

DRAFT Minutes—Indiana Medicaid DUR Board  
Meeting of May 15, 2009—Meeting No. 149

**In attendance:**

**Brian Musial, R.Ph.** - Chair  
**John Wernert, M.D.** - Vice-Chair  
**Philip N. Eskew, Jr., M.D.**  
**Patricia Treadwell, M.D.**  
**Kent Summers, R.Ph., Ph.D.**  
**Jeff Brown, R.Ph., MS, BCPS**

**Also present:**

Michael Sharp, R.Ph. - OMPP  
Marc Shirley, R.Ph. - OMPP  
Medina Lee, R.Ph. - OMPP  
Kristin Johnson - OMPP  
Emily Hancock, PharmD, MPA - OMPP  
Jeannine M. Murray, R.Ph. - Anthem  
Chris Johnson, R.Ph. - MDwise  
Kelly Henderson, PharmD - MDwise  
Randall Renshaw, PharmD, BCPS - ACS  
John Stancil, Jr., R.Ph. - ACS  
James V. Berger, R.Ph., - EDS

**MEETING CALLED TO ORDER:** Mr. Brian Musial, Board chairman, called the meeting of the Indiana Medicaid DUR Board to order.

**APPROVAL OF MINUTES:** The request for approval of the draft minutes from the April meeting was moved, seconded, and carried with a unanimous vote.

**REMARKS FROM THE CHAIR:** Because a couple of speakers had signed in, Mr. Musial stated that the public comment section would be moved between opening comments and the Therapeutics Committee (T Committee) recommendations.

**OPENING COMMENTS:** As a result of discussions at the April DUR Board, Mr. Marc Shirley advised the Board of recent communications between the Office of Medicaid Policy and Planning (OMPP) and ACS regarding the development of a schedule showing both past and future retrospective drug utilization review (retro-DUR) interventions. Mr. Shirley stated there were also discussions between OMPP and ACS about changes to the retro-DUR process that would result in a more meaningful process for both practitioners and OMPP. Furthermore, that OMPP is suggesting that only written interventions be used for retro-DUR interventions instead of both phone and written interventions as is the current practice. With the Chair's permission, Mr. Shirley gave Dr. Emily Hancock, a new OMPP unit employee, the floor to provide additional details about these proposed changes. Dr. Hancock, Manager of Interventions and Outcomes, shared her background, her roles and responsibilities, and the new vision for retro-DUR interventions. She added that the new approach for retro-DUR interventions will be to have one well-chosen retro-DUR intervention per quarter with the retro-DUR intervention corresponding to the quarterly newsletter. Dr. Hancock added that each newsletter will contain the current retro-DUR intervention along with its background, announce future retro-DUR interventions, and provide results of previous retro-DUR interventions. Dr. Hancock turned the floor over to Mr. John Stancil with ACS who described how currently approved retro-DUR interventions would be managed into the new process. Mr. Stancil outlined how the approved interventions would be handled in following way: the anticonvulsant intervention will be mailed in May, 2009, the hypertension intervention will be mailed in June, 2009, the metabolic syndrome intervention will be mailed in August, 2009, the diabetes intervention will be mailed in November, 2009, the gastrointestinal intervention will be mailed in February, 2010, and the short-acting opiates intervention will be mailed in May, 2010. Mr. Stancil added that a newsletter topic for the last four of the aforementioned retro-DUR interventions will be published one month prior to each corresponding retro-DUR intervention. Dr. Kent Summers asked if standard operating procedures included the provision of feedback about intervention outcomes

after a reasonable period of time. Dr. Hancock responded that there was a methodology to report results but the methodology to report outcomes is currently explored. Dr. Summers commented that having outcomes information for these interventions may help tailor future interventions. Dr. Hancock added that beginning in July 2010, she hoped to coordinate future interventions with the State Department of Health. Dr. John Wernert expressed gratitude for providing structure to this process but mentioned concern about the contractual number of 3,600 interventions per year. Dr. Hancock stated that we are moving away from a specified number of practitioner interventions per year to one intervention topic per quarter. Dr. Summers suggested that national quality metrics be used for assessing these interventions. The motions to approve the new retro-DUR process and the new retro-DUR schedule were seconded and approved unanimously.

**PUBLIC COMMENT:** Ryan Read, representing Taro Pharmaceuticals, spoke on behalf of Ovide. Mr. Read presented two physician letters supporting Ovide. Mr. Musial pointed out that the proper procedure for submission of information, including physician letters, is to send the information to the T Committee through the web interface. Dr. Summers asked if the T Committee had received this information. Mr. Read responded by saying the T Committee had the information. Mr. Read referred to the American Academy of Pediatrics (AAP) Guidelines as it applies to treatment of head lice in children greater than five years old. He said that the guidelines state that an over-the-counter product should be used first before using Ovide unless resistance has been demonstrated. He also stated that the utilization data is low for Ovide because many doctors' offices do not have adequate staff to call for prior authorizations. Mr. Read went on to say that his company has offered a generous supplemental rebate offer and he respectfully asked the Board to consider giving Ovide equal access status with the other pediculocide medications.

Jennifer Beasley, medical assistant, stated that she works at one of the busiest doctors' offices in Indianapolis that treats head lice. In her practice setting, she usually observes multiple failures with over-the-counter pediculocide treatment but does not typically see treatment failures with Ovide. Ms. Beasley stated that she would like to see Ovide used as a first-line agent. Dr. Wernert asked if Ms. Beasley sees any treatment success with the over-the-counter pediculocides. Ms. Beasley stated that in her experience, the over-the-counter agents usually fail. Dr. Wernert asked if the over-the-counter pediculocide treatment failures might be due to improper technique. Ms. Beasley responded that patients are educated about the proper use of pediculocides over the phone and that she sees more treatment failures with the over-the-counter agents. Mr. Jeff Brown asked for some data relating to resistance. Mr. Brown noted that the information presented today is anecdotal and that Ovide is over one-hundred dollars. Mr. Read referenced a study performed in Florida where twice applied over-the-counter pediculocides were less than fifty percent effective while twice-applied Ovide was shown to be one hundred percent effective. He noted that he did not bring the study with him today. Mr. Read also mentioned other issues that need to be taken into consideration are school absenteeism and missed work days by parents. Dr. Wernert said that it is unfair to assume that the DUR Board does not consider indirect costs. He went on to say that he felt the problem with resistance to these agents is improper technique and uncleanliness. Mr. Read offered to submit clinical studies for T Committee's review. Mr. Musial pointed out that these studies would be reviewed for the November T Committee meeting.

Dr. Christopher Rizzo, medical director with Medimmune, spoke in support of Synagis. He stated that he is a board certified pediatrician with 20 years in practice. Dr. Rizzo respectfully asked the Board to consider the scientific evidence and make exposure to tobacco smoke a risk factor for obtaining Synagis. He also asked the Board to make the Synagis criteria consistent among all plans.

**THERAPEUTICS COMMITTEE MEETINGS/PDL REVIEW:** Dr. Randall Renshaw of ACS presented the Therapeutics Committee's recommendation from their May 1, 2009 meetings. He stated that, as always, the three primary drivers behind those recommendations were clinical implications, drug costs, and total program costs. The Therapeutics Committee reviewed eight therapeutic groupings and the FFS Indiana Medicaid OTC Drug Formulary; they offered the recommendations listed below. The Board discussed and acted on each class individually.

## 1. CNS and Others

- ◆ Antiemetic Agents
  - Add Sancuso to non-preferred status with a step-edit – physician documentation required indicating oral medications are unsuitable for patient use
  - Maintain Oxycodone/APAP 2.5/325 mg as preferred
  - Maintain the status of the other agents
- ◆ Brand-Name Narcotics

- Maintain Avinza 45 mg and 75 mg as non-preferred
- Maintain Oxycodone/APAP 2.5/325 mg as preferred
- Move Repraxain to non-preferred status
- Maintain the current status of the other agents
- ◆ Narcotic Antitussive/First Generation Antihistamine Combinations
  - Add quantity limit to promethazine with codeine – six ounces per prescription; add age limit – six years of age and older
  - Maintain the status of the other agents
- ◆ COX-II Inhibitors
  - No changes recommended
- ◆ Skeletal Muscle Relaxants
  - No changes recommended
- ◆ Smoking Deterrent Agents
  - No changes recommended
- ◆ NSAID/PPI Combination
  - No changes recommended

**Public Comment:** None

**Board Discussion:** Mr. Brown asked if there was a provision in the Suboxone/Subutex PA criteria for off-label use for chronic pain. Dr. Renshaw responded by saying there is not a provision in the Suboxone/Subutex PA criteria for off-label use for chronic pain. Dr. Wernert asked if this PA criteria was compared to other Managed Care Organizations' (MCOs') PA criteria. Dr. Renshaw responded by saying this criteria had been compared to other MCO Suboxone/Subutex criteria. Dr. Wernert pointed out that the MDwise Suboxone/Subutex PA criteria has been made less stringent when compared to the ACS-recommended PA criteria. Dr. Wernert added that Suboxone and Subutex cause less drowsiness when compared to methadone and those patients on Subutex or Suboxone seemed to function better when compared to those patients on methadone. Dr. Wernert and Dr. Kelly Henderson discussed the presented Suboxone/Subutex PA criteria and concluded the presented criteria were the older version of the Suboxone/Subutex PA criteria. Mr. Brown expressed that patients with chronic pain issues should have access to Suboxone or Subutex. He stated that Suboxone and Subutex have been used in Europe for chronic pain and, anecdotally, he has seen some impressive results. Dr. Wernert pointed out that the intention of the T Committee was to ensure these medications are being used appropriately because there were not PA criteria previously. Mr. Brown stated that in his experience, patients are not sleepy and are able to function while taking Suboxone or Subutex. Dr. Summers asked why the Suboxone/Subutex criteria are being proposed now. Dr. Renshaw responded by saying that we have seen increased utilization of Suboxone and Subutex over the past couple of years, and we have also seen patients taking Suboxone or Subutex concurrently with other narcotics. Mr. Brown pointed out that physicians who prescribe Suboxone or Subutex for addiction must have specialized training but if a physician prescribes these medications for an off-label use, then no training is needed. A motion was made and seconded for the acceptance of ACS' recommendations for CNS and others as well as including Suboxone and Subutex as a new Preferred Drug List (PDL) class with the ACS-recommended PA criteria. The vote resulted in a tie, three in favor of the motion and three opposed. Another motion to approve ACS's recommendations for the CNS and others class without considering Subutex and Suboxone was seconded. This motion passed unanimously. Another motion was made to send the Suboxone/Subutex criteria back to the T Committee for consideration of off-label use for pain, consideration of grandfathering, consideration of MCO Suboxone/Subutex PA criteria, and consideration of the use of these agents concurrently with other opiates. The presentation will be given at the August, 2009 T Committee meetings. The motion passed with five in favor and one opposed.

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

## 2. Dermatological Agents

- ◆ Acne Agents
  - Add Acanya, Aczone, and Epiduo to non-preferred status
  - Maintain the status of the other agents
- ◆ Antipsoriatic Agents
  - Add Vectical ointment to non-preferred status
  - Remove Raptiva from the PDL document

- Maintain the status of the other agents

**Public Comment:** None

**Board Discussion:** None

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

### 3. Endocrine Agents

- ◆ Antidiabetic Agents
  - Add Prandimet to non-preferred
  - Maintain the status of the other agents
- ◆ Injectable Hypoglycemics
  - No changes recommended
- ◆ Thiazolidinediones
  - No changes recommended
- ◆ Bone Formation Stimulating Agents
  - Maintain non-preferred status of Forteo 600/2.4 ml pen with current PA criteria
- ◆ Bone Resorption Suppression Agents
  - No changes recommended
- ◆ Growth Hormones
  - Maintain the preferred status of Omnitrope 10 mg/1.5 ml cartridge with current PA criteria
  - Maintain the status of the other agents

**Public Comment:** None

**Board Discussion:** None

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

### 4. Gastrointestinal Agents

- ◆ Chronic Constipation Agents
  - No changes recommended
- ◆ H. Pylori Agents
  - No changes recommended
- ◆ H2 Receptor Antagonist
  - Maintain Pepcid AC 20 mg chewable tablets (OTC) as not covered on the OTC Drug Formulary; No changes recommended to the PDL. Maintain the status of the other agents
- ◆ Ulcerative Colitis Agents
  - Add Apriso capsules to non-preferred status; Maintain SF Rowasa enema as non-preferred
  - Maintain the status of the other agents
- ◆ Proton Pump Inhibitors
  - Remove omeprazole OTC and Prilosec OTC from all step edits requiring a trial of omeprazole (Rx or OTC) or Prilosec OTC so that only a trial of omeprazole 20 mg is required prior to receiving other PPIs
  - Maintain Protonix tablets as preferred, but change current step edit to “must fail omeprazole 20 mg within the past 90 days”
  - Add Kapidex to non-preferred status with the step edit – must fail omeprazole 20 mg and then a preferred PPI for a total length of therapy of 4 weeks, unless patient is intolerant to these agents
  - Move omeprazole 40 mg capsules to non-preferred status with the step edit – two 20 mg caps required
  - Remove omeprazole OTC and Prilosec OTC from both the OTC Drug Formulary and the PDL
  - Maintain Prilosec 2.5- and 10-mg packets as non-preferred and add the following limits/step edits: “must be 12 years of age or younger; quantity limit - 1 packet/day; must

fail Nexium packets or Prevacid solutabs for a total length of therapy of 4 weeks, unless patient is intolerant to these agents”

- Add the step edit – must fail omeprazole 20 mg and then a preferred PPI for a total length of therapy of 4 weeks, unless patient is intolerant to these agents for all non-preferred agents, except Prilosec packets
- Maintain the status of the other agents

**Public Comment:** None

**Board Discussion:** Mr. Brown pointed out recent information involving an interaction between Plavix and omeprazole. He said patients at his institution are placed on Protonix if the patient is taking Plavix concurrently. There was much discussion among the Board members about this interaction. A motion was made to approve the presented recommendations and add to the motion that if patients are taking Plavix, these patients may have pantoprazole first instead of trying omeprazole.

**Board Action:** A motion was made to approve the presented recommendations and add to the motion that if patients are taking Plavix, these patients may have pantoprazole first instead of trying omeprazole. The motioned was seconded and the motion for the gastrointestinal agents passed unanimously.

## 5. Genitourinary Agents

- ◆ BPH Agents
  - Add Rapaflo capsules to non-preferred status
  - Maintain the status of the other agents
- ◆ Urinary Tract Antispasmodics
  - Add Toviaz tablets to non-preferred status with the step edit – must fail oxybutynin IR
  - Maintain the status of the other agents

**Public Comment:** None

**Board Discussion:** None

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

## 6. Hematologic Agents

- ◆ Hematinics
  - No changes recommended
- ◆ Heparin and Related Agents
  - 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. Ophthalmic Agents

- ◆ Eye Antihistamines/Mast Cell Stabilizers
  - No changes recommended
- ◆ Glaucoma Agents
  - Move both generic dorzolamide and generic dorzolamide/timolol solutions to non-preferred status

- Maintain both Cosopt and Trusopt solutions as preferred
- Maintain the status of the other agents

**Public Comment:** None

**Board Discussion:** None

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

## 8. Topical Agents

- ◆ Topical Estrogen Agents
  - No changes recommended
- ◆ Topical Immunomodulators
  - No changes recommended
- ◆ Wound Care Products
  - No changes recommended
- ◆ Topical Anti-inflammatory NSAIDs
  - Add both Flector patch and Voltaren gel to non-preferred status and add the following step edit for both agents – physician documentation required indicating oral medications are unsuitable for patient use
- ◆ Topical Anti-virals
  - Add Abreva cream (OTC) as a covered item on the OTC Drug Formulary
  - Add Abreva cream to preferred status on the PDL
  - Add Zovirax ointment to preferred status
  - Add Zovirax cream to non-preferred status
  - Add Denavir cream to non-preferred status

**Public Comment:** None

**Board Discussion:** None

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

## 9. Synagis

- ◆ Add Synagis to preferred status
- ◆ Remove the word “tobacco” from the phrase “tobacco smoke” in the current PA criteria

**Public Comment:** None

**Board Discussion:** Dr. Renshaw stated that the T Committee recommended adding Synagis to preferred status but changing the existing PA criteria from “tobacco smoke” to “smoke” in the home. Furthermore, the T Committee recommended that if the smoke is tobacco smoke, the PA should address whether the caregiver has had a discussion with the parent or caregiver regarding the risks of second-hand smoke to the child and referral to a smoking cessation program, if desired. Dr. Renshaw added that controversy exists because tobacco smoking is considered a controllable risk factor. He also went on to say that tobacco smoking may not be controllable because it is difficult to quit and other members of the household may smoke. There was much discussion among the Board members about if tobacco smoking is a controllable or non-controllable risk factor. Dr. Henderson, from MDwise, presented data from various Medicaid programs where the cost of Synagis prophylaxis outweighed the cost of decreased hospitalization. She went on to say that Synagis was very effective in decreasing hospitalizations in the 32 to 35 week treatment group but there was not a difference in mortality. She added that the severity of hospitalization and length of stay was decreased with Synagis but these factors did not outweigh the cost of Synagis prophylaxis. There was much discussion among the Board members as to whether the cost of the medication outweighs hospitalization costs. Dr. Henderson pointed out that different committees approve medications for the different MCOs. Ms. Jeanine Murray, from Anthem, stated Synagis is covered under the medical benefit and does include exposure to pollutants as part of its PA criteria. Dr. Katasha Butler, from Managed Health Services, indicated that Synagis is covered under the medical benefit and does not include

exposure to smoking as a risk factor. There was also much discussion among the Board members about how many risk factors should be included in the Synagis criteria.

**Board Action:** It was moved and seconded the word “tobacco” be removed from the phrase “tobacco smoke” in the Synagis PA criteria and that two risk factors must be present to get Synagis. The motion passed unanimously.

#### **10. Additional Therapeutics Committee Recommendations**

- ◆ Although the Topical Antiparasitics class was not reviewed, the T-Committee recommends consistency across all formularies regarding the non-restricted coverage of Ovide
- ◆ T-Committee also recommends consistency across all formularies regarding PA criteria for Synagis

**Public Comment:** (Please refer to the section following “Opening Comments”.)

**Board Discussion:** Dr. Patricia Treadwell and Dr. Summers voiced their support for consistency across all types of Medicaid coverage. Dr. Wernert expressed concern about subverting the approval process for all types of Medicaid. He gave an example of a manufacturer that didn’t like the outcome of a T Committee meeting could petition the DUR Board for a different outcome for their product. There was much discussion among the Board members about PA consistency and whether the T Committee could make this recommendation without clinically and financially reviewing the pediculocide products. Dr. Wernert stated that the T Committee’s recommendation to make all types of Medicaid plans consistent was out of their jurisdiction. He went on to say that he appreciates the T Committee’s recommendations input.

**Board Action:** The Board Chair stated that the recommendations stand due to a lack of a motion.

**MENTAL HEALTH QUALITY ASSURANCE COMMITTEE UTILIZATION EDITS:** Dr. Renshaw presented the proposed utilization edits including: velafaxine HCl 37.5 mg tab OSM 24 oral – 1 per day, venlafaxine HCl 75 mg tab OSM 24 oral – 2 per day, venlafaxine HCl 150 mg tab OSM 24 oral – 1 per day, and venlafaxine 225 mg tab OSM oral – 1 per day. Dr. Wernert asked if different strengths could be taken to achieve 300 mg of venlafaxine. Dr. Renshaw responded affirmatively. The motion to pass these recommended utilization edits was seconded and passed unanimously.

**DUR ANNUAL REPORT:** Dr. Renshaw covered various aspects of the DUR Annual Report including the summary table, an overview of retro-DUR activity totaling 3,712 interventions, and the generic dispensing rate of 76.8%. He also pointed out that the pro-DUR savings for Federal Fiscal Year (FFY) 2008 was \$14.5 million and the retro-DUR savings was \$219,458 providing a total savings of \$14.72 million. Dr. Renshaw stated that the cost to administer the program was \$630,000 providing a net savings of \$14.09 million. He stated that for every dollar spent in the program, \$22.36 is saved. This net savings equates to a return on investment of 2,136%. Dr. Wernert asked to whom the administration costs go. James V. Berger, from EDS, responded that edits are systematically maintained in the processing system by EDS and then ACS enters the PAs when the edit is encountered. Dr. Renshaw also covered how the savings numbers were determined. Dr. Wernert asked why the pro-DUR savings is trending downward. Dr. Renshaw responded that this FFY, there had been a 2% reduction in claims. Dr. Wernert asked for the total amount of dollars being spent in the Medicaid program. Dr. Renshaw responded that \$305 million is being spent in the Medicaid program. Mr. Musial pointed out duplicate pages on pages 52 and 53. Dr. Renshaw indicated that the duplicate page would be removed. The motion to approve the DUR Annual Report for FFY 2008 was seconded and passed unanimously.

**ACS UPDATE:** Dr. Randall Renshaw presented the prior authorization statistics for the month of April. He indicated that there were 3,842 prior authorizations for the month of April. In response to a question from Dr. Wernert at the April DUR Board meeting, Dr. Renshaw provided the names of the medications for “brand medically necessary” PAs for the month of March. The PAs were for Fosamax, Zocor, Inderal, and Glucophage. Dr. Renshaw went on to say that in April, the “brand medically necessary” PAs were for Vicodin ES, Coreg, Motrin, and Neoral. Mr. Musial asked if there were any brand medically necessary PAs for the antiepileptic drugs. Dr. Renshaw responded that the antiepileptic drugs were considered as being preferred, by statute.

**MANAGED CARE ORGANIZATION UPDATE:**

- Proposed PDL Changes—MDwise: Mr. Chris Johnson did not present any PDL changes but commented on a post-implementation analysis on the topic of pediculocides. Mr. Johnson stated that a step-edit requires a three week trial of a first-line agent, an over-the-counter pediculocide, before getting a second-line agent, Ovide. He pointed out that a three percent increase in claims was observed but the overall cost dropped by 75%. Mr. Johnson referred to a second study where approximately 73% of patients received only one course of an over-the-counter product in the study quarter. He went on to say that approximately 84% of cases received only one course of the legend product. He summarized by saying approximately 15% of all patients in the study required re-treatment.

**NEW DRUGS:** None.

**LIAISONS WITH OTHER BOARDS:** None.

**PUBLIC COMMENT:** None.

**OLD BUSINESS:** None.

**NEW BUSINESS:** Mr. Musial announced that Dr. Eskew was running for the Indiana University Board of trustees.

**MEETING ADJOURNED.**