# Drug Utilization Review Board
## Meeting Minutes, Open Session
### September 10, 2008

### Members Present:
- Michael Burke, M.D. Ph.D., Chair
- Brenda Schewe, M.D.
- Roger Unruh, D.O.
- Judy McDaniel-Dowd, PA-C
- Dennis Grauer Ph.D.

### KHPA Staff Present:
- Margaret Smith, M.D.
- LeAnn Bell, Pharm.D.
- Shelly Liby

### EDS Staff Present:
- Deb Quintanilla, R.N.
- Lisa Todd, R.Ph.
- Karen Kluczykowski, R.Ph.
- Nancy Perry, R.N.

### ACS Staff:
- Jerry Bowmer, R.Ph.

### Representatives:
- Charles Dahm, Amgen
- Scott Sabrswa, Amgen
- Dave Walters, Centocor Ortho Biotech
- Jim Baumann, Pfizer
- Kate Kwlesner, Wyeth
- Matthew Stafford, Merck

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<tr>
<th>TOPIC</th>
<th>DISCUSSION</th>
<th>DECISION AND/OR ACTION</th>
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<td>I. Call to Order</td>
<td>Dr. Michael Burke, Chair called the meeting to order at 10:05 a.m.</td>
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<td>II. Announcements</td>
<td>Dr. Margaret Smith introduced LeAnn Bell, Pharm.D., as the new Pharmacy Program Manager and Shelly Liby as the new Assistant Pharmacy Program Manager. She also announced that Tom Wilcox has resigned his position on the Board.</td>
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<td>III. Review and Approval of July 9, 2008 Minutes</td>
<td>Dr. Schewe pointed out that under New Business the list for tumor necrosis factor medication is missing number 1. Lisa Todd pointed out that it should be listed as 1-5 instead of 2-6. Mrs. Dowd made a motion to approve the minutes with the corrections previously mentioned. Dr. Schewe seconded the motion and it carried</td>
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IV. Old Business
   a  Tumor Necrosis Factor Medications
      i.  Update DMARD requirements on PA criteria

During the review of PA criteria at the last meeting it was unclear that there may have been some dynamic changes with regard to indication and age. Lisa Todd put together a table to summarize the current state of affairs with the tumor necrosis factor antagonists. Ms. Todd stated that currently all TNF medication PA criteria require a DMARD or failed therapy. Updates to some of the package inserts show that this is no longer the case for all of the TNF medications. For example Humira® can be used as a single agent for adult rheumatoid arthritis. Where as Remicade® must be used in conjunction with a DMARD. Cimzia® still requires a DMARD or failed therapy.

Dr. Dahm, medical liaison for Amgen, requested that the Enbrel® PA question on line five come in line to reflect the package guidelines. Dr. Burke stated that according to the updated information the change is appropriate.

Dr. Burke commented about the FDA alert regarding the TNF antagonists and the risk of by a unanimous vote.

Dr. Burke asked for a motion to bring the corrected table back with recommendation for PA modifications consistent with the table.

So moved by Dr. Schewe.

Dr. Grauer seconded the motion and it carried by a unanimous vote.
infections, in particular Histoplasmosis. This should not affect the PA criteria.

V. New Business
   a. ACS Heritage – Presentation of Annual Assessment

   b. Relistor® (methylnaltrexone bromide)
      i. Presentation of proposed PA criteria
      ii. Public Comment
      iii. DUR Board Discussion / Recommendation

Presentation of Annual Assessment
Jerry Bowmer R.Ph., ACS, presented the Pharmacy Program Assessment. The time period reviewed was July 2007-June 2008. The Pharmacy Program Assessment included the total number of pharmacy claims paid and the expenditures for these claims. These totals were broke down into average members per month and the average amount paid per member per month (PMPM).

There was discussion around the PMPM. It was verified that this data historically has included Managed Care and Fee for Service (FFS) members and claims. Dr. Smith suggested a new report be created to reflect FFS data only. This new format would give KHPA a more accurate picture of PMPM data.

Relistor®
Lisa Todd presented the proposed PA criteria for Relistor®. It is indicated for the treatment of opioid induced constipation in patients with advanced illness who are receiving palliative care when response to laxative therapy has not been sufficient.

CRITERIA: (must meet all of the following)
1. Patient must be at least 18 years old.
2. Patient must have opioid-induced
c   Uroxatral™ (Alfuzosin)
   i.  Recommendation of removal of gender restrictions


constipation with advanced illness.

3.  Patient must be receiving palliative care.

4.  Documentation of current opioid therapy.

5.  Pretreatment documented inadequate laxative therapy.

6.  Patient does not have known or suspected mechanical gastrointestinal obstruction.

7.  Patient is not pregnant or breast feeding.

Prior Authorizations will be approved for 4 months per lifetime.

Dr. Burke asked for public comment. There was none.

The board discussed the PA criteria. Nancy Perry, an EDS nurse, expressed concern that Hospice palliative care is different from general palliative care, but combining bullets 2 and 3 would take care of that concern. It was decided that bullets 2 and 3 would be combined.

Deb Quintanilla asked for more clarification on inadequate laxative therapy. In response to this Dr. Burke stated that bullet 5 should be changed to say “response to standard laxative therapy has not been sufficient.”

Uroxatral™

Ms. Todd stated that Uroxatral™ is a drug only

Dr. Burke asked for a motion to approve the PA criteria with the changes discussed.

So moved by Dr. Grauer.

Dr. Schewe seconded the motion and it carried by a unanimous vote.

Dr. Burke stated that the board will review the utilization data in 6 months.
approved for use in men. The Pharmacy Helpdesk phone has received feedback from Urologists stating that they would like to use this drug for women to help with incontinence. There is currently a gender restriction on this drug in the computer system. A pharmacy claim for Uroxtat™ for a female patient will deny.

Dr. Smith stated that there are similar drugs being used in women that are all off label.

Dr. Grauer asked if there were any studies in women with this drug. The board was not aware of any scientific studies.

There was discussion about Flomax® and whether or not there is a hard edit for males; there is not. However, it is FDA approved only for males. It is believed that indicators received from FDB don’t require gender restrictions on Flomax®, Karen Kluczykowski can verify.

Dr. Burke stated we may permit off label use inadvertently, but our policies are not intended to promote off label use particularly without any scientific evidence of effectiveness.

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<th>VI. Miscellaneous</th>
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<td>a. New location</td>
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<td>EDS, an HP company</td>
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<tr>
<td>6700 SW Topeka Blvd.</td>
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<tr>
<td>Building 283 (2 North &amp; J Street)</td>
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<td>Topeka, KS 66619</td>
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Ms. Todd announced that the next meeting is November 12, 2008 and will be held at the new location. She will provide directions.

Dr. Burke asked if there was any other business. Dr. Smith reminded the Board that we are in need of a long term care and retail pharmacist to serve on the Board. Dr. Burke suggested a pharmacist, Dr. Meg Damon, who is working in.
the hospital environment. Dr. Smith said that she would look at the specific criteria.

| VII. Adjournment | Dr. Burke announced the meeting was adjourned. | Dr. Unruh made a motion to adjourn the meeting. Mrs. Dowd seconded and it was carried by a unanimous vote. |