

**Drug Utilization Review Board
Meeting Minutes, Open Session
November 12, 2008**

<p>Drug Utilization Review Board Meeting Minutes, Open Session EDS / Forbes Field Capital / Cedar Crest Room Topeka, KS November 12, 2008</p>	<p>Members Present: Michael Burke, M.D.Ph.D., Chair Dennis Grauer Ph.D. Judy McDaniel-Dowd, PA-C Brenda Schewe, M.D. Daniel Sutherland, R.Ph. Roger Unruh, D.O. Kevin Waite, Pharm.D. KHPA Staff Present: LeAnn Bell, Pharm.D. Aimee Grubb Shelly Liby EDS Staff Present: Karen Kluczykowski, R.Ph. Deb Quintanilla, R.N. Lisa Todd, R.Ph.</p>	<p>Representatives: Michael Lanford, Abbott Gianna Riconi, Abbott Charles Dahm, Amgen Stephanie Miller, Amgen Terri Hurley, AstraZeneca Robert Auerbach, CVT Richard Mesquias, Eli Lilly Dave Walters, Johnson & Johnson Barbara Belcher, Merck Matthew Stafford, Merck Joe Summers, Takeda Kate Kwlesner, Wyeth</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Michael Burke, Chair called the meeting to order at 10:05 a.m.	
II. Announcements	<p>LeAnn Bell introduced Aimee Grubb as the new Administrative Specialist for the Pharmacy Program and Dr. Smith. She also introduced Daniel Sutherland, R.Ph., as our new Board member. He is a pharmacist in St. Mary's.</p> <p>Lisa Todd stated all meeting attendees need to stop in the lobby to sign in and out. She asked that the up front parking spaces be reserved for the Board members and asked that the public park in the back parking lot. She asked the public to fill out the conflict of interest forms if they wanted to speak to the board, and she stated there is a limit of five minutes per drug.</p>	
III. Review and Approval of September 10, 2008 Minutes	No changes to the minutes.	<p>Judy McDaniel-Dowd moved that we accept the minutes.</p> <p>Dr. Roger Unruh seconded the motion and it carried by a unanimous vote.</p>

<p>IV. Old Business</p> <p>A. Tumor Necrosis Factor Medications</p> <p>1. Update DMARD requirements on PA criteria</p> <ol style="list-style-type: none"> a) Cimzia® b) Humira® c) Orencia® d) Remicade® e) Enbrel® <p>B. State Fiscal Year 2008 Drug Expenditure Overview</p>	<p><u>TNF Medications</u></p> <p>Dr. Burke reminded the Board of their previous discussion regarding the Tumor Necrosis Factors (TNF) and there were a number of somewhat dynamic changes related to indications and ages. Lisa Todd put TNF data in a table; it is up-to-date as of September 10, 2008. The terminology used in the table was defined. Reference was made to the table as the individual TNF agents were reviewed to update the PA requirements.</p> <p>Dr. Burke stated the latest package inserts and edited version of the PA criteria for the TNF agents were included in the packets.</p> <p>Dr. Burke asked Ms. Todd to comment on the PA criteria for the TNF agents. She stated she used all of the existing PA criteria and updated it according to the current data found in the package inserts. It is stated on the PA criteria under 'NOTE' if the agent can be used as monotherapy or 1st line without regard to Methotrexate and DMARD therapy.</p> <p>Dr. Burke stated prior to the meeting a note regarding serious adverse affects was added to the criteria. Corrections will be made to those.</p> <p><i>Cimzia</i>[®]</p> <p>No public comment.</p> <p>Dr. Burke stated the note 'Increased incidence of serious infections' should be changed to say, 'Increased incidence of opportunistic infections and tuberculosis'.</p> <p><i>Humira</i>[®]</p> <p>Dr. Burke stated the changes in the PA criteria are all consistent with the current package insert with one exception under the safety notation, 'Increased incidences of serious infection and lymphomas'. Lymphomas are not listed. He suggested the notation be changed to say, 'Increased</p>	<p>Dr. Kevin Waite moved to approve the Cimzia® PA criteria with changes discussed.</p> <p>Dr. Dennis Grauer seconded the motion and it carried by a unanimous vote.</p>
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incidence of opportunistic infections and tuberculosis’.

Gianna Riconi, Abbott Laboratories, stated that lymphoma is not in their Black Box warning, but it is a warning across all TNFs.

She stated for their Juvenile Idiopathic Arthritis (JIA) indication there is a weight based restriction; however, that restriction is not in the label. There is not enough data to support the use in children less than 15 kg. When you observe another product’s package insert for JIA, there is a restriction for children that weigh less than 31 kg. If there is a restriction based upon weight for Humira[®], she asked to have the same restriction added to the PA criteria for the other product or to have the weight restriction removed from the PA criteria for Humira[®].

Ms. Riconi stated that on the grid for the plaque psoriasis indication, Humira[®] is 2nd line, but there are some studies that say it can be used as 1st line or combination therapy. The label states, ‘when conventional therapies are medically less appropriate’.

Dr. Burke stated on page four of the package insert there are guidelines for dosing starting at 15 kg to less than 30 kg, and it states limited data is available for less than 15 kg. But it does not say use is restricted. Ms. Riconi stated in the other product, it specifically say ‘restricted’.

Dr. Burke stated although there isn’t any data that addresses less than 15 kg body weight, we have required the prescription to be written by a Rheumatologist who would have particular knowledge of JIA and these medications.

Dr. Unruh stated JIA usually occurs after the weight/age restrictions.

Dr. Unruh said he would be in favor of striking the weight restriction bullet.

Dr. Brenda Schewe moved to approve the Humira[®] PA criteria with the changes to the Black Box Warning and weight restrictions under JIA.

Ms. Dowd seconded and it carried with a unanimous vote.

	<p><i>Orencia</i>[®]</p> <p>No public comment.</p> <p>Dr. Burke stated this medication does not have a Black Box Warning. He suggested a change to the warning from, 'Increased risk of serious infections and malignancies' to 'May have increased risk of serious infection'.</p> <p><i>Remicade</i>[®]</p> <p>No public comment.</p> <p>Ms. Todd stated under 'Rheumatoid Arthritis' (RA) the bullet 'Given in combination with methotrexate' was added because it is a specific guideline.</p> <p>Dr. Grauer stated that under notes Psoriatic is spelled wrong.</p> <p>Dr. Burke stated that under warnings, the Black Box would be added.</p> <p><i>Enbrel</i>[®]</p> <p>Charles Dahm, Amgen, commented the PA criteria under RA states two or more NSAIDs should be used for Ankylosing Spondylitis. He said that is the consensus guidelines, but it isn't included in the PA criteria for the other TNFs. He also stated the dosing for Enbrel[®] does not preclude use in children less than 31 kg. It states the pre-filled syringe may not be used; we have a multidose vial that may be used in children less than 31 kg.</p> <p>Dr. Burke stated under the note 'lymphoma' should be crossed out and 'Tuberculosis' should be put in its place.</p> <p>A proposed change was to change the bullet under RA, 'Be prescribed by a Rheumatologist or Dermatologist' to state, 'Be prescribed by a Rheumatologist'.</p>	<p>Dr. Schewe moved that we accept the Orencia[®] PA criteria with changes discussed.</p> <p>Dr. Grauer seconded it and it carried with a unanimous vote.</p> <p>Dr. Schewe moved to accept the Remicade[®] PA criteria with changes discussed.</p> <p>Ms. Dowd seconded it and it carried with a unanimous vote.</p> <p>Ms. Dowd moved to accept the Enbrel[®] PA criteria with changes discussed.</p> <p>Dr. Grauer seconded and it carried with a unanimous vote.</p>
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SFY 2008 Drug Expenditure Overview

Karen Kluczykowski presented the (KMAP) Drug Expenditure Report for State Fiscal Year 2008. She stated this report shows the beneficiaries eligible for fee-for-service payments for drugs.

During the State Fiscal Year (SFY) of 2008, July 2007 through June 2008, the Kansas Medical Assistance Program (KMAP) paid over \$158 million (rebates not included) on approximately two million prescriptions for fee-for-service (FFS) beneficiaries.

Ms. Kluczykowski broke out pharmacy claims and compound claims because they are processed differently in the system. The pharmacy claim is one National Drug Code (NDC) per claim, but the compound claim can be more than one NDC per claim. Even though compounds comprise only 1.4% of the total claims expenditures, excluding compound data would have resulted in a shift to the various drug class rankings, mainly due to antihemophilic factors. Dr. Burke asked what a compound claim is. Ms. Kluczykowski stated that it is mixing ingredients together to give the patient one drug.

The monthly drug expenditure statistics shows a decrease in the beneficiary population as far as fee-for-service, which could be due to more patients moving into the Managed Care option. The paid amounts per claim or for beneficiary went up sometimes, which could be due to the patients using more drugs, taking more acute drugs, going to the pharmacy more often, etc.

In addition to reporting drug expenditures according to beneficiary lives, claim numbers, paid amounts, and so forth, it is important to review the drug expenditures by varying degrees of drug classifications, from a general level to a more specific level. As the levels become specific, more classes are available within each level.

The degrees of drug classifications used for this report, from general to specific, include:

- General Drug Class Level
 - Specific Drug Class Level
 - Ingredient(s) Level
 - Ingredient/Dosage Form/Strength Level
- Each claim detail was broken down into the above components.

The general drug classification level is the broadest classification. Out of 41 general drug classes, KMAP paid claims in 38 of these classes. The following shows the top general drug classifications by paid amounts:

- Psychotherapeutic Drugs - \$54,099,006.73
- CNS Drugs - \$17,956,200.94
- Antiinfectives/Misc - \$13,556,749.49
- Gastrointestinal - \$9,767,153.29
- Blood - \$8,706,340.48
- Antiasthmatics - \$7,396,088.60
- Cardiovascular - \$6,453,985.05
- Analgesics - \$6,173,445.99
- Hypoglycemics - \$5,128,084.74
- Unclassified Drugs - \$4,363,837.78

Psychotherapeutic agents have always been a top drug expenditure for KMAP beneficiaries. The CNS Drugs rank second in terms of paid dollars. The majority of use within the CNS Drug class is for anticonvulsants, many of which are used for their psychotherapeutic benefits.

The following shows the top general drug classifications by paid per detail amounts:

- Biologicals - \$1,511
- Blood - \$465
- Antineoplastics - \$324
- Immunosuppressant - \$310
- Antiinfectives/Misc - \$272
- Unclassified Drugs - \$168
- Anti-Obesity Drugs - \$164
- Antidotes - \$136
- Psychotherapeutic Drugs - \$129
- CNS Drugs - \$112

As with paid amounts it makes sense the expensive biologicals are at the top of the list in terms of paid dollars

per detail. This is followed by blood, which includes the highly expensive antihemophilic factors. Given the paid per detail is at a general level, the amount paid per detail is somewhat diluted. The amount paid per detail when viewing the more specific drug classifications provides truer examples.

The top three general classes, which were psychotherapeutic drugs, CNS drugs, and antiinfectives, were broken down further into specific drug classes. Atypical antipsychotics make up 70% of the paid dollars for psychotherapeutic drugs. Anticonvulsants make up 99% of the paid dollars for CNS drugs. For antiinfectives most of dollars spent are in HIV agents.

The Biological general class topped the paid per detail list and only has one specific drug class. The Antisera specific drug class paid \$1511 per detail. Drugs within this class include the immune globulins.

The Blood general class consists of several specific classes including the expensive antihemophilic factors along with inexpensive warfarin and such. Given the high cost of several of the blood drugs dispensed to select populations, it makes sense this class would fall under the top three for paid per detail.

The antineoplastic general class ranks third in terms of paid amount per claim. The antineoplastic class is broken down further into specific classes. Most of the paid claims for these classes are for oral antineoplastic medications.

The top 10 paid drugs in the ingredient(s) classification level comprises 33% of the dollars paid. These top 10 comprise less than 1% of all ingredient levels paid. This is a significant amount of paid dollars for a small portion of drug ingredients.

Furthermore, the 'Top 10' paid per detail at the ingredient(s) level demonstrates a high cost to KMAP that could potentially be 'lost' in the 'Paid' category because these are dispensed less often.

	<p>The ingredient(s)/dosage form/strength level is the most specific reporting level for the SFY08 paid FFS pharmacy claims data. The 'Top 10' Paid at this level comprises 15% of the paid dollars under KMAP. With the exception of Risperidone which recently went generic, all others are branded products.</p> <p>In conclusion the amount that is being paid for mental health medications is growing. The antiinfectives which includes the HIV medications is slowly moving up on the list along with the blood medications.</p> <p>Dr. Burke asked what percentage of the beneficiary population has mental health disorders. Ms. Kluczykowski stated that she doesn't have that information.</p> <p>*Dr. Schewe asked Ms. Kluczykowski about Flomax® in regards to hard edits for males and females. Ms. Kluczykowski stated she had looked it up, but forgot to bring it to the meeting. She stated she will bring it to the next meeting.</p>	
<p>V.New Business</p> <p>A. Age Limitation for OTC Cough/Cold Medications</p> <ol style="list-style-type: none"> 1. Public comment 2. Board discussion <p>B. Proposed Change to PPI PA Criteria</p> <ol style="list-style-type: none"> 1. Public Comment 2. Board Discussion <p>C. Proposed PA Requirement for Ranexa®</p> <ol style="list-style-type: none"> 1. Public Comment 2. Board Discussion 	<p><u>Age Limitation for OTC Cough/Cold Meds</u></p> <p>Dr. Burke stated this is a big item in the news.</p> <p>Ms. Todd stated the Board decided to adopt the FDA recommendation of restricting the use of OTC cough and cold medications in children two years of age and under.</p> <p>Dr. Burke stated the FDA is still investigating this issue and is wondering if the restriction should be four years of age and under, but there is no formal FDA recommendation.</p> <p>Dr. Grauer stated there are very few products that say 2 and over; most say 6 and over.</p> <p>Ms. Todd stated KHPA sent a DUR newsletter to remind families about proper use of medications.</p> <p>Daniel Sutherland stated he advises families to check with their doctor for dosing children less than four.</p>	

Dr. Unruh indicated this area has created a lot of confusion. It is hard for a physician to determine doses as there are not any readily available sources.

Proposed Change to PPI PA Criteria

Ms. Todd presented a presentation on PPI utilization. Policy E2005-032, “Prior Authorization for Proton Pump Inhibitors at Acute (Maximum) Dosing for Greater than 60 Days”, was implemented on Feb. 8, 2008.

Beginning on or after Apr. 8, 2008 (60 days after policy implementation), PPI claims denied if a beneficiary had received 60 days of PPI acute dosing within the last rolling calendar year.

A Prior Authorization would then be required in order for the beneficiary to receive additional claims at the acute dosing schedule.

The following demonstrates a reduction in claims at the acute dosing schedule, as a result of this PPI policy.

The number of PPI claims for greater than one unit per day was 2,677 in 2007 and 698 in 2008. The total number of PPI claims was 15,211 in 2007 and 15,435 in 2008. Claims are for dates-of-service July 1 through October 31, in 2007 and 2008 respectively. In 2007, 17.6% of all PPI claims were for greater than one unit per day; this number dropped to 4.5% in 2008.

The number of PPI units dispensed for greater than one unit per day was 155,403 in 2007 and 37,351 in 2008. The total number of PPI units dispensed was 524,215 in 2007 and 471,435 in 2008. The number of units dispensed were taken from claims for dates-of-service July 1 through October 31, in 2007 and 2008 respectively. In 2007, 29.7% of all PPI units dispensed were from claims for greater than one unit per day; this dropped to 7.9% in 2008.

The number of unique beneficiaries with greater than one unit per day was 977 in 2007 and 326 in 2008. The number

of unique beneficiaries on all PPI claims was 5,610 in 2007 and 5,838 in 2008. Unique beneficiaries were obtained from claims for dates-of-service July 1 through October 31, in 2007 and 2008 respectively. In 2007, 17.4% of beneficiaries receiving PPIs had claims for greater than one unit per day; this number dropped to 5.6% in 2008. While the number of unique beneficiaries on claims for greater than one unit per day has gone down, there has been an increase in the total number of beneficiaries the state has served on all paid PPI claims.

Dr. Burke spoke about the 'American Gastroenterological Association Medical Position Statement on the Management of Gastroesophageal Reflux Disease'. It stated it was appropriate to try twice daily PPI therapy if there was an inadequate response to once daily therapy. It also stated patients who have not responded to an empirical trial of twice daily PPI therapy should have further evaluation and an endoscopy. Dr. Burke stated the report does not contain duration of use.

Dr. Waite noted that extended use of PPIs were related to NSAIDS.

Terri Hurley, AstraZeneca, commented there is a study that shows there is better management in once daily Nexium® 40 mg. She recommended that if a patient is placed on twice daily Prevacid® 30mg and requires continued therapy then the patient should be switched to Nexium® 40mg once daily. The clinical data supports the fact that there is symptomatic relief that occurs in those patients who require twice daily dosing of Prevacid® 30mg.

Dr. Burke asked Ms. Hurley to clarify that Nexium® 40mg once daily dosing is as effective as Prevacid® 30mg twice daily dosing.

Dr. Burke asked Ms. Hurley to make the data available to the Board for future consideration and follow up. Ms. Hurley stated this was a private study, therefore she could not provide it to the Board.

	<p>Dr. Burke asked if there was any reason to change the PA. The Board agreed there should be no changes made.</p> <p><u>Proposed PA Requirement for Ranexa®</u></p> <p>Dr. Burked noted a new package insert and recommended to table this item. He mentioned the issue was risk factors possibly associated with Ranexa® and how to maintain and optimize safety. First, the Board needs to review the new data. Another reason to table it is because there is very little use of this drug.</p> <p>Dr. Burke asked if there were anymore public comments.</p> <p>There was a question of when the next Preferred Drug List (PDL) meeting will be held. LeAnn stated it is December 10, 2008. These meetings are held every six months. The PDL agenda is not posted at this time.</p> <p>Robert Auerbach, CVT, stated his company is very excited about the new label for Ranexa®. It is a safe label. Safety was everyone's concern early on. He stated they are confident that with optimum medical therapy this drug will be a great addition.</p> <p>Barbara Belcher, Merck, asked if we could post the five drug limitation. Dr. Bell stated it is posted on the front page of the PDL on the KHPA website. Ms. Belcher asked if it had a list of drugs that are excluded. Dr. Bell stated preferred drugs do not count toward the five drug limit. Ms. Todd stated it is in the pharmacy manual on the KMAP Web site.</p>	
VI. Adjournment	Dr. Burke announced the meeting was adjourned.	<p>Ms. Dowd made a motion to adjourn the meeting.</p> <p>Dr. Schewe seconded and it was carried by a unanimous vote.</p>