

**Drug Utilization Review Board
Meeting Minutes
Open Session
May 14, 2008**

<p>DRUG UTILIZATION REVIEW BOARD</p> <p>Meeting Minutes, Open Session</p> <p>EDS/White Lakes Mall</p> <p>Wichita/Kansas City Room</p> <p>Topeka, Kansas</p> <p>May 14, 2008</p>	<p>Members Present: Brenda Schewe, M.D., Acting Chair; Roger Unruh, D.O.; Tom Wilcox, R.Ph.; Kevin Waite, PharmD; Judy McDaniel Dowd, PA-C; Dennis Grauer, Ph.D.</p> <p>KHPA Staff Present: Dr. Margaret Smith;</p> <p>EDS Staff Present: Deb Quintanilla, R.N.; Lisa Todd, R.Ph., Karen Kluczykowski, R.Ph.</p> <p>ACS Heritage Staff: Jerry Bowmer R.Ph.</p>	<p>Representatives: Ann Gustafson, GSK; Richard Mesquias, Eli Lilly; Jeff Knappen, Allergan Inc.; Phil King, Pfizer; Joe Summers, TAP; Colette Wunderlich, AstraZeneca; George Stamboulieh, Cephalon; Bruce Christian, Eli Lilly; Lon Lowrey, Novartis; Patty Laster, Genetech; Chris Golden, Merck; Matt Stafford, Merck; John Rysavy, Genetech; Don Larsen, Forest; James Baumann, Pfizer; William Dozier, Gilead; Susan Zalenski, Johnson and Johnson; Stephanie Miller, Amgen</p>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Schewe, Acting Chair, called the meeting to order at 10:08am	

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II. Announcements	<p>Lisa Todd requested members of the public sign the attendance form. She requested pharmaceutical representatives include their email address on the sign in sheet. She instructed them to 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, they must split the time limit between speakers.</p>	
III. Review and Approval of March 12, 2008 Meeting Minutes	<p>Dr. Unruh requested his first name be corrected on page two, column two of the minutes.</p> <p>Mrs. Dowd informed the Board she had contacted Lisa prior to the meeting about a correction to her title on page three, column three of the minutes. Lisa stated the correction had been made prior to the meeting.</p>	<p>Dr. Unruh made a motion to approve the minutes with the corrections previously mentioned.</p> <p>Mrs. Dowd seconded the motion and it carried by a unanimous vote.</p>
IV. Old Business A. Update: Report of Adjunct Anti-epileptics	<p>Lisa presented a report containing data regarding the adjunct anti-epileptic medications. She informed the Board the data in the "Amount Paid" column was incorrect and should be ignored. She reassured the Board the other columns were correct. Lisa offered to bring the correct amounts to the next meeting. Dr. Schewe stated the Board could address the issue without considering the paid amounts.</p> <p>Dr. Schewe reminded the Board the issue is whether to remove the diagnosis code requirement on gabapentin and pregabalin, place the requirement on all of the adjunct anti-</p>	

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	<p>epileptics, or keep the requirements as they are.</p> <table border="1" data-bbox="760 383 1335 756"> <thead> <tr> <th data-bbox="760 383 999 480">Medication</th> <th data-bbox="999 383 1199 480"># of Rx's</th> <th data-bbox="1199 383 1335 480"># of unique patients</th> </tr> </thead> <tbody> <tr> <td data-bbox="760 480 999 516">Gabapentin</td> <td data-bbox="999 480 1199 516">6870</td> <td data-bbox="1199 480 1335 516">1891</td> </tr> <tr> <td data-bbox="760 516 999 552">Levetiracetam</td> <td data-bbox="999 516 1199 552">2493</td> <td data-bbox="1199 516 1335 552">537</td> </tr> <tr> <td data-bbox="760 552 999 587">Lamotrigine</td> <td data-bbox="999 552 1199 587">8030</td> <td data-bbox="1199 552 1335 587">1760</td> </tr> <tr> <td data-bbox="760 587 999 623">Topiramate</td> <td data-bbox="999 587 1199 623">5303</td> <td data-bbox="1199 587 1335 623">1282</td> </tr> <tr> <td data-bbox="760 623 999 659">Tiagabine</td> <td data-bbox="999 623 1199 659">252</td> <td data-bbox="1199 623 1335 659">52</td> </tr> <tr> <td data-bbox="760 659 999 695">Zonisamide</td> <td data-bbox="999 659 1199 695">750</td> <td data-bbox="1199 659 1335 695">135</td> </tr> <tr> <td data-bbox="760 695 999 756">Total</td> <td data-bbox="999 695 1199 756">23698</td> <td data-bbox="1199 695 1335 756">5657</td> </tr> </tbody> </table> <p data-bbox="760 776 1335 867">Lisa reminded the Board that gabapentin and pregabalin are the only adjunct anti-epileptic medication that requires a diagnosis code.</p> <p data-bbox="760 922 1335 1369">Jim Baumann, Pfizer, stated his concern for the increase of the administrative burden placed on the providers when diagnosis codes are required. In addition to the prescribing provider's burden, the pharmacy provider may have to submit the claim multiple times to have the claim pay. He reminded the Board there is a cost to the pharmacy each time a claim is sent point of sale (POS), therefore submitting a claim multiple times increases the pharmacies' cost to dispense the prescriptions. Jim stated his concern for the potential disruption of therapy for patients that have been on medications long term if new diagnosis code limitations are placed on additional adjunct anti-epileptic medications.</p>	Medication	# of Rx's	# of unique patients	Gabapentin	6870	1891	Levetiracetam	2493	537	Lamotrigine	8030	1760	Topiramate	5303	1282	Tiagabine	252	52	Zonisamide	750	135	Total	23698	5657	
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	<p>Jim stated there are sixteen Food and Drug Administration (FDA) approved indications for this class of medications. He pointed out there is a large number of cooresponding ICD-9 codes that could be used for the approved indications. He is concerned with the large number of diagnosis codes the providers potentially have to use for prescribing these medications. He predicted this may be cumbersome and confusing for the providers and difficult for KHPA to manage.</p> <p>Jim stated diagnosis codes are not required for all of the adjunct anti-epileptic medications. The medications with a psychiatric indication cannot be restricted by diagnosis codes due to state statutes in place. He pointed out Lyrica[®] is indicated for adjunct treatment of partial-seizures and currently has diagnosis code limitations. Lamictal[®], Keppra[®], Trileptal[®] and Topamax[®] do not have diagnosis code limitations in place, but are indicated for adjunct treatment of partial-seizures also. Jim added physicians could prescribe Keppra[®], Trileptal[®], and Topamax[®] for the non-approved indication of fibromyalgia since there were no diagnosis code requirements on these agents. Jim states this sends an inconsistent message to physicians, pharmacists, and patients about the coverage regarding adjunct anti-epileptic therapy.</p> <p>Jim proposed all diagnosis requirements be removed from Lyrica[®] and gabapentin. He stated this will ensure the patients continued therapy</p>	

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	<p>and decrease the administrative costs to physicians, pharmacists, and KHPA.</p> <p>Mrs. Dowd requested in future that reports brought to the Board contain the brand and generic name of the medications. Lisa stated she would include both names on future reports.</p> <p>Mrs. Dowd referred to the Adjunct Anti-Epileptic Medication Report provided to the Board while inquiring about Lyrica[®]. Lisa stated Lyrica[®] was not on this report and reminded the Board Lyrica[®] has always been handled a little differently due to it is a controlled substance status. Lyrica[®] is a schedule five narcotic and the only controlled drug in this class of medications.</p> <p>Dr. Schewe inquired of the current restrictions on pregabalin. Karen Kluczykowski referred to the Pharmacy Provider Manual available on the KMAP website on pages 8-14 through 8-15, April 10, 2008 version.</p> <p style="text-align: center;"><i>Excerpt from the Pharmacy Provider Manual:</i></p> <p>Pregabalin (Lyrica[®]) An ICD-9-CM diagnosis code is required on all pregabalin (Lyrica[®]) claims. The pharmacy will need to contact the prescribing provider if no diagnosis is noted on the prescription. Pregabalin is only covered for the following conditions or diagnoses:</p> <ol style="list-style-type: none"> 1. Neuropathic pain: for a diagnosis indicating neuropathic pain, submit diagnosis 	

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	<p>code 3569</p> <p>2. Epilepsy: for a diagnosis of epilepsy, submit the most appropriate one of the following diagnosis codes (KMAP will accept 34500 for epilepsy diagnoses within the range of 34500 to 34591):</p> <p>3. Fibromyalgia: for a diagnosis of fibromyalgia, submit diagnosis code 7291</p> <p>8400. Updated 02/08 Pregabalin (Lyrica) continued</p> <p>In addition to the diagnosis requirement, pregabalin (Lyrica) is only covered for ages 18 and older. Dosage is not to exceed 600 mg per day or 18,600 mg in a 31-day period. The 600 mg per day limitation can be overridden by obtaining prior authorization if criteria has been met.</p> <p>Pregabalin (Lyrica) claims will be denied if the following units (capsules) per day are exceeded:</p> <ul style="list-style-type: none"> • 300 mg capsules: two units (capsules) per day • 225 mg capsules: two units (capsules) per day • 200 mg capsules: three units (capsules) per day • 150 mg capsules: three units (capsules) per day 	

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	<ul style="list-style-type: none"> • 100 mg capsules: three units (capsules) per day • 75 mg capsules: three units (capsules) per day • 50 mg capsules: three units (capsules) per day • 25 mg capsules: three units (capsules) per day • <p>Note: Prior authorization will not override the unit (capsule) limit per day.</p> <p>Karen referred to the current restrictions regarding Lyrica[®] listed in the Pharmacy Provider Manual. She added there are quantity restrictions and diagnosis code restrictions on Lyrica[®]. A PA is required when a provider prescribes Lyrica[®] at a dose above the recommended dose. Karen stated the quantity limitations regarding the number of tablets or capsules could not be exceeded, but the maximum dose per day can be exceeded through the PA process.</p> <p>Dr. Schewe wanted to clarify that all of the restrictions Karen mentioned pertain to Lyrica[®]. Karen verified she was referring to Lyrica[®] only.</p> <p>Dr. Schewe asked if any of the others medications in this class had any restrictions. Karen stated gabapentin does have a diagnosis code restriction but not a dose or quantity per day limit like Lyrica[®]. Gabapentin does not require a PA.</p>	

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	<p>Dr. Schewe is concerned that requiring the diagnosis codes on a select few agents, but not on the entire class may drive the prescribing to another agent that is not approved for the specific indication, which promotes off-label use. She speculated physicians may prescribe another agent to avoid the diagnosis code requirement.</p> <p>Dr. Grauer stated the decision should be to restrict all or none of the medications in the class. Dr. Waite agreed with Dr. Grauer. Dr. Waite suggested the Board removes the diagnosis restrictions and then revisit the data six months after the removal of the restrictions.</p> <p>Dr. Smith asked the Board if the controlled status of Lyrica® impacts the decision. Dr. Schewe suggested the PA remain in place for Lyrica®, but remove the diagnosis code restrictions.</p> <p>Dr. Grauer mentioned if the goal is to limit off-label use, then the data shows the current diagnosis restrictions do not achieve that goal.</p> <p>The Board discussion surrounded the idea of removing the diagnoses code restrictions and look at the prescription usage in six months. It was also mentioned that the only change to the Lyrica® restrictions would be the removal of the diagnosis code requirements. Therefore, the quantity and dose related PA would remain unchanged.</p>	<p>Dr. Waite made a motion to approve the removal of all diagnosis codes restrictions on the adjunct anti-epileptics while maintaining the current quantity and PA restrictions on Lyrica®.</p> <p>Dr. Grauer seconded the motion.</p> <p>The motion carried with a unanimous vote by the Board.</p>

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	<p>Karen asked the Board if they would want to review data concerning prescribing habits regarding dosing limits on all of the adjunct anti-epileptics. The Board agreed they would like to review that data.</p>	
<p>B. Update: New Threshold</p>	<p>Lisa informed the Board that the design of a new Threshold process for monitoring polypharmacy is currently underway. KHPA is working with Electronic Data Systems (EDS) to design an effective review process based on the new Threshold level set at the last DUR Board meeting. The Board set the new level at fifteen or more medications per month. Lisa announced the data will be presented to the Board at a future meeting.</p>	
<p>C. Update on Celebrex[®] usage</p>	<p>Lisa referred to a report containing claims data for Celebrex[®], Proton Pump Inhibitors (PPIs), and Non-Steroidal Anti-Inflammatory (NSAIDs) for years 2006 and 2007. These reports contained the number of unique patients, the number of paid claims, and the dollar amount paid. Lisa reminded the Board of a previous request to review the data one more time since Celebrex[®] had been taken off PA. The PA requirement was removed from Celebrex[®] in May of 2006. The Board</p>	

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	<p>had approved the removal of the PA requirement because there had been a ninety-five percent approval rate for Celebrex[®] PA requests in 2005. The Board had reviewed the June – December 2006 data at a previous meeting and had determined Celebrex[®] should remain off of PA because there was not much change in the data. The Board then asked to review the 2007 data at a future 2008 meeting.</p> <p>The Board reviewed the reports. The discussion revolved around there had not been a significant change in claims data since the removal of the PA requirement on Celebrex[®].</p>	<p>The Board decided not to make any changes regarding Celebrex[®] coverage.</p>

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<p>V. New Business</p> <p>A. OTC Cough/Cold Medications</p> <ol style="list-style-type: none"> 1. Addition of new age limitations 2. FDA recommendation – not safe or effective in children 2 years of age or younger <p>B. Public comment*</p> <p>DUR Board Discussion / Recommendation</p>	<p>Lisa stated the FDA recommends limiting use of over-the-counter cough and cold products for patients under two years of age. They determined the treatment with these products may cause serious and potentially life-threatening side effects. The FDA is currently reviewing the use of the cough and cold medication in children ages two to eleven years, but has not made a decision.</p> <p>Dr. Schewe mentioned these products were only covered for Kansas Medical Assistance Program(KMAP) patients if they were in the Kan Be Healthy(KBH) program. Lisa verified these medications are restricted to KBH patients ages zero to twenty years old. Karen reminded the Board that there is an age restriction on promethazine. Currently, patients under the age of two years cannot receive a promethazine containing product.</p> <p>Dr. Grauer wanted to clarify the age restriction recommended by the FDA. He wanted to verify whether the restriction included or excluded two year olds patients. Lisa referred to the FDA Recommendation dated January 17, 2008. The FDA refers to children less than two should not receive these medications.</p> <p>No public comment</p>	<p>Mrs. Dowd made a motion to adopt the FDA recommendation of restriction the use of OTC cough and cold medications to children two years of age and older.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion carried by unanimous vote.</p>

<ul style="list-style-type: none"> • DUR Board Discussion / Recommendation 	<p>regardless of PDL status that require a specific PA for access.</p> <p>The Board fielded a question from the general public regarding how the PDL status effects the five name brand limitation. Karen stated if a product is considered a single source product it will count against the five branded medications per month. If a medication has a "Preferred" status, then it is exempt from the five name brand medication per month limit.</p>	
<p>D. Drugs for Osteoporosis – Bisphosphonates</p> <ul style="list-style-type: none"> • Boniva® • Public Comment • DUR Board Discussion / Recommendation 	<p>Ann Gustafson, Glaxo Smith Kline, stated this class of medications was on the agenda for the PDL committee meeting to be held in December 2007. They had prepared to have someone present to provide clinical information regarding Boniva® at the meeting, but it was cancelled. They did not have enough time to arrange for a clinical presentation today, therefore are requesting this issue be tabled until next meeting.</p> <p>Dr. Schewe asked if this drug has ever been discussed at a PDL meeting. Dr. Smith verified it had been discussed.</p> <p>Ms. Gustafson stated the cancelled December 2007 PDL was to re-review this drug class. Dr. Schewe said the reason the meeting was cancelled was there was no new data since the class had been reviewed previously.</p> <p>Dr. Schewe asked Dr. Smith if the status' on the PDL are re-evaluated every year. Dr. Smith said the length of the contract drives the review process. Some contracts are for a</p>	

	<p>longer period of time.</p> <p>Dr. Waite asked if the new formulation of Actonel[®] would fall under the current PDL status of Actonel[®]. Dr. Smith verified the new form would fall under the current PDL status of Actonel[®].</p> <p>Dr. Grauer asked if KHPA requires pharmacists to dispense the generic. Karen stated KHPA cannot require the pharmacist to dispense generic medications, but it is strongly encouraged. She explained the reimbursement of Average Wholesale Price (AWP) – 27% for multi-source products as opposed to AWP - 13% for the brand name medications encourages dispensing of generics.</p>	<p>Dr. Waite made the motion to approve the PDL status change for Boniva[®] from “Non-Preferred status” to “Non-Preferred/Prior Authorization Required status”.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The motion carried by unanimous vote by the Board.</p>
<p>E. Urinary Incontinence Drugs – Anticholinergics</p> <ul style="list-style-type: none"> • Enablex[®] • Public Comment • DUR Board Discussion / Recommendation 	<p>Lon Lowrey, Novartis State Government Affairs, stated they had inadvertently let the contract expire and apologized for letting this issue get this far. He stated their intention is to renew the contract. He has already been in contact with Dr. Smith to negotiate a new contract. He requested a delay in the PDL status change until next meeting to allow the new contract to be put in place.</p> <p>Dr. Smith verified he had contacted her about the renewal of the contract. She recommended the issue be deferred.</p>	<p>Ms. Dowd made the motion to table the issue of the proposed change in PDL status change for Enablex[®] from “Non-Preferred status” to “Non-Preferred/Prior Authorization Required status” until the next DUR meeting.</p> <p>Dr. Grauer seconded the motion.</p> <p>The motion carried by unanimous vote by the Board.</p>

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<p>F. Cimzia®</p> <ul style="list-style-type: none"> • Proposed PA Criteria • Treatment of Crohn's Disease 	<p>Dr. Schewe stated Cimzia® is a tumor necrosis factor blocker.</p> <p>Lisa stated Cimzia® is indicated for use in patients eighteen years or older who have Crohn's disease. The other medications in this class currently require PA. Karen stated the PA criteria is similar to the other medications in this class such as, Humira® and Remicade®. The PA criteria was also based on the manufacturer's package insert.</p> <p>Karen mentioned there is not a HCPCS currently assigned to this medication to be used for billing professional claims. She mentioned other biologicals such as Humira® and Remicade® require PA for pharmacy and professional claims. This request to require a PA is for the NDCs and the HCPCS code when it becomes available.</p> <p><u>Proposed PA CRITERIA for Cimzia®:</u></p> <p>Criteria for Crohn's Disease</p> <p>Must meet all of the following:</p> <ul style="list-style-type: none"> • Diagnosis of moderate to severe, active Crohn's Disease <p>AND</p>	

<p>G. Public comment*</p> <p>H. DUR Board Discussion / Recommendation</p>	<ul style="list-style-type: none"> • Patient must be 18 years of age or older <p>AND</p> <ul style="list-style-type: none"> • Documentation of inadequate response to conventional therapies. Conventional therapy for Crohn's Disease would include the following drugs: 5-ASA (Mesalamine and Rowasa), Sulfasalazine, Corticosteroids (prednisone, etc.), and Budesonide (Entocort EC) <p>AND</p> <ul style="list-style-type: none"> • Prescribed by a gastroenterologist • Evaluation for latent tuberculosis infection with TB skin test <p><u>NOTE:</u> This drug carries a Black Box Warning: Increased incidence of serious infections</p> <p>Prior Authorization will be approved for six (6) months.</p> <p>No public comment</p> <p>Dr. Waite referred to the prescribing provider restriction in the proposed PA</p>	
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	<p>criteria when he asked if any other medications in this class have PA criteria allowing a rheumatologist to prescribe the medication. He asked the Board if a patient would always go to a gastroenterologist to treat Crohn's disease. The Board agreed the patient should be under the care of a gastroenterologist for Crohn's disease.</p> <p>Dr. Unruh asked for the monthly cost to KHPA for this medication. Karen stated we did not have specific amounts. She reassured the Board the medication is expensive, but in line with the other medications in it's class.</p> <p>Dr. Unruh inquired how many patients this would effect. Karen stated there was no way to predict. She stated a report could be run on patients with Crohn's diagnoses to see what agents they are on.</p> <p>Dr. Waite said at the hospital they have already looked at the medication. They determined it would primarily be used in patients that have only had a partial response to the other monoclonals. In regard to pricing, there does not seem to be any economic advantage to use this agent over the others.</p>	<p>Mrs. Dowd made a motion to adopt the PA criteria for Cimzia[®] and to require a PA for the HCPCS code when it becomes available.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion carried by unanimous vote by the Board.</p>
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<p>C. ACS Heritage Update</p>	<p>Jerry Bowmer stated the interventions selected by the Board at the last meeting are underway. Heart Failure , osteoporosis, and diabetes are the three currently being reviewed. The letters will be mailed as soon as editing is complete. He mentioned the newsletters about inhalers and the program assessment are being sent out. He stated there is one newsletter topic left to fulfill this year's requirement. He stated a topic needed to be decided regarding the remaining thirty academic detail visits.</p> <p>Lisa suggested osteoporosis as a topic for the last newsletter to correspond with the intervention.</p> <p>Dr. Schewe inquired as to how many academic detailing visits are conducted on a yearly basis. Jerry stated a total of sixty per year. Thirty were conducted in March of 2008 on patients identified in the previous hypertension intervention.</p> <p>Jerry suggested diabetes as the topic for academic detailing which would correlate with the diabetic intervention currently being conducted. Dr. Schewe asked for some examples of issues he would detail. Jerry gave an example of visiting physicians that have not ordered an A1C in the past six months for their diabetic patients. Dr. Schewe asked if all academic detailing visits are based on interventions. Jerry said they do not have to be.</p> <p>Dr. Schewe opened the floor to the public for any further comments or questions.</p>	<p>Dr. Schewe requested the newsletter be brought to the next meeting for review.</p>
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	<p>Jim Baumann asked for the effective date on the removal of the ICD-9 codes. Dr. Smith stated the effective date is not known yet. An email will be sent to Mr. Baumann when it is known.</p>	<p>The Board decided the remaining thirty academic detailing visits to be based on the diabetic intervention data.</p>
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VII. Adjourn to Executive Session	<p>Dr. Schewe announced the meeting is adjourned.</p> <p>Lisa announced the next DUR meeting is July 9th, 2008 and the next PDL meeting is June 4th, 2008.</p>	<p>Dr. Waite made a motion for adjournment of the meeting.</p> <p>Dr. Grauer seconded the motion. The motion carried by a unanimous vote by the Board.</p>