

Drug Utilization Review Board

Meeting Minutes

Open Session

July 9, 2008

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session
EDS/White Lakes Mall
Wichita/Kansas City Room
Topeka, Kansas
July 9, 2008

Members Present:

Michael Burke, M.D., Chair
Brenda Schewe, M.D.
Roger Unruh, D.O.
Tom Wilcox, R.Ph.
Kevin Waite, PharmD
Judy McDaniel Dowd, PA-C
Dennis Grauer, Ph.D.

KHPA Staff Present: Dr. Margaret Smith;

EDS Staff Present:

Deb Quintanilla, R.N.
Lisa Todd, R.Ph.
Karen Kluczykowski, R.Ph..

ACS Heritage Staff:

Jerry Bowmer R.Ph.

Representatives:

Dave Croft, Bristo-Myers
James Lierurance, Endo Pharmaceuticals
Don Larsen, Forest
Mike Lafond, Abbott
Doug Brown, Sepracor
Ann Gustafson, GSK
Jim Baumann, Pfizer
Barbara Lussenhop, Roche
Lon Lowrey, Novartis
Perry Johnosn, Graceway
Dave Walters, Centocor Ortho Biotech
Susan Zalenski, Johnson and Johnson
Carol Curtis, Astra Zeneca
Matthew Stafford, Merck
Barbara Belcher, Merck

TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Burke called the meeting to order at 10:05am	
II. Announcements	<p>Dr. Margaret Smith announced Kevin Kentfield's resignation from the DUR Board. She stated the long term care pharmacist position would need to be filled. Referrals may be forwarded to her.</p> <p>LeAnn Bell, PharmD, is the new Pharmacy Program Manager. Her first day will be July 21st, 2008.</p> <p>Lisa Todd reminded the Board that EDS will be in the process of moving to a new location in September. She stated the September 10, 2008 DUR Board meeting will be held at the same White Lakes Center EDS location.</p> <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 May 14, 2008 Meeting Minutes	Dr. Burke reviewed the Preferred Drug List medication status' and made the appropriate corrections to clarify the minutes.	<p>Dr. Schewe made a motion to approve the minutes with the corrections previously mentioned.</p> <p>Mrs. Dowd seconded the motion and it carried</p>

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		<p>by a unanimous vote.</p> <p>Dr. Schewe suggested the title on the Prior Authorization Form be changed.</p>
<p>IV. Old Business</p> <p> A. ACS Heritage: Osteoporosis Newsletter</p>	<p>Jerry Bowmer presented a draft copy of the Osteoporosis Newsletter to the members of the Board.</p> <p>The Board had an extensive discussion surrounding the layout and content of the newsletter. The Board favored having the information presented in bullet format. They requested the opening paragraph contain Kansas specific data. Present the facts from the chart in bullet fashion. Risks and prevention should be the focus of the newsletter. Dr. Schewe suggested issues to be addressed should be checking vitamin D levels and the risk associated with use for more than five years.</p>	<p>The Board decided to have Ms. Todd make the desired changes to the newsletter and send the edited version to the Board members for editing and approval.</p>
<p>V. New Business</p> <p> A. Update Tumor Necrosis Factor PA Criteria</p> <p> 1. Addition of “18 years of age or older” age limitation where appropriate</p>	<p>Dr. Burke referred to the current PA criteria for the tumor necrosis factor medications. There is no age restriction currently in place for these medications with the exception of Humira for juvenile idiopathic arthritis (JIA).</p> <ol style="list-style-type: none"> 1. Cimzia® 2. Humira® 3. Orencia® 4. Remicade® 5. Enbrel® 	

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	<p>Orencia has recently been approved for the use in the treatment of JIA for patients six years of age and older.</p> <p>Dr. Beal, PharmD; representing Orencia[®], stated this medication has been approved by the FDA for use in the treatment of pediatric moderate to severe polyarticular arthritis in patients six years of age or older. He pointed out there was an additional change to the package insert for Orencia[®] regarding the adult indication of rheumatoid arthritis. Previously the labeling indicated a patient must have an inadequate response to methotrexate or TNF antagonists. This recommendation has been removed and now can be used regardless of past therapy. It can be used as monotherapy or in conjunction with methotrexate.</p> <p>Dr. Burke referred to change in the package insert of Orencia[®]. He confirmed the old package insert stated Orencia[®] should be used in patients with an inadequate response to methotrexate or a TNF antagonist. Dr. Beal explained studies were conducted on patients that had an inadequate response to methotrexate or a TNF antagonist. Post marketing data from the open label trial was presented to the FDA. The long term safety data was consistent with the data from the double-blind studies in Orencia[®]. The FDA removed the recommendation of requiring methotrexate or a TNF antagonist therapy</p>	

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	<p>prior to Orencia[®] therapy.</p> <p>Dr. Smith asked if this was the same for JIA. Dr. Beal stated The AWAKEN Trial studied juvenile patients that had different sub-types of JIA. The results of The AWAKEN trial were presented to the FDA and this granted the label change regarding JIA.</p> <p>Dr. Grauer inquired if there are any studies comparing Orencia[®] to methotrexate used as initial therapy. There were some trials involving Orencia[®] as monotherapy. These trails convinced the FDA to allow Orencia[®] to be used as a single agent. Most of the trials are based on the addition of an agent to methotrexate. Dr. Beal stated methotrexate is considered the gold standard of treatment and therefore most trials are based on add-on therapy of the TNF medications. He mentioned Enbrel had conducted a study that shown clearly the superiority in result of the combination therapy of methotrexate and a TNF medication.</p> <p>Dr. David Walters, RPh., Johnson and Johnson, mentioned Remicade[®] had received approval for the treatment pediatric Crohn's disease on May 19, 2006. This is based on age groups from six years of age to seventeen years of age. The other indications for Remicade[®] do not have a pediatric indication.</p> <p>Dr. Schewe asked for clarification on the</p>	

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	<p>Crohn's disease treatment. Dr. Walters stated the package insert reads "Ages six to seventeen with moderate to severe Crohn's disease who have responded well to other therapies."</p> <p>Dr. Schewe noted that several of the TNF medication package inserts state the individual medications are approved for monotherapy. Dr. Walters stated Remicade® is not approved for monotherapy.</p> <p>Dr. Burke reminded the Board the original purpose was to update the age limitations on the existing PA criterion for all of the TNF medications to eighteen years of age or older.</p> <p>Exceptions:</p> <ul style="list-style-type: none"> • Orenzia indicated for JIA in patients six years of age and older. • Remicade® indicated for Crohn's disease in patients six years of age or older. <p>Dr. Burke informed the Board that each medication would be addressed individually.</p> <ol style="list-style-type: none"> 1. Cimzia® <p>Add eighteen years of age or older restriction to the existing PA criteria.</p>	<p>Dr. Grauer made a motion to approve the addition of the eighteen years of age or older restriction to the existing PA criteria for Cimzia®.</p> <p>Dr. Schewe seconded the motion.</p> <p>The motion carried by a unanimous vote by the DUR Board.</p>

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	<p>2. Humira®</p> <p>Add eighteen years of age or older restriction to the existing PA criteria. The age restriction already in place for JIA will remain the same.</p> <p>3. Enbrel®</p> <p>Add eighteen years of age or older restriction to the existing PA criteria.</p> <p>4. Orenzia®</p> <p>Dr. Grauer suggested the layout of the PA criteria be changed since there is a new addition to the indications. Ms. Dowd stated the age restrictions should be listed with each individual indication separately. Dr. Smith suggested use the Humira® criteria layout as a template.</p> <p>There was discussion concerning all of the TNF medications and the use of these agents as monotherapy or in conjunction with other medications. The second bullet on the current Orenzia® PA criteria was referred to for this discussion. The updated package inserts do not require documentation of inadequate response to DMARDs for RA.</p> <p>It was decided to update indications today, but conduct research on the DMARD requirement for all of the indications of this</p>	<p>Dr. Schewe made a motion to approve the addition of the eighteen years of age or older restriction to all of the indications listed in the existing PA criteria for Humira except for JIA.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion carried by a unanimous vote by the Board.</p> <p>Dr. Schewe made a motion to approve the addition of the eighteen years of age or older restriction to the existing PA criteria for Enbrel®.</p> <p>Dr. Waite seconded the motion.</p> <p>The motion carried by a unanimous vote by the DUR Board.</p>

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	<p>meeting.</p> <p>RA criteria will remain the same. JIA will be added as a separate indication with an age restriction and a weight restriction. Patients six years of age or older may be treated with Orencia® for JIA. The weight restriction will be limited to 75kg.</p> <p>5. Remicade®</p> <p>Discussion held around the addition of the age restriction of six years of age and older for the treatment of Crohn's disease. There was concern the package insert was not clear on this age. Verification in another document will be required.</p>	<p>Dr. Grauer made a motion to have each indication listed separately with the appropriate age restriction regarding the Orencia® PA criteria.</p> <p>Dr. Schewe seconded the motion.</p> <p>All of the Board members voted in favor and the motion passed.</p> <p>It was decided to bring back the issue regarding the requirements of the package inserts for the different indication requirements of the documentation of inadequate response.</p> <p>Dr. Schewe made the motion to separate indications and to add the age limitation of six years of age or older be placed in the Remicade® PA criteria for Crohn's disease barring the verification of this age in another document.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion carried by a unanimous vote by the Board.</p>
<p>B. Updates to Regranex® limitations regarding FDA warning</p> <p>1. Proposed PA criteria</p>	<p>Ms. Todd stated Regranex is a recombinant human platelet-derived growth factor (rhPDGF-BB) topical gel used to treat diabetic ulcers on the lower extremities. This medication is currently requires a PA.</p>	

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	<p>The FDA issued the following warning; An increased rate of mortality secondary to malignancy was observed in patients treated with three or more tubes of Regranex[®] gel in a post-marketing retrospective cohort study. Regranex[®] gel should only be used when the benefits can be expected to outweigh the risks. Regranex[®] should be used with caution in patients with known malignancy.</p> <p>The following additions to the PA criteria were proposed;</p> <ul style="list-style-type: none"> • Limit treatment to lower extremity diabetic neuropathic ulcers • Patient must be 16 years of age or older • Patient must not have neoplasms at the site of application <p>Ms. Quintanilla stated the current PA criterion does allow the patient up to a maximum of 3 tubes of Regranex[®] or 12 weeks duration with each request.</p> <p>Ms. Todd stated a “hard” edit in the computer system is recommended to match the current PA criteria. Dr. Schewe inquired if this edit would be for a lifetime. Ms. Kluczykowski stated the edit could be set up as desired.</p> <p>Ms. Quintanilla stated there were four requests for Regranex[®] in 2008, but only one was approved. The number of requests for this medication has decreased tremendously since 2006 due to many patients were covered by Medicare D. In 2005, prior to Medicare D, the PA</p>	

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	<p>unit received 41 requests for Regranex[®]. Most of these requests were for the elderly population residing in nursing homes. In 2006, the number of requests decreases to eleven. Seven of those requests were denied because they did not meet the PA criteria.</p> <p>There was discussion around the issue of three tubes in a lifetime use. Dr. Burke expressed his concern of the treatment of two separate ulcers with three tubes each and the increased exposure to the patient. Dr. Schewe stated she would encourage a lifetime edit because patients may see multiple physicians for treatment during their lifetime. Dr. Smith also noted the lifetime limit of three tubes still puts the patient at risk according to the FDA warning.</p> <p>Dr. Waite suggested an educational piece be added to the PA form, such as the black box warning. Dr. Burke referenced to the “patient and/or caregiver have been instructed on the appropriate application, storage, and cost of Regranex” bullet on the current PA criteria when asking how the patient or caregiver is instructed. Ms. Quintanilla stated a nurse’s or progress note documenting the patient/caregiver have received instructions.</p> <p>Dr. Burke reviewed the proposed changes to “draft 1” of the Regranex[®] PA criteria. The Board agreed with all of the highlighted changes. The educational bullet should be changed to “patient and/or caregiver have been instructed on the appropriate application, storage, costs, and risks of Regranex[®].” The black box warning should be</p>	

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<p>C. PA Criteria for renewal PA</p> <ol style="list-style-type: none"> 1. Symlin 2. Byetta 	<p>inserted after this bullet. Under approval duration there should be up to a lifetime maximum of three tubes.</p> <p>Dr. Burke requested the Regranex[®] PA form be updated to include the FDA black box warning. Additionally, a “hard” edit be put in place to enforce the lifetime limitation in the computer system.</p> <p><u>Symlin and Byetta</u></p> <p>Dr. Burke recommended the Board review these PAs together. The issue is to clarify renewal criteria for Symlin and Byetta. Ms. Quintanilla explained the clarification of the renewal criteria surrounds the issue of the HbA1c levels. The initial PA criteria states a patient must have HbA1c ≤ 9%. The initial PA is approved for a six month time period. The current renewal criteria states approvals will be based on documented improvement to postprandial glycemic control.</p> <p>The current renewal criteria states the HbA1c has to decrease. This value cannot be zero. Currently, the KHPA Pharmacy Program manager must approve the renewal in this situation.</p> <p>The proposed renewal criteria states the HbA1c must be lower than the pretreatment levels or achievement of therapy goals.</p> <p>Dr. Grauer inquired to the differing initial HbA1c levels for Symlin and Byetta. Ms. Quintanilla</p>	<p>Dr. Schewe made the motion to all of changes made to the Regranex[®] PA criteria.</p> <p>Dr. Waite seconded the motion.</p> <p>The motion carried by a unanimous vote by the Board.</p>

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	<p>stated the current PA criteria are from the medications' package inserts.</p> <p>Ms. Dowd inquired as to the type of documentation required regarding glycemic control. Ms. Quintanilla stated they rely on verification from the provider.</p> <p>The Board had an extensive discussion around the renewal criteria. It was decided to remove the last two paragraphs on the proposed PA criteria for Symmlin and Byetta.</p> <p>The following statement will replace the deleted paragraphs;</p> <p>"Renewals will be approved based on documented improvement of glycemic control (HbA1c lowering from pretreatment levels) and/or achievement of therapeutic goals (e.g. Improvement of postprandial glycemic control) and lack of severe hypoglycemic episodes.</p>	<p>Ms. Dowd made a motion to except all of the changes to the PA criteria for Symmlin and Byetta as discussed by the Board.</p> <p>Dr. Waite seconded the motion.</p> <p>The motion passed with a unanimous vote by the Board.</p>

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<p>D. ACS Heritage presentation of possible intervention proposals</p>	<p>Mr. Bowmer stated he would present four potential interventions.</p> <ol style="list-style-type: none"> 1. Anticonvulsants <ol style="list-style-type: none"> a. 5,400 opportunities 2. Cerebral Palsy <ol style="list-style-type: none"> a. 691 opportunities 3. Cardiovascular disease(CVD) in women <ol style="list-style-type: none"> a. > 15,000 opportunities 4. Insomnia <ol style="list-style-type: none"> a. > 3,200 opportunities <p>Mr. Bowmer added Cerebral Palsy has never been selected before and the others have not been reviewed since 2003.</p> <p style="text-align: center;"><u>Anticonvulsants</u></p> <p>The purpose of this intervention is to ensure safe and effective use of anticonvulsants by identifying approved indications, common off label uses, and potential risks for adverse drug events (ADE).</p> <p>Anticonvulsants are the fourth highest prescribed drug class for KMAP patients.</p> <p>Focus:</p> <p><i>Drug/drug interaction</i></p> <p><i>Increased ADEs</i></p>	

	<p><i>Off label use</i></p> <p><i>Toxicities</i></p> <p><i>Contraindications</i></p> <p style="text-align: center;"><u>Cerebral Palsy</u></p> <p>The purpose of this intervention is the safe and effective use of antisecretory, anticonvulsant, and osteoporosis agents in the management of disorders secondary to cerebral palsy.</p> <p>There are 1,591 KMAP patients with a cerebral palsy diagnosis.</p> <p>Focus:</p> <p><i>Drug/drug interactions</i></p> <p><i>Increase ADE from medications aggravating GERD</i></p> <p><i>Off label use</i></p> <p><i>Toxicities</i></p> <p><i>Contraindication</i></p> <p><i>Underutilization of medications</i></p> <p><i>Inappropriate use of osteoporosis agents</i></p> <p style="text-align: center;"><u>Cardiovascular Disease (CVD) in Women</u></p> <p>The purpose of this intervention is to identify opportunities that improve cardiovascular related therapy in women where CVD is the largest cause of death.</p> <p>Focus:</p> <p><i>Underutilization of:</i></p>	
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	<ul style="list-style-type: none"> • beta blockers • angiotensin modulation therapy • beta blockers in systolic heart failure • aldosterone in heart failure • aspirin in high risk patients • thiazide diurectics in hypertensive patients • lipid lowering therapy • angiotension modulating therapy in diabetes <p><i>Discontinuation or non-compliance of:</i></p> <ul style="list-style-type: none"> • Antihypertensive medications • Antidiabetic medications • Antilipidemic medications • Antiplatelet medications <p><i>Long term use of estrogen replacement therapy</i></p> <p><i>Estrogen use following MI or stroke</i></p> <p><i>Underutilization of</i></p> <ul style="list-style-type: none"> • Antihypertensive medications • Antidiabetic medications • Antilipidemic medications • Antiplatelet medications <p>In metabolic syndrome.</p>	
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	<p style="text-align: center;"><u>Insomnia</u></p> <p>The purpose of this intervention is to increase physician awareness of pharmacological and nonpharmacological treatment options for insomnia.</p> <p>The use of sedative hypnotics serves as first line therapy very effectively. These medications carry risks of side effects, tolerance, and dependence. Nonpharmacological interventions can be effective, safe, and provide improvements.</p> <p>Focus:</p> <p><i>Extended duration of therapy</i></p> <p><i>Excessive dosage</i></p> <p><i>Duplicate therapy</i></p> <p><i>Drug/drug interaction</i></p> <p><i>Drug/disease interaction</i></p> <p>Dr. Burke reminded the Board that four interventions should be selected each Fiscal year. The ideal situation is select one or two interventions today</p> <p>Dr. Waite suggested the Anticonvulsant intervention remarking it presented a lot of opportunities.</p> <p>Dr. Grauer expressed interest in the CVD in Women intervention.</p> <p>There was extensive discussion around the intervention options.</p>	<p>Dr. Unruh made the motion to select the Anticonvulsant and CVD in Women interventions for the current Fiscal year.</p> <p>Dr. Grauer seconded the motion.</p> <p>The motion carried by a unanimous vote by the Board</p>
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VI. Adjourn to Executive Session	<p>Dr. Burke announced the meeting was adjourned.</p> <p>Lisa announced the next DUR meeting is September 10, 2008. and will be held at the same location.</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>