b>
I. Call to Order	Dr. Waite called the meeting to order at 10:02 a.m.	
II. Announcements	Dr. Churchwell 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 introduced the new Nurse Utilization Review Manager for HP's Prior Authorization Unit, Pam Girard, RN to the board. Dr. Melton informed everyone that public comments are limited to five minutes and a public disclosure form will need to be completed and returned.	
III. Old Business A. Review and Approval of 10/12/11 Meeting Minutes	No changes made. The minutes were approved.	Dr. Kollhoff moved to approve the minutes.  Ms. Dowd seconded motion and it carried with a unanimous vote.

<p>IV. New Business</p> <p>A. Xarelto (rivaroxaban)</p> <p>i. Update for DUR Board</p> <p>ii. Board Discussion</p>	<p><u>Background</u></p> <p>In October 2011, the DUR Board voted to place a day supply limit of 35 days on rivaroxaban based upon the package insert and indications available at that time. In November 2011, rivaroxaban received approval for a new indication for use in atrial fibrillation. The new indication extends the amount of time a patient would use rivaroxaban; therefore, DHCF has decided not to move forward with restrictions on rivaroxaban. Presented by Dr. Churchwell, HID</p> <p>No Public Comments.</p> <p><u>Board Discussion</u></p> <p>There was no discussion.</p>	
<p>B. Pradaxa (dabigatran)</p> <p>i. Update for DUR Board</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>In June 2011, the DUR Board voted to place quantity and day supply limits on dabigatran based upon the storage and handling information in the package insert available at that time. In October 2011, new information became available that extended the expiration of the medication from 30 days to 4 months after opening the bottle, if the drug is stored in the original container. Based upon the new information available, DHCF has decided not to move forward with restrictions on dabigatran. Presented by Dr. Churchwell, HID</p> <p>No Public Comments</p> <p><u>Board Discussion</u></p> <p>There was no discussion.</p>	
<p>C. Bile Acid Sequestrants</p> <p>i. PDL Non-Preferred Agent Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Bile Acid Sequestrants include cholestyramine (Questran®, Questran Light®, and Prevalite®), colestipol (Colestid®), and colesevelam (Welchol®). These agents are used to treat hypercholesterolemia by binding intestinal bile acids. Bile Acid Sequestrants are a new PDL class approved by the PDL committee on March 14, 2012. It is recommended that PDL non-preferred criteria be approved for the bile acid sequestrants. Larry Dent, ACS presented this drug.</p> <p>No Public Comments</p> <p><u>Board Discussion</u></p> <p>Dr. Kollhoff asked if all the drugs were preferred.</p> <p>Dr. Melton explained that the state later determines what agents fall into the preferred and non-preferred categories. The board is being asked to approve criteria that beneficiaries</p>	<p>Dr. Kollhoff made a motion to approve the PDL non-preferred Criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>

	would have to meet to access non-preferred agents.	
<p>D. Incretin Mimetics</p> <p>i. PDL Non-Preferred Agent Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Incretin mimetics include Byetta® (exenatide), Victoza® (liraglutide), and Bydureon® (exenatide extended-release). These agents are glucagon-like peptide-1 (GLP-1) receptor agonist that are indicated as adjuncts to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Incretin Mimetics are a new PDL class. Byetta and Bydureon were approved for inclusion by the PDL committee on March 14, 2012. Victoza was not approved until further studies could be evaluated. It is recommended that PDL non-preferred criteria be approved for the Incretin Mimetics.</p> <p>Larry Dent, ACS presented this drug.</p> <p>No Public Comments</p> <p><u>Board Discussion</u></p> <p>There was no discussion.</p>	<p>Ms. Dowd made a motion to approve the non-preferred criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>E. Bydureon (exenatide extended-release)</p> <p>i. New Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Bydureon 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. Bydureon is not recommended as first-line therapy. Other GLP-1 receptor agonists include Byetta (exenatide) and Victoza (liraglutide), which has approved prior authorization criteria requiring a look back for maximum tolerated doses of a sulfonylurea or metformin. It is recommended that Bydureon be added to the current criteria.</p> <p>Larry Dent, ACS presented this drug.</p> <p>Public Comment</p> <p><u>Board Discussion</u></p> <p>Dr. Waite mentioned that it's the same basic criteria as Byetta.</p>	<p>Dr. Kollhoff made a motion to add Bydureon to the current criteria.</p> <p>Dr. Grauer seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>F. Onfi</p> <p>i. Diagnosis Restrictions</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Onfi is a new benzodiazepine indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older. Due to the potential for off-label use and abuse of this drug, the DUR Board is asked to approve diagnosis restrictions for use in patients with epilepsy.</p> <p>Larry Dent, ACS presented this drug.</p> <p>No Public Comments</p> <p><u>Board Discussion</u></p> <p>Dr. Kollhoff asked if pharmacies are required to enter a diagnosis code. He would like to do away with the diagnosis code requirements. Dr. Melton explained that until the drug goes through the Rules &amp; Regulations process, it cannot be placed on PA. In the meantime, DHCF would like to manage the drug with diagnosis restrictions, but can make a plan to</p>	<p>Dr. Kollhoff made a motion to approve the restrictions.</p> <p>The motion was seconded by the Dr. Grauer.</p> <p>The motion passed unanimously.</p>

	eventually put Onfi on PA.	
G. Long-Acting Opioids Dose Optimization (Nucynta ER (tapentadol) i. Revised Clinical Prior Authorization Criteria ii. Public Comments iii. Board Discussion	<p><u>Background</u> Nucynta ER is an opioid analgesic indicated for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. All long-acting opioids require prior authorization above the DUR approved units/day. It is recommended that Nucynta ER be added to other long-acting opioids limitation criteria. Larry Dent, ACS presented this drug.</p> <p><u>Public Comments</u> Kathleen Karnik, Janssen, explained this is a new drug and a different molecular entity from other opioids. She stated that she is available for comments or questions.  Dr. Kollhoff asked if the higher strengths were extended release and the lower strengths were immediate release. Ms. Karnik answered no, they are different formulations.</p> <p><u>Board Discussion</u> There was no board discussion.</p>	<p>Dr. Kollhoff made a motion to add Nucynta ER to the other long acting opioids limitation criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>
H. Botox i. Revised Clinical Prior Authorization Criteria ii. Public Comments iii. Board Discussion	<p><u>Background</u> The botulinum toxin criteria were last approved in January 2011 by the DUR board. In September 2011, the FDA approved urinary incontinence as a new indication for Botox. It is recommended that current criteria be revised to include use of Botox for urinary incontinence. Larry Dent, ACS presented this drug</p> <p>No Public Comment</p> <p><u>Board Discussion</u> Dr. Waite mentioned the background is pretty straight forward.</p>	<p>Dr. Grauer made a motion to accept the revision.</p> <p>Dr.Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>
I. Prolia (denosumab) i. Revised Clinical Prior Authorization Criteria ii. Public Comments iii. Board Discussion	<p><u>Background</u> In October 2010, the DUR Board approved clinical prior authorization criteria for Prolia. At that time, the only FDA approved indication was for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapy. In September 2011, two new indications were approved; these include treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer and treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. The DUR Board is asked to approve revised clinical prior authorization criteria that include the two new indications. Nicole Churchwell from HID presented this drug.</p>	<p>Dr. Kollhoff made a motion to approve the revised PA.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>

	<p><u>Public Comments</u> Risa Reuscher, Amgen, stated there were no head-to-head trials and she was available to answer questions.</p> <p><u>Board Discussion</u> No discussion</p>	
<p>J. Mozobil (plerixafor)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> Mozobil was last approved by the DUR Board in March 2009. It is indicated to be used in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma (NHL) and multiple myeloma (MM). The prior authorization criteria are being updated to reflect the most recent package insert. Nicole Churchwell from HID presented this drug</p> <p>No Public Comment</p> <p><u>Board Discussion</u> No discussion</p>	<p>Ms. Dowd made a motion to update the PA criteria. Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>K. Remicade (infliximab)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> The Remicade prior authorization criteria were last revised in June 2011. In September 2011, the indication for ulcerative colitis was expanded from patients 18 years of age and older to include patients 6 years of age and older. The prior authorization criteria are being revised to reflect this change. Nicole Churchwell from HID presented this drug.</p> <p><u>Public Comments</u> Terry Rehmus, Janssen, informed the board that he was in available to answer questions.</p> <p><u>Board Discussion</u> No discussion</p>	<p>Dr. Kollhoff made a motion to make the change.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>L. Orencia (abatacept)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> Orencia is indicated for rheumatoid arthritis and juvenile idiopathic arthritis. Orencia prior authorization criteria were last approved by the DUR board in November of 2008. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent. Larry Dent, ACS presented this drug.</p> <p>No Public Comments</p>	<p>Dr. Unruh made a motion to revise the current criteria.</p> <p>Ms. Dowd seconded The motion.</p> <p>The motion passed unanimously.</p>

	<p><u>Board Discussion</u> No discussion</p>	
<p>M. Kineret (anakinra)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> Kineret is indicated for rheumatoid arthritis. Kineret prior authorization criteria were last approved in April 2004 by the DUR board. The manufacturer recommends that neutrophil counts be assessed prior to initiating Kineret, and while receiving Kineret, monthly for 3 months, and thereafter quarterly for a period up to 1 year. It is recommended that current criteria be revised to include laboratory monitoring criteria, TB skin test, and criteria to look for a history of another biologic agent. Larry Dent, ACS, presented this drug.</p> <p>No Public Comments.</p> <p><u>Board Discussion</u> Ms. Dowd asked about therapy renewals and if a timeline had been established.</p> <p>Dr. Melton stated that requiring a PA to account for each month's lab draw is excessive. The proposal includes reviewing the patient's lab draws initially and then again at renewal.</p> <p>Dr. Waite thought the 90 days seemed to make sense.</p>	<p>Dr. Unruh made a motion to revise the current criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>N. Actemra (tocilizumab)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> Actemra was last reviewed by the DUR Board in April 2010; since that time an indication for juvenile idiopathic arthritis was approved by the FDA. The prior authorization criteria are being revised to reflect the new indication, update the appropriate lab monitoring for renewals, and add criteria that look for the history of another biologic agent. Nicole Churchwell from HID presented this drug.</p> <p>No Public Comments.</p> <p><u>Board Discussion</u> Ms. Dowd mentioned concern for consistency and this update followed the criteria for other agents in this class.</p>	<p>Ms. Dowd made a motion to revise the current criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>O. Simponi (golimumab)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> Simponi is indicated for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. Simponi was last approved by the DUR board in January 2011. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent. Larry Dent, ACS, presented this drug.</p> <p><u>Public Comments</u> Terry Rehmus, Janssen, was available to answer questions.</p>	<p>Dr. Grauer made a motion to revise the current criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>

	<p><u>Board Discussion</u> Dr. Waite stated this is very straight forward.</p>	
<p>P. Stelara (ustekinumab)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> Stelara is indicated for plaque psoriasis. Stelara was last approved by the DUR board in January 2011. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent. Larry Dent, ACS, presented this drug.</p> <p>No Public Comments.</p> <p><u>Board Discussion</u> Dr. Gauer asked what happens if a patient is already on another biologic agent? Larry Dent stated it will deny if the other agent had been filled within 30 days.</p>	<p>Dr. Kollhoff made a motion to revise the current criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>Q. Rituxan (rituximab)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u> Rituxan was last approved by the DUR Board in June 2011; it is being revised to include a criteria check for the history of another biologic agent as well as renewal criteria for appropriate lab monitoring. Nicole Churchwell from HID presented this drug.</p> <p>No Public Comments.</p> <p><u>Board Discussion</u> Dr. Kollhoff asked how long would the PA be good for? Dr. Churchwell answered that the PA would be for six months.</p>	<p>Dr. Kollhoff made a motion to revise the criteria.</p> <p>Dr. Grauer seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>R. Cimzia (certolizumab)</p> <p>i. Revised Clinical Prior Authorization Criteria</p> <p>ii. Public Comments</p> <p>iii. Board Discussuib</p>	<p><u>Background</u> Cimzia is indicated for rheumatoid arthritis and Crohn's disease. Cimzia was last approved by the DUR board in January of 2010. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent. Larry Dent from ACS presented this drug.</p> <p>No Public Comments.</p> <p><u>Board Discussion</u> No discussion.</p>	<p>Dr. Kollhoff made a motion to revise the current criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>S. Tysabri (natalizumab)</p> <p>i. Revised Clinical Prior Authorization Criteria</p>	<p><u>Background</u> Tysabri is indicated for the treatment of multiple sclerosis and Crohn's disease; it was last reviewed by the DUR Board in January 2010. The prior authorization criteria are being revised to include a criteria check for a history of another biologic agent and evaluation for latent tuberculosis with a TB skin test.</p>	<p>Dr. Kollhoff made a motion to revise the current criteria.</p> <p>Ms. Dowd seconded the motion.</p>

<p>ii. Public Comments iii. Board Discussion</p>	<p>Nicole Churchwell from HID presented this drug.</p> <p>No Public Comments.</p> <p><u>Board Discussion</u> No discussion</p>	<p>The motion passed unanimously.</p>
<p>T. Kalydeco (ivacaftor) i. New Clinical Prior Authorization Criteria ii. Public Comment iii. Board Discussion</p>	<p><u>Background</u> Kalydeco is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator. It is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene. Kalydeco is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene and has not been studied in other patient populations with CF. Prior authorization criteria is being proposed to include criteria for diagnosis of CF in patients who are 6 years of age or older. Larry Dent from ACS presented this drug.</p> <p><u>Public Comments</u> Lisa Borland, Vertex, stated this drug is for Cystic Fibrosis. It is the first drug to target a specific cause of CF and there are no contraindications. Dr. Melton mentioned that the state doesn't pay for genetic testing</p> <p>Dr. Kollhoff asked if there are studies on younger people. Lisa Borland answered that studies had been done on 2 to 5 year olds.</p> <p>Dr. Melton stated that although the criteria is in line with the package insert and is limited to patients 6 years of age and above, there is an appeal process available for patients younger than 6 years old.</p> <p><u>Board Discussion</u> Ms. Dowd asked if the criteria should be re-worded if the interactions presented are not true contraindications. She suggested the wording of the criteria be changed.</p> <p>Lisa Todd asked if a diagnosis restriction was necessary. Dr. Melton stated that based on rates of this particular variant of Cystic Fibrosis, there may be around 15 patients in Kansas that would qualify for the drug. It's a low risk and the patients taking this drug off-label will likely all have CF so a diagnosis restriction would not be specific enough.</p>	<p>Dr. Unruh made a motion to approve the criteria as revised.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>U. Retro-DUR Intervention Outcomes i. Retro-DUR Outcomes Report</p>	<p><u>Background</u> Health Information Designs (HID) presented Retro-DUR outcomes for the intervention letters mailed in State Fiscal Year 2011. The five intervention topics that were mailed include: Increased Risk of Serotonin Syndrome, Appropriate ADHD Treatment, Psychotropic Use in Children and Adolescents, History of Drug Abuse, and Appropriate</p>	

<p>ii. Board Discussion</p>	<p>Narcotic Utilization.</p> <p>Dr. Churchwell introduced herself and informed everyone of what Health Information Designs does for the program.</p> <p>Dr. Churchwell presented the State Fiscal Year 2011 Intervention Outcomes Reports. She focused on the summary reports.</p> <p>A total of 936 coded responses were received from prescribers who were sent an intervention letter. The response rate was 27.4%.</p> <p>Out of the 936 coded responses received, 740 provided additional feedback. A total of 52.1% of feedback responses ranked the letters as ‘useful’ or ‘extremely useful’.</p> <p>A total of 3,144 beneficiaries were selected for intervention. Six months after the letters were mailed to the prescriber, 2,493 of those original 3,144 beneficiaries had at least one claim for any drug and could be evaluated. Of those 2,493 beneficiaries, 54.1% were found to no longer have the same therapy problem, in the follow up period, that their prescriber received a letter regarding,</p> <p>The Estimated Cost Avoidance for the Kansas Medical Assistance Program was \$921,237 for the 6 months following the mailing of the intervention letters.</p> <p><u>Board Discussion</u></p> <p>Dr. Grauer asked which one had the biggest impact. Dr. Churchwell answered the history of abuse, even though it had a lower cost savings than some of the other intervention topics it showed the largest decrease in criteria exceptions in the follow-up period.</p>	
<p>V. Medicaid Reform Update</p>	<p>Dr. Melton stated there will still be a DUR Board after health reform is implemented, but not sure what it will look like. The state will keep the board updated as DHCF moves forward.</p> <p>Dr. Grauer asked if there is a term limit to serving on the board. Dr. Melton stated, no. The contracts are renewable every three years.</p>	
<p>VI. Selection of New Chairperson</p>	<p>Ms. Dowd nominated Dr. Kevin Waite to serve as Chairperson. Dr. Waite accepted the nomination.</p>	<p>Ms. Dowd made the motion to nominate Dr. Waite as the new Chairperson.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>VII. Public Comments</p>	<p>Susan Zalenski, Johnson and Johnson, asked for more insight into the Kansas Pharmacy</p>	

	benefits and the role of the committee moving forward into managed care. Dr. Melton answered the state will be responsible for a one central preferred drug list, but that there is a lot that is still being decided.	
VIII. Adjourn	<p>The meeting was adjourned at 11:22 am</p> <p>The next DUR Board meeting will be on Wednesday, July 11, 2012. It will begin at 10:00 am at the HP Enterprises Services Office.</p>	<p>Dr. Kollhoff made a motion to adjourn.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>