In attendance:
Terry D. Lindstrom, Ph.D. - Vice Chairman
Patricia Treadwell, M.D.
Philip N. Eskew, Jr., M.D.
Petra Fippen, R.Ph.
Carol Ott, PharmD, BCPP
Rhea Ellen Miller-Boley, R.Ph.
Brian Musial, R.Ph.

Also present:
Marc Shirley, R.Ph. - OMPP
Emily Hancock, PharmD, MPA - OMPP
Kristin Baldock - OMPP
Beth McCarty, PharmD, MSc - Anthem
Chris Johnson, R.Ph. - MDwise
Kimberly Hunton, PharmD - ACS (via conference phone)
John Ross, R.Ph., RN - ACS
Randall Renshaw, PharmD, BCPS - ACS

MEETING CALLED TO ORDER: In absence of the Chair, Board Vice Chairman Terry Lindstrom called the meeting of the Indiana Medicaid DUR Board to order.

APPROVAL OF MINUTES: Approval of the minutes from the April meeting was moved, seconded, and carried with a unanimous vote.

REMARKS FROM THE CHAIR: Dr. Lindstrom suggested rearranging the agenda so that the Smart PA proposal for COX II Inhibitors and brand only NSAIDs would be presented first. He also expressed his preference to vote at the end of the presentation of each therapeutic grouping. Dr. Lindstrom announced that there were six speakers and that each speaker would be allowed time to speak prior to a vote being taken for the relevant therapeutic grouping.

OPENING COMMENTS: None

SMART PA RULES PRESENTATION: Mr. John Ross, Clinical Call Center Pharmacist for ACS, indicated he was going to present Smart PA rules approved by the Therapeutics Committee.

1. COX II Inhibitors
   ♦ Approval criteria (past two years)
     ● GI Bleed
     ● GERD
     ● PUD
     ● GI Perforation
     ● Crohn’s Disease
     ● Familial Adenomatous Polyposis (FAP)
     ● Anticoagulation/antiplatelet therapy in past 30 days
     ● Chemotherapy in past 30 days
     ● Failure of two separate two week trials of NSAIDs (two unique agents) in past three months and failure of a two week trial of acetaminophen in past 3 months
     ● History of liver failure in the past two years (Call Center only)
     ● Allergic reaction to NSAIDs (Call Center only)
- Aspirin allergy (Call Center only)
- A GI risk score of 13 points or higher (Call Center only)
  - Denial criteria – Failure to meet approval criteria

2. **Arthrotec (diclofenac/misoprostol)**
   - Approval criteria
     - Failure of two separate two week trials of NSAIDs (two unique agents) in past three months and failure of a two week trial of acetaminophen in past three months
     - History of liver failure (Call Center only)
     - A GI risk score of 13 points or higher (Call Center only)
   - Denial criteria – Failure to meet approval criteria

3. **Brand Only NSAIDs**
   - Approval criteria
     - Failure of two separate two week trials of NSAIDs (two unique agents) in past three months and failure of a two week trial of acetaminophen in past three months
     - History of liver failure (Call Center only)
   - Denial criteria – Failure to meet approval criteria

**Public Comment:** None.

**Board Discussion:** Dr. Lindstrom asked if the Therapeutics Committee specified whether or not a trial of maximum doses of acetaminophen was required. Mr. Ross responded by indicating the Committee did not specify a maximum dose of acetaminophen.

**PREFERRED DRUG LIST REVIEW / THERAPEUTICS COMMITTEE RECOMMENDATIONS:**
Mr. Ross presented the Therapeutics Committee’s recommendations from their May 7, 2010 meetings. Mr. Ross stated that – as always – the three primary drivers behind those recommendations were clinical implications, drug costs, and total program costs. The Committee reviewed nine therapeutic class groupings and four new therapeutic classes and offered the recommendations listed below. The Board discussed and acted on each class individually. Smart PA rules were discussed separately.

1. **CNS and Others**
   - Antiemetic agents – No changes recommended
   - COX II inhibitors and brand only NSAIDS
     - Non-preferred with Smart PA criteria
   - Brand name narcotics
     - Move buprenorphine sublingual tablets to non-preferred with current PA criteria for Suboxone/Subutex
     - Move fentanyl citrate lozenges to non-preferred with same PA criteria as for fentanyl products
     - Add Onsolis buccal film to non-preferred with same PA criteria as for fentanyl products
     - Remove the following statement from PA criteria for fentanyl products: Must have a medically justifiable diagnosis associated with moderate to severe pain
     - Move tramadol ER tablets to non-preferred with a quantity limit of one tablet/day
   - Narcotic antitussive/1st generation antihistamine combinations – No changes recommended
   - NSAID/prostaglandin combinations
     - Add Arthrotec to non-preferred with Smart PA criteria
   - Skeletal muscle relaxants – No changes recommended
   - Smoking deterrent agents – No changes recommended

**Public Comment:** Rick Vissing, PharmD, representing Pfizer, spoke in support of Celebrex. Dr. Vissing requested that the Board reconsider the requirement of a patient trying acetaminophen prior to obtaining Celebrex. He noted that there is debate over acetaminophen’s efficacy in certain pain states. Dr. Vissing stated that only the American Geriatric Society recommends the use of acetaminophen before the use of NSAIDs and COX II inhibitors. Dr. Eskew wanted to know if this information was presented at the Therapeutics Committee meetings, and Mr. Ross responded that it had not been presented. There was much discussion among the Board members about an age restriction with COX II use. There was also extensive discussion among the Board members about
the 13 point scale included in the COX II Smart PA criteria. Dr. Renshaw pointed out that greater than 61 years of age had been changed to 8 points on the 13 point scale. Mr. Brian Musial asked if the acetaminophen in narcotic combination products counted towards a trial of an acetaminophen product. Dan Carpenter, representing HP, answered affirmatively. There was much discussion among the Board members about adequate trials of generic NSAIDs and acetaminophen.

Tammy Wilson, PharmD, representing Pfizer, stated that she agreed with the comments made by Dr. Vissing. Dr. Wilson also requested the Board reconsider the requirement of a patient trying acetaminophen prior to obtaining Celebrex. Dr. Philip Eskew suggested that the pharmaceutical companies address their comments to the Therapeutics Committee prior to presenting at the DUR Board. Dr. Wilson stated that manufacturers’ representatives are not given the chance to speak after decisions are made behind closed doors during the second session. Marc Shirley of OMPP responded that, in compliance with the Indiana Open Door Law, all deliberations are made in public meetings. Further, that notices of all meetings of the DUR Board and Therapeutics Committee are posted in accordance with the Open Door Law, with the information being available on the Web, outside of FSSA main offices, and outside of the Conference Center rooms in which the meetings are held. He stated that agendas for the meetings provide for public comment. He also noted that executive session meetings of the Therapeutics Committee are solely for the purpose of consideration of confidential and proprietary pricing data. Mr. Shirley encouraged those individuals with comments for the Therapeutics Committee to attend both of the Committee’s public meetings on days on which Committee meetings are held.

**Board Discussion:** Dr. Lindstrom recommended that the same terminology used on the Preferred Drug List (PDL) be used when discussing therapeutic classes. He also asked if NSAID/Prostaglandin Combinations was a new therapeutic class. Dr. Hunton answered affirmatively.

**Board Action:** It was moved and seconded that the recommendations for CNS and Others be approved. The motion passed with six ayes and one abstention.

2. **Dermatologic Agents**

   ◆ Acne agents
     - Move benzoyl peroxide/clindamycin topical gel to non-preferred
     - Move 0.1% Differin lotion to non-preferred for all recipients with the step edit "must have failed a tretinoin product"
   ◆ Antipsoriatic agents
     - Maintain Soriatane 17.5 mg and 22.5 mg strengths as preferred
     - Add Stelara prefilled syringes and vials to non-preferred

**Public Comment:** None

**Board Discussion:** Dr. Eskew asked why some generic products are moved to non-preferred. Mr. Musial responded by indicating such action is tied to pricing issues.

**Board Action:** It was moved and seconded that the recommendations for Dermatologic Agents be approved. The motion passed unanimously.

3. **Endocrine Agents**

   ◆ Antidiabetic agents – No changes recommended
   ◆ Bone resorption suppression agents/SERMS – No changes recommended
   ◆ Bone formation stimulating agents – No changes recommended
   ◆ Growth hormones
     - Maintain Genotropin 5 mg and 12 mg strengths as preferred with current PA criteria
     - Maintain Nutropin AQ 5 mg/2mL strength as preferred with current PA criteria
   ◆ Injectable Hypoglycemics
     - Add Victoza prefilled pen to preferred with the step edit "must currently be on metformin and/or a sulfonylurea and/or a thiazolidinedione or combo including such"

**Public Comment:** Leonard Bennett, PharmD, representing Novo Nordisk, spoke in support of Victoza. Dr. Bennett concurred with a suggestion to broaden this category to Non-Insulin Injectable Hypoglycemics and yielded the remainder of his time back to the Board.
**Board Discussion:** There was much discussion surrounding the re-naming of the therapeutic class Injectable Hypoglycemics. Mr. Musial suggested changing the name of this class to Non-Insulin Injectable Hypoglycemics.

**Board Action:** It was moved and seconded that the recommendations for Endocrine Agents be approved, including the SERMS, and that the Injectable Hypoglycemics therapeutic class be renamed Non-Insulin Injectable Hypoglycemics. The vote passed unanimously.

4. **Gastrointestinal Agents**
   - Chronic constipation agents – No changes recommended
   - Anti-Ulcer Preparations
     - Add the following products to preferred
       - sucralfate tablets
       - misoprostol tablets
       - Carafate suspension
     - Add the following products to non-preferred
       - Cytotec tablets
       - Carafate tablets
       - sucralfate suspension
     - Maintain current PA criteria for both Carafate & Cytotec
     - Add the following step edit for both sucralfate & Carafate suspension: trial on tablets within the past 90 days is required for patients 18 years of age or older or must be unable to swallow tablets; must also meet PA criteria
   - H. Pylori Agents – No changes recommended
   - H2 Receptor Antagonist
     - Move nizatidine oral solution to non-preferred
   - Pancreatic Enzymes
     - Add Zenpep capsules to preferred
     - Remove the following from the PDL
       - Pancre carb-MS
       - Ultrace and Ultrace MT
       - Viokase
   - Proton Pump Inhibitors
     - Move lansoprazole capsules to non-preferred with the following step edit: must fail omeprazole and then a preferred proton pump inhibitor (PPI) for a total length of therapy of 4 weeks, unless patient is intolerant to these agents
     - Prevacid OTC 15 mg capsules - maintain as not covered
   - Ulcerative colitis agents – No changes recommended

**Public Comment:** Ms. Ia Dac-Korytko, from AstraZeneca, spoke in support of Vimovo. Ms. Dac-Korytko stated that this product contains naproxen and esomeprazole magnesium. She referenced the estimated global prevalence of rheumatoid arthritis and osteoarthritis and stated the FDA-approved indications for the product are treatment of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis. She further noted that the PPI component was added to decrease the risk of gastrointestinal ulcers in patients at risk of developing same.

**Board Discussion:** Dr. Hunton pointed out that the anti-ulcer preparations were a new class. Dr. Lindstrom noticed that Carafate (sulcralfate) appears on the monthly prior authorization (PA) statistics but is not shown on the PDL document. Dr. Renshaw advised that while the Clinical Call center has handled PA requests for the product as part of the old Indiana Rational Drug Program, it nonetheless needs to be shown on the PDL. There was much discussion among the Board members about the number of failures of certain agents before getting a preferred PPI.

Dr. Hunton went over the existing PA criteria for Carafate, noting the following: 1) Carafate is indicated for open wounds (e.g., ulcer) within the GI tract; 2) Carafate is considered duplicate therapy when prescribed concurrently with other peptic acid drugs beyond an initial 30 days and will not be approved in such circumstances; 3) Carafate will not be authorized for treatment of GERD; and 4) the maintenance dose of Carafate (1 gram twice daily) does not require PA. Dr. Hunton then related the PA criteria for Cytotec, as follows: 1) Cytotec is indicated only for the prevention of side effects associated with use of NSAIDs; 2) prior authorization requires that the patient have a GI risk rating of at least 13 points; and 3) Cytotec is considered duplicate therapy when prescribed concurrently with other peptic acid drugs and will not be approved in such circumstances.
**Board Action:** It was moved and seconded that the recommendations for Gastrointestinal Agents be approved and that H. pylori and antiulcer agents be separated into two distinct therapeutic classes. The motion passed unanimously.

5. **Genitourinary Agents**
   - BPH agents
     - Move tamsulosin capsules to non-preferred
   - Urinary tract antispasmodics – No changes recommended

**Public Comment:** Daniel Shull, MD, a family physician from Zionsville, spoke in support of Toviaz. Dr. Shull indicated that he had seen many anticholinergic side effects with other genitourinary agents. He maintains, based on his experience, that Toviaz has fewer gastrointestinal motility issues. Dr. Shull respectfully requested that Toviaz be available without PA.

**Board Discussion:** Mr. Musial advised that, based on the cognitive effects these agents can have on some patients, the Therapeutics Committee wanted this class reviewed for possible application of Smart PA. There was much discussion among the Board members about when these agents would next be reviewed. Dr. Renshaw pointed out that this review was a clinical review and the review in November will be both clinical and financial. He also pointed out that supplemental rebate contracts are written for a year and a review in August may be detrimental to existing contracts.

**Board Action:** It was moved and seconded that the recommendations for Genitourinary Agents be approved and that Smart PA criteria be developed for this class for the November 2010 review. The motion passed unanimously.

6. **Hematologic Agents**
   - Hematinics – No changes recommended
   - Heparin and related products – No changes recommended
   - Leukocyte (WBC) stimulants – No changes recommended
   - Platelet aggregation inhibitors – No changes recommended

**Public Comment:** None

**Board Discussion:** None

**Board Action:** It was moved and seconded that the recommendations for hematologic agents be approved. The motion passed unanimously.

7. **Topical Agents**
   - Eye antihistamine/mast cell stabilizers
     - Move azelastine 0.05% ophthalmic solution to non-preferred
     - Move ketotifen 0.025% eye drops to preferred
     - Add Zyrtec (ketotifen 0.025%) Itchy Eye (OTC) to preferred
   - Ear Preparations
     - Add the following products to preferred
       - OtiRx
       - Oto-End
       - acetic acid drops
     - Add the following products to non-preferred
       - Acetasol HC
       - acetic acid HC
       - acetic acid/aluminum
       - Borofair
       - RE Pramoxine-HC
       - Vosol® and Vosol HC drops
   - Glaucoma agents
     - Move brimonidine 0.15% ophthalmic solution to non-preferred
   - Topical anti-inflammatory, NSAIDs – No changes recommended
◆ Topical antiparasitics – No changes recommended
◆ Eye anti-inflammatory agents
  ● Add the following products to preferred
    o flurbiprofen eye drops
    o ketorolac 0.4% ophthalmic solution
    o ketorolac 0.5% ophthalmic solution
    o Voltaren eye drops
  ● Add the following products to non-preferred
    o Acuvail ophthalmic solution
    o Acular eye drops
    o Acular LS ophthalmic solution
    o diclofenac eye drops
    o Nevanac eye drops
    o Ocufen eye drops
    o Xibrom eye drops
◆ Ophthalmic anti-inflammatory, immunomodulator-type
  ● Restasis 0.05% eye emulsion - add to non-preferred with a quantity limit "60 vials/month" and the step edit "trial of artificial tears within the past 90 days"
◆ Topical estrogens
  ● Vagifem 10 mcg tablets - Maintain as preferred
◆ Topical immunomodulators – No changes recommended
◆ Topical post-herpetic neuralgia agent – No changes recommended
◆ Wound care products
  ● Remove the following products from the PDL
    o Accuzyme
    o Allanfil
    o Allanzyme
    o Ethezyme
    o Gladase and Gladase-C
    o Kovia
    o Panafil
    o Ziox

Public Comment: Richard Fiscella, PharmD, from the University of Illinois at Chicago, spoke in support of Restasis. Referring to a large Gallop poll, Dr. Fiscella stated that most people who suffer from dry eyes have tried artificial tears in the past. He also referred to clinical trials and studies demonstrating the benefits of cyclosporine in dry eye disease.

Board Discussion: Dr. Lindstrom asked for clarification on the new PDL classes in this grouping. Dr. Hunton indicated that immunomodulator-type ophthalmic anti-inflammatory agents, ear preparations, and eye anti-inflammatory agents were the new PDL therapeutic classes in this grouping.

Board Action: It was moved and seconded that the recommendations for the Topical Agents be approved. The motion passed unanimously.

8. Oral Contraceptives – No changes recommended

Public Comment: None

Board Discussion: None

Board Action: It was moved and seconded that the DUR Board accept the Therapeutics Committee’s recommendations for the Oral Contraceptive products. The motion passed unanimously.

9. Prenatal Vitamins – No changes recommended

Public Comment: None
**Board Discussion:** None

**Board Action:** It was moved and seconded that the recommendations for the Prenatal Vitamins be approved. The motion passed unanimously.

**DRAFT INDIANA MEDICAID DUR ANNUAL REPORT:** Dr. Renshaw presented an overview of the Medicaid DUR Annual Report and specifically noted the following: 1) The estimated costs avoided or savings for the year for the pro-DUR portion was $19.25 million; 2) for the retro-DUR portion, the savings was $2.37 million; 3) the grand total in savings was $21.62 million; 4) the estimated annual cost to administer the pro-DUR and retro-DUR programs was $630,000; 5) the net savings for the program equals $20.99 million; and 6) for every dollar spent on the program, the State saved $32.32.

Dr. Lindstrom pointed out that numbers on pages 187 and 188 did not match corresponding information on page 72. Mr. Shirley stated that CMS is working on a revised format for future DUR Annual Reports. He noted that this has been an ongoing project and that it was his understanding that CMS has, or will soon have, a revised format available. He further stated that the new format should differ substantially from the current one.

The DUR Annual Report for FFY 2009 was approved as drafted.

**ACS UPDATE:** Dr. Renshaw presented the prior authorization statistics for the month of May 2010. Dr. Lindstrom asked if anything significant stood out among the Mental Health Quality Assurance Committee (MHQAC) edits. Dr. Carol Ott responded by saying that one of the challenges of interpreting these numbers is that the denominator is not always known. Dr. Ott stated that she becomes concerned when the denial numbers are low and the approval numbers remain constant.

**UTILIZATION EDITS – QUARTERLY REVIEW/RECOMMENDATIONS:** Dr. Renshaw presented the quarterly utilization edits recommended by the MHQAC. He stated that Focalin XR 30 mg is a new strength and the proposed utilization edit is one per day. Dr. Renshaw also stated that the utilization edit for Focalin XR 15 mg was revised from two per day to one per day. It was moved and seconded that the DUR Board accept the MHQAC recommendations for the utilization edits. The motion passed unanimously.

**NEW DRUGS:** None.

**LIAISONS WITH OTHER BOARDS:** Dr. Ott stated that the MHQAC is planning to consider pediatric issues with psychiatric medications. She also stated that Dr. David Posey gave a presentation to the MHQAC in April regarding standards of care he employs in his practice in an autism clinic. Dr. Ott summarized by saying that pediatric issues will be the focus of the MHQAC for a while.

**PUBLIC COMMENT:** No additional comments.

**OLD BUSINESS:** None.

**NEW BUSINESS:** Mr. Ross stated that the following statement was read to the Therapeutics Committee with no resulting objections: ACS recommends evaluating the specialty classes currently on the PDL and developing Smart PA criteria; any new Smart PA criteria for existing PDL classes will be presented according to the PDL review cycle. New classes will continue to be evaluated for addition to the PDL.

**MEETING ADJOURNED.**