

DRUG UTILIZATION REVIEW BOARD
Meeting Minutes, Open Session
March 12, 2008

<p>DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas March 12, 2008</p>	<p>Members Present:, Michael Burke M.D. Ph.D. Chair; Brenda Schewe, M.D., Acting Chair; Roger Unruh, D.O.; Tom Wilcox, R.Ph.; Kevin Waite, PharmD; Judy McDaniel Dowd, PA-C; KHPA Staff Present: Dr. Margaret Smith; Ashley Salyers- KU Pharmacy Student; LaTikka Moore; Dennise Weichert EDS Staff Present: Deb Quintanilla, R.N.; Lisa Todd, R.Ph. ACS Heritage Staff: Jerry Bowmer R.Ph.</p>	<p>Representatives: Michael Lafond, MT (ASCP), MBA Abbott; Thomas Holder, Valeant; Ann Gustafson, GSK; Richard Mesquias, Eli Lilly; Jeff Knappen, Allergan Inc.; Phil King, Pfizer; Michelle Terry, Merck; Jason Demuth, TAP; Joe Summers, TAP; Mark Rostine, Proctor & Gamble; Nancy Perry R.N., EDS</p>
<p align="center">TOPIC</p>	<p align="center">DISCUSSION</p>	<p align="center">DECISION AND/OR ACTION</p>
<p>I. Call to Order</p>	<ul style="list-style-type: none"> • Dr. Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 10:08 a.m. 	
<p>II. Announcements</p>	<ul style="list-style-type: none"> • Dr. Smith announced Phillip Hayes has resigned as the Pharmacy Program Manager and KHPA is currently seeking another Pharmacist. • Lisa Todd requested members of the public sign the attendance form and fill out a conflict of interest disclosure form if they would like to speak during the public comment period. She explained the comment period is limited to five minutes per product with additional time allowed at the discretion of the Board. If there is more than one speaker for the same product, she requested they split the time limit between the speakers. 	
<p>III. Review and Approval of November 14, 2007 Meeting Minutes</p>	<ul style="list-style-type: none"> • Dr. Michael Burke stated the minutes have received a lot of attention. Lisa Todd and Dr. Burke have edited the minutes. The most recent version was distributed to the Board members prior to the meeting. 	

	<ul style="list-style-type: none"> • Dr. Roger Unruh states he had one correction to make. On page 11 under “Whooping Cough” bronchitis should be changed to bronchiolitis. • Judy Dowd requested the minutes reflect the meaning of SURS located on page four. • Lisa stated this will be corrected and spelled out. She defined SURS as Surveillance Utilization Review Sub-System. • Dr. Smith stated the name “Candice Taylor” was misspelled and should be corrected to Candace Taylor. • Lisa Todd stated on page 4 of the minutes she misspelled Debra Quintanilla name. • Dr. Burke stated under “Members Present” his titles should be M.D. Ph.D. 	<ul style="list-style-type: none"> • Ms. Dowd motioned to approve the minutes after all corrections have been noted and changed. • Seconded by Dr. Unruh and the motion carried unanimously by role call and approved.
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>IV. Old Business</p> <p>A. Threshold Report- Update</p>	<ul style="list-style-type: none"> • Dr. Burke summarized the issues stated from our legislators to the board. They have asked the board to examine the issue of polypharmacy. • Dr. Burke reminds the Board that legislature has asked the DUR Board to review the issue of polypharmacy. The Board had selected ten or more drugs as the current Threshold. This number was generating a large number of cases to review. There is a high incidence of repeat patients meeting the current Threshold. The objective is to consider a new Threshold level. • Lisa Todd presented a report containing the number of patients to see how a Threshold change will affect a number of beneficiaries that can be identified. • Lisa presented a report containing the number of patients meeting various levels of Threshold in 2007. 	

These were the Threshold levels listed on the report:

- 10-11
 - 12-14
 - 15-19
 - 20 or greater
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- Dr. Burke reminded the Board the Threshold review process should be a polypharmacy review. The question is what would be the Threshold number that will generate a manageable number of cases that can be reviewed on a monthly basis.
 - A threshold of 15 or greater drugs per month will generate an average 50 charts a month for review. Dr. Burke feels this would be an incremental change from the 10 -15 drugs a month and would reduce the burden considerably.
 - Dr. Kevin Waite commented setting a Threshold level lower than 15 drugs a month may generate an abundance of charts to review.
 - Dr. Schewe asked if there were many of the same patients every month. Lisa Todd explained there are many of the same beneficiaries that meet Threshold every month.
 - Dr. Schewe suggested reviewing these charts after three or four months.
 - Dr. Waite recommended the education letter following a case review state our records indicate these prescriptions were filled for your patient and ask the physician to review their records for accuracy.
 - Dr. Burke requested a summary report presented quarterly describing the activity and intervention of the polypharmacy review program.

- Dr. Waite motioned to approve the new Threshold level of 15 or more unique drugs per month.
- Mrs. Judy Dowd Mc-Daniel seconded the motion. The motion is carried by a unanimous vote by the Board.

B. Report of Adjunct Anti-Epileptics

- Dr. Burke reminded the board members a diagnosis code is currently required on pharmacy claims for Neurontin (Gabapentin). Lyrica (Pregabalin) currently requires a prior authorization (PA). An issue was raised at the last meeting about the restrictions on these two medications, but not on the other adjunct anti-epileptics.
- Lisa referred to the adjunct anti-epileptics prescriptions filled from July 2007 through December 2007 while discussing the following data:

Medication	Number of Prescription Claims for July to December 2007	Number of Unique Patients
Lamotrigine	8030	1760
Topiramate	5303	1282
Tiagabine	252	52
Levetiracetam	2493	537
Zonisamide	750	135
Total	16828	3766

Medication	Number of Unique Patients with Professional Claims with Epileptic Diagnosis
Lamotrigine	1077
Topiramate	782
Tiagabine	16
Levetiracetam	39
Zonisamide	9
Total	1,923

- Lisa noted the diagnosis codes of 780.39 or 345.0 through 345.99 were retrieved from professional claims

from January to December 2006. She stated after consulting with an EDS systems engineer this date range would give the best match considering the lag time of professional claim filing.

- Dr. Burke commented the data made sense for some of the medications in regards to the patients without an epilepsy diagnosis. For instance, Lamotrigine is also indicated for bi-polar disorder. Topiramate is also indicated for migraine headache. Tiagabine, levetiracetamine, and zonisamide are only indicated for seizures.
- Dr. Burke reminded the board members that some of the discrepancies of no indications of an epilepsy diagnosis may be due to the limitation of gathering the diagnosis since it is not required on the point of sale pharmacy claim.
- Ms. Dowd inquired if there were other instances where a diagnosis code is required on a few medications in a drug class and not on the entire class of medications. Lisa Todd stated this was not a unique situation. Ms. Dowd wondered if the reason why the diagnosis code was not required on all medications in a certain class of drugs was because of the difficulty of entering the diagnosis or if there wasn't a need for the limitation. Lisa explained diagnosis codes are required when there is a concern to limit the prescribing of the medication for a particular diagnosis. Lisa explained that requiring diagnosis codes when it is not necessary does put the burden on the providers. She used an example of a pharmacist receiving a prescription without a diagnosis code which would require the pharmacist to call the physician for the appropriate code for the prescription before the medication could be dispensed to the patient. The goal has always been to require diagnosis codes only when necessary.
- Dr. Burke reminded the board members that limitations were placed on gabapentin due to the considerable off-label use. He mentioned there had been off-label marketing of gabapentin. This is one of the contributing factors of the diagnosis code requirement.
- Dr. Burke stated the issue is whether to remove the diagnosis codes requirement on gabapentin, place the requirement on all of the adjunct anti-epileptics, or keep

the requirements as they are.

- Dr. Burke presented a letter of study from Dr. Jessica Hollins, KU Assistant Professor. She conducted a study involving her patients. She found gabapentin is very effective for behavioral control in the developmentally disabled youth population. Due to the requirement of a diagnosis code on gabapentin, her patients do not have access to a medication that helps them.
- Dr. Smith asked if the study was the only one or if it has been replicated. She stated her concern of how the study was implemented and may have produced biased results. Dr. Burke reported the study was not double-blind and had not been replicated.
- Lisa Todd referred to an expenditure report presented to the Board when Lyrica[®] was placed on PA that indicated large dollar figures concerning off labeled use of Lyrica[®]. Lisa suggested an updated expenditure report could be brought to the next meeting.
- Dr. Burke stated the minutes should reflect that a large number of patients are receiving Adjunct Anti-Epileptics and their diagnosis is unaccounted for in our reports. The Board is looking at the benefit of requiring diagnosis codes at point of sale and to gather all data for compare economics.
- Dr. Schewe requested the proposed diagnosis code requirements for each adjunct anti-epileptic be presented at the next meeting. She suggested a vote can be taken after the data is presented.
- Dr. Burke stated the purpose of the Board is to ensure safe and effective use of pharmaceuticals in Kansas Medical Assistance Program (KMAP) beneficiaries.
- Dr. Burke requested a report on the expenditures for Zonegran[®], Keppra[®] and gabapentin with the date range of July through December 2007. This report should include the number of patients who received

	<p>these medications.</p> <ul style="list-style-type: none"> • Dr. Burke stated the Board would evaluate this data at the next meeting and make a decision regarding the requirement of diagnosis codes on the adjunct anti-epileptic class. • Lisa Todd clarified that this report should be based on paid prescription claims for the previously mentioned medications. • Dr. Burke requested gabapentin be included along with the dollar amount spent in the report. • Dr. Kevin Waite wants the board to look at Keppra[®] he stated we can do a proportion to figure out what part of those dollars are unsubstantiated dollars that we can save if the Board require diagnosis codes on more products. 	
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>V. New Business</p> <p>A. ACS Heritage Presentation of Potential Interventions.</p> <p>1. Interventions</p>	<ul style="list-style-type: none"> • Lisa Todd introduced Jerry Bowmer as a pharmacist with ACS Heritage. She reminded the board he would be presenting five interventions to the Board. The objective is to choose three interventions to be conducted throughout the rest of the fiscal year. • Jerry Bowmer presented an intervention proposal for all five interventions using power point. • Mr. Bowmer listed the following information regarding the potential intervention topics. Amount of money spent on KMAP claims, date of last intervention, and number of potential opportunities. <ul style="list-style-type: none"> ○ Asthma > \$16 billion, 2006, 6,136 potential opportunities ○ Osteoporosis > \$14 billion, never, 8,800 potential opportunities ○ Diabetes > \$132 billion, 2006, 18,300 potential opportunities 	

a) Asthma

- Heart Failure > \$34 billion, 2003, 7,538 potential opportunities
- NSAID >\$4 billion, 2005, 2,500 potential opportunities

1. Asthma

a. Purpose:

- i. To improve the treatment of asthma by identifying patients who appear to have problematic therapies.

b. Why issue was selected:

- i. The CDC website estimates thirty million people have been diagnosed with asthma nationally.
- ii. Direct healthcare costs and indirect costs of missed work or school total \$16.1 billion annually nationwide.

c. Performance indicators:

- i. Non-compliance with drug regimens: 2,010 exceptions
- ii. Underutilization of influenza vaccine: 2,771 exceptions
- iii. Inappropriate utilization of beta₂ agonist therapy: 795 exceptions
- iv. Increase risk of adverse drug events: 405 exceptions
- v. Underutilization of inhaled corticosteroids: 155 exceptions

d. Anticipated Results:

- i. Increases awareness of latest clinical practice guidelines
- ii. Reveal patient's medication compliance, potential interactions, and costs/outcomes of therapy
- iii. Improved clinical outcomes with client cost savings

2. Osteoporosis

a. Purpose:

- i. To improve safety and efficacy of therapy for osteoporosis

b) Osteoporosis

<p>c) Diabetes</p>	<ul style="list-style-type: none"> ii. Identify opportunities for drug therapy and bone density screening iii. It is estimated that 44 million people in the United States are threatened by osteoporosis—sixty-eight percent of whom are female. iv. Osteoporosis is responsible for an estimated fourteen billion dollars in expenditures. b. Performance indicators: <ul style="list-style-type: none"> i. Underutilization: density screenings, treatment/therapy in fractures, and osteoporosis medications: 7,447 exceptions ii. Risk of adverse events: fall risk, fracture/thiazolidinedione use, GERD and hypocalcemia/bisphosphonates: 1028 exceptions iii. Discontinuation of osteoporosis agents: 187 exceptions iv. Appropriate use of first-line calcitonin-salmon and Fosamax[®] dose optimization: 111 exceptions v. Non-adherence with bisphosphonates and raloxifene: 80 exceptions c. Anticipated results: <ul style="list-style-type: none"> i. Improved adherence in osteoporosis therapies ii. Re-initiation of discontinued therapies iii. Increased bone density screening iv. Changes in Fosamax[®] dosing based on documented diagnosis v. Decreases in medication potentiating falls <p>3. Diabetes</p> <ul style="list-style-type: none"> a. Purpose: <ul style="list-style-type: none"> i. Improve quality and safety of diabetic therapy based upon the 2007 clinical practice recommendations published 	
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d) NSAIDS

by the American Diabetes Association.

- ii. It is estimated that eighteen million people in the United States are diabetic
- iii. Diabetes is responsible for an estimated \$132 billion in expenditures
- iv. Diabetes is associated with considerable morbidity; blindness, end stage renal disease, amputation, heart disease, and stroke

4. Performance indicators:

- i. Encourage labs and preventative screenings: 11,535 exceptions
- ii. Enhance adherence of medications: 2,779 exceptions
- iii. Encourage antilipemics when not contraindicated: 1,641 exceptions
- iv. Promote safe/effective medications by identification of adverse events and drug interactions: 1,382 exceptions
- v. Encourage metformin in type 2 when not contraindicated: 755 exceptions
- vi. Encourage angiotensin modulating medications in hypertensive patients when not contraindicated: 269 exceptions

5. Anticipated Results:

- i. Encourage recommended labs and preventive screenings
- ii. Improved compliance with meds
- iii. Encourage antilipemic therapy
- iv. Increase metformin in type 2 patients

6. NSAID Drug Usage Evaluation

a. Purpose:

- i. Assist providers in the treatment of patients using non-steroidal anti-inflammatory therapy
- ii. Data is based upon recommendations of the American College of Cardiology

<p>e) Heart Failure</p>	<p>and the American Heart Association</p> <ul style="list-style-type: none"> b. Why issue was selected: <ul style="list-style-type: none"> i. NSAID-induced toxicities have significant morbidity/mortality ii. National costs are an estimated four billion dollars in expenditures iii. Kansas drug spend last year was \$828,151. Fifty-seven percent came from COX-2 alone. c. Performance Indicators: <ul style="list-style-type: none"> i. Identify patients at risk of increased GI toxicity from NSAIDS themselves, tobacco/alcohol use, and bisphosphonates: 1,298 exceptions ii. Risk of cardiovascular events: 623 exceptions iii. Reconsider NSAID use with CHF: 411 exceptions iv. Reserve use of COX-2 inhibitors for patients at risk of GI toxicity: 174 exceptions v. Recognize patients with concurrent use of >1 NSAID: 34 exceptions vi. Reconsider NSAID's in recent myocardial infarctions: 4 exceptions d. Anticipated Results: <ul style="list-style-type: none"> i. Encourage safe and cost effective NSAID therapy ii. Identify duplicate therapy and DDI's involving NSAID's iii. Recognition of costs of non-selective NSAID's, COX-2 inhibitors, and GI agents used for prophylactic therapy <p>7. Heart Failure (HF)</p> <ul style="list-style-type: none"> a. Purpose: <ul style="list-style-type: none"> i. Improve treatment of HF by reducing practice variance from clinical practice guidelines ii. Why issue was selected: iii. American Heart Association identifies 	
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	<p>five million patients affected by HF. There are 500,000 newly diagnosed cases annually</p> <ul style="list-style-type: none"> iv. Approximately 300,000 deaths annually v. Estimated direct and indirect costs > \$34 billion vi. Seventy percent economic burden is hospitalization of which up to sixty-six percent may be preventable <p>b. Performance indicators:</p> <ul style="list-style-type: none"> i. Compliance, digoxin and antihypertensive medications: 2,623 exceptions ii. Underutilization of angiotensin modulating therapy: 2,264 exceptions iii. Underutilizations of beta blockers: 1,977 exceptions. iv. Drug-drug and drug-disease interactions, duplicate therapy of medications: 675 exceptions <ul style="list-style-type: none"> • Dr. Burke stated the Board Members had the Executive summaries and letters for these interventions. Asked the Board for any thoughts or comment they would like to share on these Interventions. • Dr. Kevin Waite suggested the NSAID and Asthma interventions may be more appropriate at a later date. • Dr. Burke recommends the letters be concise and kept to one page. • Dr. Burke suggested no changes be made to the leaving Chronic Heart Failure and Osteoporosis letters. • Dr. Schewe suggested modifying the letter with specific osteoporosis treatment information. She would like the letter to provide more education to the provider. • Dr. Kevin Waite stated on the third bullet on the back to remove the specific drug name. He is concerned that it 	
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	<p>may be misconstrued as promoting a certain product.</p> <ul style="list-style-type: none"> • Dr. Schewe suggested using the Heart Failure letter as a guide--she believes it more helpful. • Dr. Burke asked that the letter be modified with the noted changes and send a copy to Dr. Margaret Smith for approval and review with Lisa Todd on final version • Jerry Bowmer was instructed to send the final draft to Lisa Todd and Dr. Smith prior to mailing to providers. • Dr. Burke stated this concludes today's meeting. • Dr. Burke asked for any final public comments for the board members. • Dr. Burke stated the meeting was adjourned at 11:45 p.m. 	<ul style="list-style-type: none"> • Dr. Unruh made a motion to select Osteoporosis, Diabetes, and Heart Failure as the three interventions to be conducted the remainder of the fiscal year. • Dr. Schewe seconded the motion. The motion carried by unanimous vote.
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<p>B. Humira</p> <p>1. Addition of new indications to PA Criteria</p> <p style="padding-left: 40px;">a) Treatment of Juvenile Idiopathic Arthritis</p> <p style="padding-left: 40px;">b) Treatment of Plaque Psoriasis</p> <p>2. Public Comment</p> <p>3. DUR Board Discussion/Recommendation</p>	<ul style="list-style-type: none"> • Lisa Todd stated Humira[®] has recently been approved for two new indications. These are plaque psoriasis and the juvenile idiopathic arthritis. Humira[®] is currently on PA. This criterion was added based on the package insert recommendation. • Lisa Todd stated an error was made while adding the criteria and asked everyone to add under "meeting all the following" the statement Psoriatic Arthritis or active Ankylosing Spondylitis. • Dr. Burke asked for Public Comment. • Mike Lafond, Abbott Labs Medicaid Account Manager, suggested adding Rheumatologist or Dermatologist under the first section since up to thirty percent of psoriasis patients develop psoriatic arthritis. This is in addition to adding the active Ankylosing Spondylitis in the place indicated. 	<ul style="list-style-type: none"> • Ms. Dowd motioned to accept the additions discussed to the PA criteria for Humira[®]. • Dr. Schewe seconded the motion.
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	<ul style="list-style-type: none"> The Board agreed with the addition of Rheumatologist or Dermatology may prescribe for active psoriatic arthritis to the PA criteria. 	<p>The motion carried with a unanimous vote from the Board.</p>
<p>VI. Adjourn to Executive Session</p>	<ul style="list-style-type: none"> Dr. Burke stated this concludes today's meeting. Dr. Burke asked for any final public comments for the board members. Dr. Burke stated the meeting was adjourned at 11:45 p.m. 	<ul style="list-style-type: none"> Dr. Schewe motioned for adjournment. Dr. Kevin Waite seconded the motion and all voted in favor.