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

Also present:
Michael Sharp, R.Ph. - OMPP
Marc Shirley, R.Ph. - OMPP
Medina Lee, R.Ph. - OMPP
Emily Hancock, PharmD, MPA - OMPP
Kristin Baldock - OMPP

Jeannine M. Murray, R.Ph. - Anthem
Chris Johnson, R.Ph. - MDwise
Katasha Butler, PharmD - Managed Health Services
Kim Hunton, PharmD - ACS (via conference phone)
Denise Hefley, PharmD - ACS (via conference phone)
John Stancil, R.Ph. - ACS
Randall Renshaw, PharmD, BCPS - ACS

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 minutes from the October meeting were moved, seconded, and carried with a unanimous vote.

Remarks from the Chair: Mr. Musial thanked Dr. Kenneth Summers for his years of service on the DUR Board and wished him much success in his new endeavors. He also welcomed new members Ms. Fippen, Dr. Ott, and Ms. Miller-Boley to the DUR Board.

Opening Comments: Mr. Marc Shirley also thanked Dr. Kenneth Summers for his years of service on the DUR Board and welcomed the new members to the Board. Mr. Shirley reminded the attendees that the election of new Board officers will occur next month. He also pointed out that there are still open positions on the Board for a physician and a health economist. Mr. Shirley went on to say that the Office of Medicaid Policy and Planning (OMPP) is working with the Governor’s office to have these positions filled and that he would keep the Board apprised as to any updates regarding this topic.

Revisions to the Table in the Diabetes Care Newsletter: Dr. Emily Hancock, Manager of Interventions and Outcomes with OMPP, informed the Board that the requested changes to the table in the Diabetes Care newsletter had been made. Dr. Hancock indicated that eye and foot exams had been moved to the first and second row, respectively, the focus of the table now emphasizes those patients who are in compliance with guidelines, the percentages are now reported as an inverse to the way these were previously presented, and a column had been added to report Healthcare Effectiveness Data and Information Set (HEDIS)-like measures. She proposed that instead of including this table in the Gastrointestinal Disease newsletter as previously requested by the DUR Board, that it be included in an updated version of the Diabetes Care newsletter. Dr. Hancock indicated that the updated Diabetes newsletter would be re-posted. It was moved and seconded that this recommendation for re-posting the updated Diabetes Care newsletter be approved. The motion passed unanimously.

Therapeutics Committee Liaison Report: Before the Therapeutics Committee (T Committee) recommendations were presented, Mr. Musial read the following statement: The Board accepts the recommendations of the T Committee with the understanding that all applicable agreements will be executed within the time frame defined by ACS and the Office of Medicaid Policy and Planning (OMPP). This time frame...
is not negotiable. If a manufacturer does not submit the signed agreement to ACS within the specified time frame, then their drug(s) that would have been approved in accordance with the agreement will be moved to non-preferred status.

Dr. Randall Renshaw, Executive Account Manager, of ACS presented the T Committee’s recommendations from their November 6, 2009 meeting. Dr. Renshaw stated that – as always – the three primary drivers behind those recommendations were clinical implications, drug costs, and total program costs. The T Committee reviewed seven therapeutic class groupings, the Synagis® Prior Authorization (PA) criteria, the Over-The-Counter (OTC) formulary and six new therapeutic classes; the committee offered the recommendations listed below. The Board discussed and acted on each class individually. Of note, the Smart PA rules are discussed separately.

1. CNS and Others
   - Antiemetic agents – Add dronabinol and Marinol® to non-preferred with Smart PA Criteria; Maintain the current status of the other agents
   - COX II inhibitors – No changes recommended
   - Brand-name narcotics
     - Add Embeda™ to non-preferred status
     - Add Nucynta™ to non-preferred with a quantity limit six tablets per day
     - Add Ryzolt™ to non-preferred with the quantity limit 1 tab/day
     - Move brand Duragesic™ to non-preferred and maintain quantity limit
     - Maintain Ultracet® as non-preferred, but change quantity limit from 400mg/day to 8 tabs/day
     - Move brand Oxycontin® to non-preferred and maintain current quantity limits; grandfather patients currently using Oxycontin® within the past 45 days for one year with educational intervention with prescriber before the end of the grandfathering period
     - Add the following step-edit for all preferred long-acting branded agents: "patients must be tried on one generic LA narcotic (fentanyl patches, morphine sulfate ER, or methadone) within the past 6 months”
     - Grandfather patients currently using Kadian® or Oramorph® SR within the last 45 days
     - Add the following step-edit for all non-preferred agents: "patients must be tried on 2 preferred short-acting agents within the past 6 months if requesting a short-acting drug
     - Patients must be tried on 2 preferred long-acting agents within the past 6 months if requesting a long-acting drug (examples of long-acting preferred agents include fentanyl patches, morphine sulfate ER, methadone, Kadian®, and Oramorph®; all other preferred agents are considered short-acting)
     - Add Smart PA rule pertaining to opiate overutilization
     - Maintain the current status of the other agents
   - Narcotic Antitussive/1st generation Antihistamine Combinations – No changes recommended
   - NSAID/PPI Combination – Remove Prevacid Naprapac® from the PDL
   - Skeletal Muscle Relaxants – No changes recommended
   - Smoking Deterrent Agents – No changes recommended
     - Maintain Chantix® as preferred, but add Smart PA criteria
     - Maintain the PDL status of the other agents

Public Comment: None

Board Discussion: None

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

2. Dermatologic Agents
   - Acne agents – No changes recommended
   - Antipsoriatic Agents
     - Add Enbrel® and Humira® to preferred
     - Add Remicade® to non-preferred
     - Move Amevive® to non-preferred
     - Maintain the PDL 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 Onglyza™ to preferred
     • Move nateglinide to non-preferred
     • Maintain Starlix® as preferred
     • Maintain the current status of the other agents
   ♦ Bone Resorption Suppression Agents
     • Move calcitoxin-salmon to non-preferred
     • Maintain Miacalcin® as preferred
     • Move Actonel® to non-preferred and add the step-edit “trial of alendronate within the past 90 days”
     • Grandfather patients currently using Actonel® for life
   ♦ Bone Formation Stimulating Agents – No changes recommended
   ♦ Growth Hormones
     • Move Humatrope® to non-preferred with the following step-edit “patients with the diagnosis of Short Stature Homeobox-containing gene (SHOX) deficiency who meet other appropriate criteria for growth hormone therapy may receive Humatrope®”
     • Maintain Norditropin® 30 mg/3 mL pens as preferred
     • Add the following statement to the Growth Hormone PA criteria under PA requirements for pediatric patients: approvals will be granted for preferred medications only, with the exception of patients with the diagnosis of SHOX deficiency
     • Maintain the current status of the other agents
   ♦ Injectable Hypoglycemics
     • Move Novolog® and Novolin® cartridges, innolets, pens, and syringes to preferred
     • Maintain Apidra® Solostar pen as non-preferred
     • Maintain the current status of all other agents

Public Comment: None

Board Discussion: Ms. Fippen suggested that a step-edit should be placed on Onglyza™ requiring a failure of the maximum tolerable doses of metformin and a sulfonylurea. Dr. Renshaw indicated that the DUR Board does not have access to any financial information and that by making a suggestion such as adding a step-edit may actually make these products more expensive. Ms. Fippen also expressed concern over the discontinuation of Novolin® cartridges, pens, and syringes while maintaining these agents preferred. Dr. Kimberly Hunton pointed out that we had utilization for the Novolin® products and that ACS makes recommendations once the products are no longer available. Dr. Hunton also pointed out that similar products are available on the PDL.

Board Action: It was moved and seconded that the recommendations for endocrine agents be approved and that the T Committee re-evaluate adding a step-edit to Onglyza™ in February 2010. The motion passed unanimously.

4. Gastrointestinal Agents
   ♦ Chronic constipation agents – No changes recommended
   ♦ H. pylori agents – No changes recommended
   ♦ H2 Receptor Antagonist
     • Move ranitidine syrup to preferred
     • Move Zantac® syrup to non-preferred
     • Maintain the current status of all other agents
   ♦ Pancreatic Enzymes
     • Add the following agents to preferred: Creon®, Pancrease® MT, Pancrecarb®-MS, Pancrelipase®, Ultrase®, Ultrase® MT, and Viokase®
   ♦ Proton Pump Inhibitors
• Move omeprazole 40 mg capsules to preferred while adding quantity limit of “2 capsules per day”
• Maintain Protonix® tablets and vials as preferred, and maintain the tablet quantity limit but change step-edit to “must fail omeprazole within the past 90 days or be on concurrent clopidogrel therapy”
• Remove the step-edit "two 20 mg capsules required" for omeprazole 40 mg
• Move Kapidex™ to preferred with the following step-edit and quantity limit: “must fail omeprazole within the past 90 days or be on clopidogrel therapy”; quantity limit - 1 cap/day
• Change the step-edit for all non-preferred agents to the following: "must fail omeprazole and then a preferred PPI for a total length of therapy of 4 weeks, unless patient is intolerant to these agents”
• Remove Zegerid® from the PDL
• Maintain the current status of all other agents
  ♦ Ulcerative colitis agents
    • Maintain Asacol® HD 800 mg tablets as preferred
    • Maintain the current status of all other agents

Public Comment: None.

Board Discussion: None.

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

5. Genitourinary Agents
  ♦ BPH agents – No changes recommended
  ♦ Urinary tract antispasmodics
    • Add Gelnique™ to non-preferred
    • Move oxybutynin ER to non-preferred
    • Change current step-edit for all non-preferred agents from "must fail oxybutynin IR" to "must fail oxybutynin IR and another preferred UTA for a total length of therapy of 4 weeks, unless patient is intolerant to these agents”
    • Maintain the current 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 products – No changes recommended
  ♦ Leukocyte (WBC) stimulants – No changes recommended
  ♦ Platelet aggregation inhibitors
    • Add Effient™ to non-preferred with a step-edit “patient must have a diagnosis of Acute Coronary Syndrome (ACS) or current prescription for a PPI”

Public Comment: None

Board Discussion: Dr. Renshaw stated that the T Committee recommendation for the platelet aggregation inhibitors is to add Effient™ to non-preferred with a step-edit “patient must have a diagnosis of Acute Coronary Syndrome (ACS) or current prescription for a PPI”. He went on to say the intention of the T Committee with regard to this recommendation to the Board was to: 1) Ensure that Effient™ is to be approved only for the Food and Drug Administration (FDA) approved indications, especially given the increased risk of bleeding associated with this new product. 2) Allow those patients who are concurrently on a PPI to be able to get Effient™ when Effient™ is being prescribed for only the FDA approved indications and in the situation where patients would not
be able to take Plavix® due to the potential interactions with PPIs. Dr. Renshaw stated the FDA release on this
drug interaction was supplied to the DUR Board via an e-mail from OMPP and that release was not available at
the time of the T Committee meeting. He indicated that during the public comment section of the T Committee
meeting, a cardiologist mentioned several times the use of Effient™ outside of the FDA approved indications. Dr.
Renshaw mentioned that this was a significant concern as Indiana Medicaid cannot lawfully reimburse for drugs
used for indications that are not FDA-approved or medically accepted as per the Social Security Act. He also
indicated that the T Committee requested that ACS develop a Smart PA clinical rule to automate some of the PA
requests. Furthermore, Dr. Renshaw stated this clinical rule is in development and will be presented at the next
review for this therapeutic class. Additionally, he said this will allow for incorporation of the latest clinical and
safety information for this new product. In summary, Dr. Renshaw stated that removing all language after the
word “or” in the recommendation would conform with the intention of the T Committee recommendation. He
also stated that adding the word “and” would make the recommendation more restrictive. Dr. Renshaw pointed
out that the way the recommendation is currently written, a patient could get Effient™ if they were on a PPI and
not necessarily have a diagnosis of ACS.

Dr. Terry Lindstrom asked what off-label condition the physician speaker at the T committee meeting referred to
in using Effient™. Dr. Renshaw responded by saying intensive anticoagulation in the absence of ACS. Dr. Carol
Ott stated that new information came out yesterday regarding a post-hoc analysis of Effient™ indicating that there
may be issues with Effient™ and PPIs reducing platelet inhibition. There was much discussion among the Board
members about the recommendation for Effient™.

**Board Action:** It was moved and seconded that the recommendations for hematologic agents be approved with
the exception of the platelet aggregation inhibitors which will be returned for review by the T Committee for
review in February 2010. The motion passed unanimously.

7. **Synagis® PA Criteria Review**
   ♦ Synagis® - No changes recommended

**Public Comment:** Dr. Shivika Jain, a pediatrician in the Indianapolis community dealing primarily with special
needs kids, spoke in reference to Synagis®. She spoke in support of keeping the current PA criteria for Synagis®.

Dr. Lisa Goetz, representing MedImmune, let the DUR Board know that she was available as a resource for
questions.

**Board Discussion:** None

**Board Action:** It was moved and seconded that the recommendations for Synagis® PA criteria be approved. The
motion passed unanimously.

8. **Topical Agents**
   ♦ Eye antihistamine/mast cell stabilizers
      • Add Bepreve™ to non-preferred
      • Maintain the current status of all other agents
   ♦ Glaucoma agents
      • Move apraclonidine to non-preferred
      • Maintain the current status of all other agents
   ♦ Topical anti-inflammatory, NSAIDs – No changes recommended
   ♦ Topical antiparasitics
      • Add the following products to preferred on the PDL: Acticin® cream, Elimite® cream,
        permethrin 1% lotion, permethrin 5% cream, pyrethrin products, and Ovide®
      • Add the following agents to non-preferred on the PDL: Eurax® cream, Eurax® lotion, lindane
        lotion, lindane shampoo, malathion, and Ulesfa™
      • Add a quantity limit of 2 bottles or 2 tubes per 30 days for all Rx products
   ♦ Topical estrogens – No changes recommended
   ♦ Topical immunomodulators – No changes recommended
   ♦ Topical post-herpetic neuralgia agent (Lidoderm®)
      • Add Lidoderm® to non-preferred with Smart PA criteria
   ♦ Wound care products – No recommended changes
Public Comment: Dr. Gerald Butler, a pediatrician in the community, spoke in support of the Board’s recommendation for Ovide®.

Board Discussion: Dr. Renshaw indicated the recommended quantity limit 2 bottles or 2 tubes per 30 days for all topical antiparasitic Rx products. There were several board members who spoke in opposition to the recommended quantity limit.

Board Action: It was moved and seconded that the recommendations for the topical agents be approved with the exception of returning the recommendation of quantity limit for the prescription topical antiparasitic agents to the T Committee for further review at the February 2010 meeting. The motion passed unanimously.

9. Oral Contraceptives

Progestin only
- Add the following agents to preferred: Ortho-Micronor® and Nor-QD®
- Add the following agents to non-preferred: Errin®, Camila®, Jolivette®, and Nora-Be®

Low-dose monophasic
- Add the following agents to preferred: Kelnor® 1-35, Zovia® 1-35, Aviane®, Lessina®, Lutera®, Sronyx®, Loestrin® 1.5-30, Loestrin® 1-20, Loestrin® FE 1.5-30, Junel® FE 1.5-30, Microgestin® FE 1.5-30, Loestrin® FE 1-20, Junel® FE 1-20, Microgestin® FE 1-20, Cryselle®, Low-Ogestrel®, Necon® 0.5-35, Nortrel® 0.5-35, Levora®, Portia®, Apri®, Reciplen®, Solia®, Ortho-Cyclen®️, Norinyl®️ 1+35, Necon®️ 1-35, Nortrel®️ 1-35, Necon®️ 1-50, Norinyl®️ 1+50, Balziva®, Zenchent®, and Yasmin®️
- Add the following agents to non-preferred: Femcon®️ FE, Junel®️ 1.5-30, Microgestin®️ 1.5-30, Junel 1-20, Microgestin®️ 1-20, Lo-ovral®, Modicon®, Brevicon®, Nordette®, Ortho-cept®, Desogen®, Mononessa®, Previm®️, Sprintec®, Ortho-Novum®️ 1-35, Ovcon®️-35, and Ocella®️

High-dose monophasic
- Add the following agents to preferred: Zovia®️ 1-50, Ovcon®️-50, and Ogestrel®️

Biphasic
- Add the following agents to preferred: Mircette® and Necon®️ 10-11
- Add the following agents to non-preferred: Azurette® and Kariva®️

Triphasic
- Add the following agents to preferred: Cylessa®, Estrostep® FE, Ortho-Novum®️ 7-7-7, Ortho Tri-Cyclen®, Ortho Tri-Cyclen®️ Lo, Tri-Norinyl®, Leena®, Aranelle®, Enpresse®, and Trivora®️
- Add the following agents to non-preferred: Cesia®, Caziant®, Velivet®, Tilia® FE, Tri-legest® FE, Necon®️ 7-7-7, Nortrel®️ 7-7-7, Trinessa®, Tri-Previfem®, Tri-Sprintec®, and Tri-Lo-Sprintec®️

Emergency contraceptives
- Add the following agent to preferred: Plan B®️
- Add the following agents to non-preferred: Next Choice®️ (RX) and Plan B®️ One Step

Extended cycle
- Add the following agents to preferred: Loestrin®️ 24 FE, Loseasonique®, Seasonale®, Seasonique®, and Yaz®️
- Add the following agents to non-preferred: Jolessa®️ and Quasense®️ 0.15-0.03 mg

Continuous cycle
- Add the following agent to preferred: Lybrel®️

Public Comment: None

Board Discussion: Ms. Fippen commented on the number of contraceptives and asked if the number of available options was due to financial reasons. Dr. Renshaw commented that the financial aspects were looked at also and this is the way these products sorted out.

Board Action: It was moved and seconded that the DUR Board accept the T Committee recommendations for the oral contraceptive products. The motion passed unanimously.

10. Prenatal Vitamins
Legend generic
  • Add all legend generic prenatal vitamins to preferred
Legend brand-name
  • Add all legend branded prenatal vitamins to non-preferred

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.

11. Xolair® (Omalizumab)
  • Xolair®
    • Add Xolair® to non-preferred with Smart PA criteria

Public Comment: None

Board Discussion: None

Board Action: It was moved and seconded that the recommendation for Xolair® be added to non-preferred with Smart PA criteria. The motion passed unanimously.

12. OTC Formulary Recommendations
  • Cough and cold products
    • Maintain all products as covered, but add an age limit of “4 years of age and older”
  • Topical antiparasitics
    • Add the pyrethrin products to the OTC formulary
    • Maintain permethrin 1% lotion as covered

Public Comment: None

Board Discussion: Referring to the PDL as a whole, Dr. Lindstrom suggested that Xolair® and Synagis® be grouped with the respiratory agents, and likewise, all agents be grouped according to their therapeutic grouping.

Board Action: It was moved and seconded that the recommendation for Xolair® be added to non-preferred with Smart PA criteria. The motion passed unanimously.

EVALUATION OF THE INDIANA MEDICAID PDL PROGRAM REPORT #11: Dr. Renshaw stated that the evaluation period for Report #11 was from October 1, 2008 through March 31, 2009. He also stated the estimated savings to the program from the PDL program (after Federal rebates are considered) and before administrative costs are deducted are approximately $31.63 million. Dr. Renshaw added that supplemental rebate savings after six years of operation are approximately $41.09 million; therefore, the total savings are approximately $72.72 million. He pointed out that the cost to administer the PDL program over the seven-year period is approximately $8.10 million. Dr. Renshaw indicated that the total estimated net savings since the PDL program’s inception (after deducting administrative costs) are approximately $64.62 million.

Dr. Renshaw pointed out several observations that were true of the entire PDL evaluation period and the current evaluation period: 1) Once Indiana Medicaid recipients switched from non-preferred to preferred medications, the vast majority did not switch back to non-preferred medications; 2) No negative impact upon the ability of Indiana Medicaid recipients to obtain medications; 3) There are no statistically significant differences in overall medical expenditures for recipients impacted by the PDL as compared to recipients not impacted by the PDL.

Dr. Renshaw indicated that the total estimated savings (after Federal rebates were considered) were approximately $0.57 million for the current reporting period. He also indicated that associated supplemental rebate savings were approximately $3.10 million. Dr. Renshaw pointed out that the combined PDL program and supplemental rebate savings total was approximately $3.67 million for the six-month reporting period and that the costs to administer the PDL program were approximately $675,000 for the six-month reporting period. He summarized by saying the
net estimated PDL program and supplemental rebate savings after deducting administrative costs for the PDL program was approximately $3.00 million for this reporting period.

Dr. Renshaw stated that the total pharmacy expenditures for the fee-for-service Medicaid program for this report were approximately $156.8 million. He pointed out that the partition of drug expenditures was as follows: 1) Drug classes not subject to the PDL represents 25.4%; 2) Behavioral health drugs, considered as preferred by statute, represents 41.9%; 3) Drug classes subject to the PDL represents 32.7%

Dr. Renshaw indicated that the recommendations for this reporting period are as follows: 1) Continue to review criteria used in prior authorization determinations to verify where such criteria could and should be made more appropriate in ensuring clinically and fiscally responsible drug therapy; 2) Continue analysis of new medications and monitoring for new therapeutic classes in order to determine whether or not PDL updating and/or revisions are necessary; 3) Continue quantity limits on drug therapy to ensure optimization of drug use; 4) Continue step therapy to control costs, shift market share and help ensure appropriate use of PDL medications; 5) Employ SmartPA rules to decrease administrative costs, improve provider relations, and enhance call center efficiency.

In summary, Dr. Renshaw stated, from the first report to the most current report, analyses of the impact of the Indiana PDL program have shown that there is no evidence to suggest that the ability of Indiana Medicaid recipients to obtain prescription medications is being compromised or that quality of care for recipients has suffered as a result of the PDL program. Lastly, Dr. Renshaw stated that the Indiana PDL program has generated an estimated $64.62 million in drug expenditure savings.

There were a few general comments about noted trends in PDL Study #11. It was moved and seconded that PDL Study #11 be approved. The motion passed unanimously.

**UTILIZATION EDITS – QUARTERLY REVIEW/RECOMMENDATIONS:** Dr. Renshaw pointed out to the new members the purpose of the utilization edits for the mental health medications. He stated the intent of these edits is to promote patient adherence to medication regimens and to ensure safe and appropriate use of medications in the Medicaid population. Dr. Renshaw conveyed the following utilization edits from the Mental Health Quality Assurance (MHQAC) meeting: 1) Edluar® 10mg SL tablet - 1/day; 2) Edluar® 5mg SL tablet - 1/day, 3) Invega ER 1.5mg tablet - 1/day, 4) Invega Sustenna 39mg prefilled syringe - 1/28 days, 5) Invega Sustenna® 78mg prefilled syringe - 1/28 days, 6) Invega Sustenna® 117mg prefilled syringe - 1/28 days, 7) Invega Sustenna® 156mg prefilled syringe - 1/28 days, 8) Invega Sustenna® 234mg prefilled syringe - 1/28 days, 9) Nuvigil® 50mg - 2/day, 10) Nuvigil® 150mg - 1/day, 11) Nuvigil® 200mg - 1/day, 12) Nuvigil® 250mg - 1/day, 13) oxazepam 15mg tablet - 4/day; max 120, 14) risperidone 0.25mg ODT - 2/day, 15) risperidone 1mg/1mL solution - 8mL/day, 16) Saphris® 5mg sublingual tablet - 2/day, 17) Saphris® 10mg sublingual tablet - 2/day, 18) Sarafem® 15mg tablet - 1/day, 19) thiothixene 20mg capsule - 3/day. It was moved and seconded that the proposed utilization edits be approved. The motion passed unanimously.

**ACS UPDATE:** Dr. Renshaw presented the prior authorization statistics for the month of October 2009. He stated that there were a total of 3,980 prior authorizations.

**SMART PA RULES PRESENTATION:** Mr. John Stancil, Account Manager from ACS, indicated he was going to present Smart PA rules approved from the T Committee and the MHQAC.

1. **Chantix (varenicline)**
   - Approval criteria – all of the following must be met
     - Age $\geq$ 18 years
     - Less than 12 weeks (84 days) of smoking cessation therapy in the past 365 days
     - Absence of denial criteria
   - Denial criteria
     - Denial diagnosis – claim denies if the patient has not previously tried BOTH nicotine replacement therapy and bupropion in the past two years unless bupropion therapy is contraindicated
       - Depression in past year
       - Suicidal behavior/attemp in past year
       - Psychosis in past two years
     - Currently active claim for nicotine replacement therapy
     - Failure to meet approval criteria
**Public Comment**: Erin Mangan, representing Pfizer on the medical affairs team, did not agree with the denial criteria for Chantix®, as proposed. Dr. Mangan indicated that doctors need all tools available to combat tobacco addiction.

Karen Hudmon stated for the record that she has never received funding from any company. Dr. Hudmon indicated that she wished this recommendation would go back to the drawing board. She stated that smoking is most prevalent in the mentally ill and low income population, and therefore, is a problem for the Medicaid population. Dr. Hudmon also stated the real threat is the continued use of tobacco. She passed around a graph demonstrating the cost effectiveness of the treatment of tobacco abuse compared to the cost of cigarettes.

Debi Hudson, a respiratory therapist and full-time tobacco treatment specialist, indicated that Indiana has the second highest rate of cigarette smoking in the United States. Ms. Hudson said she believed that medical expenditures for the treatment of tobacco addiction would increase if barriers were put in place to prevent patients from receiving Chantix®. She also stated that the tobacco industry targets the mentally ill and low income populations. Ms. Hudson summarized by saying a significant gap exists in tobacco treatment services for people with mental illness, substance abuse, and those of lower income. She indicated this gap will increase if the Chantix® recommendation is implemented.

Clary Butler, Vice-President of External Affairs for Indiana Minority Health Coalition, raised concern over the proposed prior authorization criteria for Chantix®. Mr. Butler indicated that the smoking prevalence is highest in low income and mentally-ill populations, and a majority of which are in minority communities. He also stated that the risk of serious events while taking these products must be weighed against the significant health benefits of quitting smoking.

Tammy Wilson, Medical Outcomes Specialist with Pfizer, read from the Chantix® package insert. In summary, Dr. Wilson stated that the risk of using Chantix® should be weighed against the benefits of use.

Robbie Barkley, former Vice-President of the American Heart Association, indicated that she was standing in for Steve McCaffery of the Mental Health Association of America in Indiana (MHAI). On behalf of Steve McCaffery, Ms. Barkley stated “Because of incredible potential negative impact to the mentally ill population, MHAI recommends that the restrictions proposed for Chantix® be tabled and referred to the MHQAC for further investigation and consideration. The MHQAC possesses expertise in the impact of the drug upon the mentally ill and it is well-suited to evaluate and ensure patient safety with proposed policy. MHAI is a strong supporter of the Smart PA concept; however, at the same time they believe that the algorithms developed for the program must be clinically based. The role of Smart PA in this situation must be to alert the physician of potentially unknown past diagnostic history and then allow the physician to decide the appropriate course of treatment by balancing the risk of treatment versus the risk of addiction. Tobacco remains the single most preventable cause of death in the United States, causing some 440,000 deaths per year. Almost half of these deaths are people with mental health and substance use disorders. About 44 percent of all cigarettes sold in the United States are consumed by people with substance use and with mental health disorders. Persons with mental illness smoke nearly half of all cigarettes produced, but they are only half as likely to quit as other smokers. More than 44 percent of adults with serious mental illness are smokers compared with about 20 percent for society at large. Half of tobacco-related deaths, which would be some 200,000, are among people with mental illnesses. Studies show that people with serious mental illness die 25 years before the general population. Concurrently, this population experiences higher rates of disease and premature death and reduced quality of life. Most will die from smoking related causes. Because the algorithm on Chantix® as presented to this Board raises serious concern about the safety and well-being of the mental health population, MHAI respectfully requests that the matter be sent back to the MHQAC for further consideration.”

Ms. Barkley also stated that the American Heart Association has asked that she relay that they are also concerned about the smoking cessation drugs and they hope that the Board will consider re-evaluating this recommendation. She also stated the American Cancer Society has just received this information on both Chantix® and cancer drugs, and they are asking that they have permission at a later time to address the Board.

Sincear Fountain, Government Account Executive for Novo Nordisk, requested that Levemir® FlexPen be added to preferred status. Ms. Fountain gave information about this product and provided a product demonstration. She also informed the Board that the Novolin® pens and cartridges are the only products that are going to be discontinued. Ms. Fountain added that the Novolog® FlexPen will be available.
After hearing comments to the Board, Mr. Stancil suggested that the Chantix® rule go back to the MHQAC for review at the January meeting. Dr. Philip Eskew voiced his support of this recommendation. Dr. Ott commented that there was not much literature available in clinical trials relating to this issue and mental health but as a MHQAC member, she indicated the committee would certainly take a look at the matter. It was moved and seconded that the proposed Smart PA rule for Chantix® be returned to the MHQAC meeting for review in January 2010. The motion passed with six ayes and one abstention.

2. Sedative Hypnotic/Benzodiazepine Duplicate Therapy
   ♦ Approval criteria
   • Approvable diagnosis – Chronic Sleep Disorder, Anxiety Disorder, Muscle Disorder (diazepam only), Seizure Disorder (clonazepam, clorazepate and diazepam only) AND
   • Both agents involved in the therapeutic duplication are prescribed by or in consultation with a Psychiatrist AND
   • And one of the following
     o The medications involved in the therapeutic duplication are being cross tapered (administered by the Call Center)
     o The medication in history is being discontinued or there are plans to discontinue it (administered by the Call Center)
   • And for call center approvals only
     o Must meet utilization edits
   ♦ Denial criteria
   • Use of two sedative/hypnotics or benzodiazepines for more than 60 of the past 70 days and absence of approval criteria
   • Failure to meet approval criteria

   Notes
   • No PA is required to use trazodone in conjunction with an anxiolytic benzodiazepine
   • No PA is required for diazepam used for a muscle disorder
   • No PA is required for clonazepam, clorazepate or diazepam used for seizure disorder

Dr. Lindstrom asked how the system would understand “or in consult with a psychiatrist”? Mr. Stancil replied that this would be handled by a call center agent. Dr. Treadwell asked if a doctor in a residency program would be approved. Mr. Stancil indicated that this doctor may have to call the call center to explain the situation. It was moved and seconded that the Sedative Hypnotic/Benzodiazepane Duplicate Therapy rule be approved. The motion passed unanimously.

3. Lidoderm® (Lidocaine 2% Patch)
   ♦ Approval criteria
   • Approvable diagnoses
     o Post-herpetic neuralgia in the past year
     o Neuropathic pain in the past two years (must also have a history of at least four weeks of therapy of a tricyclic antidepressant, carbamazepine, oxcarbazepine, gabapentin, pregabalin or topical otc capsaicin in the past year)
     o Requested quantity $\leq$ 3 patches/day
   ♦ Denial criteria
   • Age $< 18$ years
   • Failure to meet approval criteria

It was moved and seconded that the Lidoderm® rule be approved. The motion passed unanimously.

4. Marinol®
   ♦ Approval criteria
   • Malignant cancer in the past two years - Recipient must also have all of the following:
     o Anti-neoplastic or radiation therapy in the past 45 days
     o An oral 5HT3 antagonist or an NK-1 antagonist in the past six months
     o NOT currently receiving megesterol acetate suspension (Megace®)
   • HIV/AIDS in the past two years - Recipient must also have all of the following:
     o Age $\geq 18$ years
A diagnosis of cachexia, anorexia or failure to thrive in the past two years
- A history of megestrol acetate suspension (Megace®) in the past six months
- NOT currently receiving megestrol acetate suspension (Megace)
- Failure to Thrive in the past two years – Recipient must also have all of the following:
  - A history of megestrol acetate suspension (Megace®) in the past six months
  - NOT currently receiving megestrol acetate suspension (Megace)

♦ Denial criteria
  Failure to meet approval criteria

It was moved and seconded that the Marinol® rule be approved. The motion passed unanimously.

5. Xolair® (Omalizumab)
   ♦ Approval criteria
   - All of the following must be met:
     - Age ≥ 12 years
     - Approval diagnosis - Asthma in the past year
     - Chronic asthma controller therapy defined as at least 90 days of therapy in the past 120 days of one of the following:
       - An inhaled corticosteroid (ICS) AND a long-acting beta agonist (LABAs)
       - A LABA/ICS combination product
       - Oral theophylline
       - Leukotriene antagonists
     - Inadequately controlled asthma as defined as one of the following:
       - ≥ 3 canisters of a short-acting beta agonist (SABAs) in the past 60 days
       - History of an oral steroid in the past 45 days
       - History of an ER visit with a primary diagnosis of asthma in the past 45 days
     - Skin testing in the past 90 days or in vitro reactivity to a perineal aeroallergan

♦ Denial criteria
  - Failure to meet approval criteria

It was moved and seconded that the Marinol® rule be approved. The motion passed unanimously.

6. Opioid Overutilization (Long-Acting Products)
   ♦ Approval criteria
     - Long Acting Products – Preferred Generic
       - Absence of denial criteria
       - Fentanyl patches – History of NPO status or dysphagia in the past six months or provider supplied information that the patient is NPO status or has dysphagia
       - NOTE: Patients with a paid claim for fentanyl (Duragesic®) patches within 45 days of the rule implementation date will be grandfathered
     - Long Acting Products – Preferred Brand
       - Absence of denial criteria
       - History of a preferred generic L.A. product in the past six months (excluding claims with an emergency indicator)
       - Call Center approvals only – must meet quantity limits
       - NOTE: Patients with a paid claim for fentanyl (Duragesic®) patches within 45 days of the rule implementation date will be grandfathered
     - Long Acting Products – Non-Preferred
       - Absence of denial criteria
       - Fentanyl Patches (Duragesic®) – history of NPO status in the past six months or provider supplied information that the patient is NPO status or has dysphagia
       - History of at least two different preferred L.A. products (2 different ingredients) in the past six months (excluding claims with an emergency indicator)
       - Call Center approvals only – must meet quantity limits
       - NOTE: Patients with a paid claim for oxycodone ER (Oxycontin®) within 45 days of the rule implementation date will be grandfathered
7. Opioid Overutilization (Short-Acting Products)

- **Approval criteria**
  - Short Acting Products – Preferred and covered
    - Absence of denial criteria
    - Must meet all applicable limits (age, dose and quantity)
  - Short Acting Products – Non-Preferred
    - Absence of denial criteria
    - History of at least two different preferred S.A. products (2 different ingredients) in the past six months (excluding claims with an emergency indicator)
    - Must meet all applicable limits (age, dose and quantity)

- **Denial criteria**
  - Multiple prescribers – 3 or more different prescribers of opiates in the past 60 days
  - Doctor shopper
    - 8 or more opiate claims and
    - 150 days or more supply and
    - Prescribed by 3 or more prescribers and,
    - Dispensed by 3 or more pharmacies in the past 60 days
  - Overutilization
    - With cancer or chronic non-malignant pain diagnosis in the past two years
      - 4 or more different opiate medications and
      - 8 or more opiate claims and
      - 150 days or more supply in the past 60 days
    - Absence of cancer or chronic non-malignant pain diagnosis in past two years
      - 3 or more different opiate medications and,
      - 8 or opiate claims and,
      - 150 days or more supply in the past 60 days

There was much discussion about including approval criteria for fentanyl patches for the diagnosis of NPO status, dysphagia, or hospice care. It was moved and seconded that the opioid overutilization rules be approved with inclusion of approval criteria for fentanyl patches for the diagnosis of NPO status, dysphagia, or hospice care.

**MANAGED CARE ORGANIZATION UPDATE:**
- **Proposed PDL Changes—MDwise:** No updates for the Board.
- **Proposed PDL Changes—Anthem:** No updates for the Board.
- **Proposed PDL Changes—MHS:** No updates for the Board.

**NEW DRUGS:** None.

**LIAISONS WITH OTHER BOARDS:** None.

**PUBLIC COMMENT:** No additional comments.

**OLD BUSINESS:** None.

**NEW BUSINESS:** None.

**MEETING ADJOURNED.**