INTRODUCTIONS

The meeting was called to order by Chairman Powers. Dr. Powers reminded all who were present at the meeting that all committee members are volunteers, appointed by the public act establishing the Pharmacy Advisory Committee (PAC) and that they have signed both confidentiality and conflict of interest statements. The conflict of interest statement was read aloud, and Dr. Powers confirmed that no conflicts of interest had been identified. The members of the Committee introduced themselves. It was noted that quorum was met and the meeting was called to order.

MINUTES

The minutes from the November 8, 2007 PAC meeting were reviewed. Dr. Capparelli stated that after reading the minutes completely, he noticed several spell type errors and one substantive error. On page 8 under the heading Respiratory Agents, Nasal Antihistamines in the discussion under the 1st sub-bullet the sentence should read, “This product does not increase blood pressure or cause urinary retention as can be seen with the oral antihistamines,” not the nasal steroids. Dr. Corley motioned to accept the minutes provided the errors pointed out were corrected. The motion was seconded and approved.

OLD BUSINESS

Dr. Capparelli asked that a revote be considered regarding looking into adding Chantix® to the formulary. Dr. Capparelli pointed out that at the last meeting discussion regarding the coverage of Chantix® took place and the Committee recommended a straw vote from the Committee to add Chantix® be taken back to the legislators. However, a quorum was not present at the time of the last vote; therefore, Dr. Capparelli wanted to take another vote. David Beshara pointed out that the determination of drug class coverage was not under the purview of the committee. Currently smoking cessation is not a covered item due to state budgeting, and based on this year’s budget, this class is unlikely to be added at this time. Dr. Powers read from the minutes of the November 7 meeting regarding the Chantix® issue aloud. Dr. Capparelli motioned that the Committee send a straw vote back to TennCare to cover Chantix® as an effort for cost savings as well as increasing the health status of TennCare enrollees. The motion was seconded and approved with one opposed.

TENNCARE UPDATE

- David Beshara announced that the Request for Proposal (RFP) for pharmacy benefit services was released on Tuesday, 2/5/08. TennCare should be selecting a vendor around mid-April with implementation expected on 10/1/08.
- The RFP for Managed Care Organizations (MCOs) are also in public view. The contract for the West Tennessee area should be awarded in the fall with the eastern portion of the state being awarded 3 months later.
• TennCare is currently in the final stages of putting together guidance on tamper resistant prescription pads. There is some new news from Centers for Medicare and Medicaid Services (CMS) that is being incorporated, and this guidance should be out within the next week. Full blown qualifications are slated to go into effect on 10/1/08; however, TennCare hopes to have their guidance out so that anyone who chooses can order their permanent supply of prescription pads for the 4/1 and 10/1 implementations.

• TennCare had hoped to have the new definition of Average Manufacturer Price (AMP) in place; however this is still under temporary injunction. Once in place, this will be used to determine the Federal Upper Limit (FUL) which will affect generic reimbursements to the pharmacy and the amount of rebates from the manufacturers. The generic piece of this is on hold so there is no information on how this will affect TennCare from a budgetary or fiscal standpoint. The rebate piece is currently in place.

• TennCare is hoping to get through all of the necessary drug categories with the Committee so there would be no need to have extra meetings if a new vendor were chosen through the RFP process.

• Dr. Capparelli pointed out that since there would be no changes to the program until after the implementation of the new Pharmacy Benefits Management (PBM) contract on 10/1/2008, it would be more than 12 months before any changes would be made. Dr. Capparelli pointed out that this was unfair to the providers, enrollees and Committee members. He was concerned about leaving things on hold as dates for implementation keep getting pushed back.
  o David Beshara acknowledged that this was a valid point, but that when the contract is awarded TennCare would be better able to access the possibility of lifting the hold. Some of these program changes may take place prior to the 10/1/2008 implementation date. Mr. Beshara pointed out that he did not want to implement changes, which would change market share, then have to remove those changes a few months later due to new contracting issues with a new PBM. He pointed out that this would also be a disadvantage to the providers and enrollees as well. He envisioned that the new vendor would implement changes leading up to the 10/1/08 implementation date.

• Dr. Capparelli expressed concern over voting on a general recommendation and not a specific list of preferred and non-preferred agents. He was concerned that a new PBM may decide to perform extensive switches of the preferred drugs. He asked Mr. Beshara what kind of disruption he expected.
  o Mr. Beshara stated that contracts may vary from vendor to vendor, but his hope was to stay as consistent with the listing of preferred and non-preferred agents as possible.

• Dr. Capparelli pointed out that a new legislative committee, chaired by Lois Deberry, has been formed to look at asthma as a major health concern. He asked if Mr. Beshara saw anything coming in the form of legislation from that committee that would affect the PAC Committee.
  o Mr. Beshara pointed out that he might not be the most qualified to answer that question, but Dr. Jeanne Jordan has spoken with the legislative committee and he would bring an update to the next meeting after discussing with Dr. Jordan.

**DRUG CLASS REVIEWS**

The drug class review section of the meeting consisted of a First Health Services presentation of background information and an overall recommendation for each therapeutic class, as well as
any proposed clinical criteria, step therapy, or quantity limits. This presentation was followed by the committee’s discussion and vote on the recommendation and any proposed restrictions.

For the purpose of the minutes, the section below reflects First Health’s proposed recommendations, the committee’s discussion, and the committee’s votes on each recommendation and criteria reviewed. For the complete background information provided by First Health Services, please refer to the February 7, 2008 PAC packet at: https://tennessee.fhsc.com/Downloads/provider/TNRx PAC 20080207 Review Packet.pdf

**Respiratory Agents, Short-Acting Beta₂ Adrenergic Agonists:**
⇒ Short-acting beta agonists (SABAs) are the therapy of choice for relief of acute symptoms of asthma and prevention of exercise inducted bronchospasms (EIB). Clinical guidelines from the National Heart Lung, and Blood Institute (NHLBI), American Academy of Allergy Asthma and Immunology (AAAAI) and Medical Advisory Panel for the Pharmacy Benefits Management Strategic Healthcare Group do not distinguish between the available SABAs when it comes to safety or efficacy. Due to the phasing out of CFC inhalers in response to environmental concerns, it is suggested that there be at least one HFA product available as preferred. Given the potential for fewer side effects with levalbuterol, it should be available for those with intolerance to albuterol products.

- **Discussion:**
  - Dr. Capparelli voiced concern over a potential new PBM vendor that might choose agents based on supplemental rebates as opposed to net-net cost. He emphasized the importance of a PBM looking at net-net cost to TennCare versus highest supplemental rebates.
    - Mr. Beshara encouraged the committee to read the RFP, including provisions for the decision making process. He further stated that it is TennCare’s policy, after therapeutic equivalence has been determined, to choose agents based on net cost to the state, regardless of the supplemental rebate to the PBM. Questions regarding the RFP should be directed to the RFP coordinator, Alma Chilton.
  - Concern was voiced that the recommendation does not address the need for a nebulized product to be available. It was pointed out that nebulized products represented 30% of utilization in the 4th quarter.
  - Concern was expressed that there is no HFA product on the short list and no generic HFA products are available, which would require patients to use one of their two branded spots to get these products. It was pointed out that this may limit asthma management since most patients already use the other branded spot for their inhaled corticosteroid.
    - Dr. Hawkins pointed out that these agents are currently on the provider attestation list. In addition, Ventolin HFA® is on the brand for generic list.
    - Committee voiced concern that the attestation list is not user friendly for chronic therapy and therefore has low utilization.
    - Mr. Beshara reminded the Committee that the auto-exemption list and the attestation list are not under purview of the Committee. However, this process is currently under review and TennCare will take into consideration the concerns of the Committee.
o Dr. Capparelli questioned whether the recent changes in Medicare part B coverage of nebulizers would affect coverage of Xopenex® nebulizers under TennCare.
   ▪ Mr. Beshara stated that he would need to do research into this matter though he does not think the changes in Medicare Part B affect TennCare.
   ▪ Dr. Capparelli recommended that if there is no price penalty, at least Xopenex® nebulizer should be moved to preferred. He also pointed out that if all nebulized solutions are the same cost, Xopenex® may be less costly due to decreased frequency of usage compared to albuterol.
   ▪ Dr. Clifford stated that with the advent of using spacers in young children use of the Xopenex® inhaler is increasing. He recommended having at least the Xopenex® inhaler as preferred.

o Dr. Capparelli motioned that we accept the recommendation with the following changes:
   ▪ PBM and TennCare look at net-net cost when picking preferred agents
   ▪ At least one nebulized solution be available as preferred
   ▪ TennCare consider moving Xopenex® nebulizer solution to preferred if comparative in pricing

o Motion was seconded and carried.

• Quantity Limits (QLs) discussion:
  o Dr. Hawkins pointed out that the QLs for these agents have changed, but are based on max daily dose.
  o Motion made and seconded to approve recommendations for the QLs.
  o Motion carried.

• Clinical Criteria for Xopenex® discussion:
  o Dr. Clifford expressed concern about prior authorization (PA) being required for Xopenex® for patients over 2 years old. He pointed out that this is a highly utilized drug due to intolerance to albuterol and that the PA process would be time-consuming for that number of patients.
  o Concern was voiced from the committee that the proposed criteria changed from what was proposed in the 11/07 PAC packet. Dr. Capparelli asked for rationale for the changes in the criteria.
  o Dr. Hawkins stated that the criteria were discussed in depth with a pediatrician on staff at TennCare who felt that the PA age dropping from 10 to 2 years of age would be clinically appropriate. The physician felt that the main reason for not trying albuterol prior to Xopenex® would be in premature infants, and by age 2 the prematurity is not as big of a factor in this decision.
  o Dr. Capparelli cited an article from the Journal of Allergy and Clinical Immunology that was used in determining the previous criteria. This article specifically compared Xopenex® and placebo and showed decreased adverse events with the use of Xopenex® in patients up to age 11. It was also pointed out that the previous criteria allowed for the use of Xopenex® nebulized solution in the elderly population.
  o Dr. Powers pointed out that utilization of Xopenex® is high across the state and that upon discussion with pediatricians across the state, implementation of the proposed criteria would result in a large number of prior authorizations.
  o Dr. Hawkins clarified that we looked at Xopenex® utilization based on age and the majority of usage was in children under the age of 2.
  o Dr. Corley pointed out that if the majority of usage was where we wanted it, maybe we should consider not changing the criteria.
Motion was made and seconded that the criteria for Xopenex® should revert back to the criteria as proposed in 11/07 PAC packet.

- A question was posed about whether the criteria for the nebulized solution in the elderly is needed with the majority of elderly patients covered by Medicare Part D.
- The committee felt it was still needed to cover those patients who do not have Medicare prescription coverage, though it was acknowledged that this patient group is less of a burden to the program than prior to the implementation of Medicare Part D. It was also thought that this patient population has a higher incidence of adverse effects from albuterol nebulizers.

Motion carried.

Respiratory Agents, Inhaled Steroids:

⇒ Efficacy studies clearly show inhaled corticosteroids (ICSs) reduce symptoms, frequency and severity of asthma exacerbations. As a result, improvements in lung function and quality of life have been observed by asthmatic patients. The 2007 NHLBI guidelines list ICSs as the preferred treatment for patients with persistent asthma at every level of severity. Although differences exist between agents in the class in dosage frequency and number of inhalations required for each dose, all ICSs appear to be equally effective when given in equipotent dosages. In order to allow provider choice among the various agents and delivery systems, it is recommended that at least three unique agents be available.

- Discussion:
  - A question was posed by the Committee as to whether mometasone and fluticasone are superior agents due to decreased systemic absorption which may result in fewer adverse events.
    - The Committee was not aware of data to support this statement.
  - Dr. Capparelli asked about the head-to-head studies on page 8 of the packet that compared mometasone and budesonide which seem to indicate mometasone is a superior agent.
    - Dr. Hawkins clarified that NHLBI clinical guidelines, published in August 2007, make no differentiation between the available agents in the class. She also clarified that the mometasone and budesonide doses used in this study were not considered equivalent doses.
  - Discussion ensued regarding questionable superiority of mometasone and fluticasone. Dr. Capparelli stated his understanding was that mometasone and fluticasone were better agents, as it pertains to adverse events, due to decreased systemic absorption compared to triamcinolone or beclomethasone. It was questioned whether triamcinolone or beclomethasone should be moved to non-preferred based on adverse events and systemic absorption.
  - Dr. Hawkins reminded the Committee that we generally try to determine if there is one agent that is superior based on literature or guidelines. If so and there is no evidence to show other agents are more hazardous, then cost can be used as a determining factor for Preferred Drug List (PDL) listing of the other agents.
  - Dr. Powers commented that society guidelines for the treatment of respiratory illness do not differentiate between the inhaled steroids in regards to efficacy. In addition, he reminded the Committee that we try not to make all the decisions for the providers in order to leave room for clinical judgement.
  - Motion was made and seconded to accept the recommendation as presented by First Health.
Motion carried.

- Quantity Limits Discussion:
  - Motion was made to accept the recommendation of the quantity limits.
  - Motion was seconded and carried.

- Clinical Criteria for Pulmicort® discussion:
  - Dr. Hawkins pointed out that until recently Pulmicort Respules® was the only inhaled corticosteroid approved for use in children 6 years old and under; however, last week Asmanex® received an FDA-approved indication for prevention and maintenance of asthma in children ages 4-11, so these criteria may end up being a non-issue.
  - Motion was made and seconded to accept the clinical criteria as presented by First Health.
  - Motion carried.
  - The Committee recommended that Pulmicort® be moved to the preferred side of the PDL with a notation that it is available without a PA for specific ages.

Respiratory Agents, Long-Acting Beta₂ Adrenergic Agents:

⇒ Long acting beta₂ agonists (LABAs) are a mainstay in the treatment of both asthma and Chronic Obstructive Pulmonary Disease (COPD). The 2007 guidelines from the NHLBI recommend a combination of a LABA and an ICS for patients who have moderate to severe persistent asthma (step 4 or higher in children < 4 years old, step 3 or higher in patients 5 and up). These guidelines also recognize the role of a LABA in the prevention of EIB; however, SABAs are preferred for frequent or chronic use. The 2006 Global Initiative For Chronic Obstructive Lung Disease (GOLD) guidelines state regular treatment using a LABA is more effective and convenient than a SABA for the symptomatic management of COPD. Neither of these clinical guidelines distinguishes between the available LABAs when it comes to safety or efficacy.

While proven effective, these agents may increase the risk of asthma-related death; therefore, they should only be used as additional therapy in patients with asthma who are uncontrolled on an ICS. Given the potential safety concerns associated with these agents, it is recommended that all agents in this class be subject to clinical criteria to ensure their appropriate use. The nebulized forms may be beneficial in patients who have difficulty synchronizing breath and actuation using the dry powder inhalers. For this reason, it is recommended that at least one nebulized formulation be available for individuals who have difficulty using a dry powder for inhalation (DPI).

- Discussion:
  - Dr. Capparelli expressed concern that the PBM was overstepping their bounds in trying to regulate the use of these agents by implementing step therapy. Dr. Capparelli stated that he feels the majority of physicians use medications appropriately and objected to the PBM and/or the Bureau acting as a regulatory agency.
    - Dr. Woods clarified that the main intention for the implementation of the class step therapy was in regards to safety concerns with these agents as well as to ensure physicians were aware if a patient was not taking their asthma medication.
    - Dr. Hawkins further clarified that the intention was to put an auto look-back in place at point-of-sale (POS) where if a SABA + ICS is active
on the patient’s profile within a specified amount of time, a PA would not be required.

- Dr. Caparelli stated that as written the criteria would require not only concomitant medication but also a diagnosis, which would require a provider to submit paperwork.
- Dr. Woods stated that the intention of changing the wording in the step therapy was not to change our current practice but rather to more closely reflect the guidelines by differentiating between asthma, EIB and COPD. Dr. Woods asked the committee to discuss what they would like the criteria to look like and what they would like incorporated into an auto look-back that would take into consideration the safety issues associated with this class but at the same time not provide undue problems for the providers requesting the PA.
- Dr. Caparelli suggested a PA not be required for patients currently taking an ICS + SABA. For patients not meeting those criteria, leave wording as is in the second and third bullet points.
  - Dr. Caparelli expressed concern that although the recommendation states “at least one nebulized formulation be available,” all of the nebulized formulations are listed as non-preferred.
    - Dr. Hawkins clarified that the nebulized formulations are available if the patient meets the criteria that they cannot use the DPI.
    - Dr. Caparelli stated that he thought this would fall under the general PA criteria.
    - Dr. Hawkins clarified that the general PA criteria state that a patient must try and fail the preferred agent. The proposed criteria would allow for patients to get the nebulizer without trial and failure of a preferred DPI if it is deemed the patient cannot use a DPI.
  - Motion was made and seconded to accept the recommendation as presented by First Health.
    - Dr. Caparelli again expressed concern over the sentence that states “to ensure appropriate use,” which seemed to indicate that the PBM knows better than the providers.
    - The Committee brought up that these agents all have black box warnings in their labeling.
    - Dr. Caparelli stated there are many agents with black box warnings and there are not clinical criteria in place for every one of those categories.
    - Dr. Woods restated that the intention of the criteria was to guard against safety concerns not to insinuate that doctors are prescribing these agents inappropriately. She further recommended that if the Committee agreed that clinical criteria was deemed necessary for these class, perhaps the sentence could be reworded.
    - Dr. Hawkins recommended deleting the phrase “to ensure appropriate use.”
  - Motion was amended to accept the recommendation as presented by First Health with the deletion of the phrase “to ensure appropriate use.”
  - Motion carried.

- Quantity Limits Discussion
  - Dr. Corley expressed concern that the quantity limits proposed do not reflect units of billing.
• Motion made and seconded to approve recommendations for the QLs with the stipulation that the QLs be published in units billed.
  • Motion carried.
• Clinical Criteria for Serevent Diskus® and Foradil® discussion:
  o See above discussion under recommendation section
  o Motion was made and seconded to accept the criteria with the following changes:
    ▪ Delete the phrase “a diagnosis of asthma (step 3 or higher, or moderate persistent to severe persistent) and” in the first bullet point
    ▪ Add a statement that no PA is required for patients receiving a SABA + ICS
  • Motion carried.
  • The Committee also recommended that an auto look-back for SABA + ICS be incorporated.
• Clinical Criteria for Brovana® or Perforomist® discussion:
  o Motion was made and seconded to accept the criteria as presented by First Health.
  • Motion carried.

**Respiratory Agents, Long-Acting Beta2 Agonists/Inhaled Corticosteroid Combinations:**  
⇒ The combination of an ICS and LABA is a reasonable agent for the treatment of asthma and COPD. There is insufficient evidence to show that one combination product is superior to another; therefore, these agents are assumed to be therapeutically equivalent. The 2007 NHLBI guidelines recommend the addition of a LABA to an ICS for patients of all ages whose asthma is not controlled on an ICS alone. The 2007 GOLD guidelines suggest the addition of an ICS to a LABA for patients with severe COPD whose symptoms cannot be controlled on a LABA and as needed SABA. Based on these guidelines and the current medical literature, it is recommended that the combination LABA/ICS agents be reserved for asthma patients who require frequent use of an inhaled short-acting bronchodilator while maintained on an optimal dose of an inhaled steroid, and for COPD patients who have symptoms despite optimal doses of a LABA.

• Discussion:
  o The Committee pointed out that the black box warning in this category is based on one study that involved Serevent® only and that the FDA has extrapolated this data to include all products that contain salmeterol. It was further clarified that there has not been a reported case of death related to any of the combination products.
  o It was noted that there are differences between the two available agents in this class specifically Advair® is indicated in patients age ≥ 4 while Symbicort® is indicated in patients age ≥ 12. Additionally, it was noted that Symbicort® does not have an FDA-approved indication for COPD.
  o Dr. Woods asked for input from the Committee about whether they felt it was reasonable to use Symbicort® in COPD patients regardless of the fact it does not have an FDA-approved indication.
  o The Committee felt this may become an issue if Symbicort® were to become the sole preferred agent due to both differences in FDA-approved indications and ages.
  o The Committee questioned whether the potential exists for a new PBM to change the PDL status of the agents.
Mr. Beshara pointed out that this potential exists even with the current PBM. He further clarified that if the Committee feels there is a situation where one of these agents is preferred in a certain subset of the population, then the recommendation needs to reflect that.

Dr. Hawkins noted that current clinical guidelines do not prefer one product over another in this class despite differing indications, so we assume they are equally efficacious.

Dr. Capparelli pointed out that the Committee has a history of trying to stay within FDA-approved indications.

Dr. Hawkins also pointed out that if there is a unique FDA-approved indication for an agent or peer-reviewed literature to support use of one agent over another for a specific indication, that agent would be approvable.

- It was also noted that compliance is improved with the use of these agents compared to the individual components.
- Motion was made and seconded to approve the recommendation of First Health as proposed.
- Motion carried.

- Quantity Limit discussion:
  - Dr. Corley expressed concern that the quantity limits do not reflect units of billing.
  - Motion was made to approve recommendations for the QLs with the stipulation the QLs are published in units billed.
  - Motion seconded and carried.

- Clinical Criteria for Advair®/Symbicort® discussion:
  - The Committee questioned whether an auto look-back could be incorporated for either: combination of SABA + (ICS or LABA) for approval of these agents.
  - Dr. Hawkins stated that the capability of the system would have to be researched.
  - Committee also questioned whether these agents would be approved for exercise-induced bronchospasm.
  - Dr. Hawkins clarified that as the criteria are written these agents would not be approved for EIB. In addition, these agents are not FDA-approved for this indication.
  - **Motion was made and seconded to table vote on criteria until First Health can look into possibility of auto look-back for this class.**
  - Motion carried.

**Respiratory Agents, Inhaled Anticholinergics:**
⇒ Inhaled anticholinergic agents can reduce or abolish symptoms, increase exercise capacity, reduce the number and severity of exacerbations and improve the health status of patients with COPD. While current clinical guidelines do not distinguish between products, head to head studies seem to indicate that the long acting agent tiotropium may produce better efficacy and safety compared to ipratropium. Therefore, to allow for prescriber choice, it is recommended that at least two agents, one of which should be tiotropium, be available.

- **Discussion:**
  - The Committee expressed concern that there is no direction given in the recommendation regarding the availability of a nebulized solution.
  - Motion was made to approve First Health’s recommendation as presented with the addition of a statement that at least one nebulized formulation be available.
• Motion was seconded and carried.
• Clinical Criteria for albuterol/ipratropium and Duoneb® discussion:
  o The committee asked for clarification of the proposed criteria.
  o Dr. Hawkins clarified that if a patient has used the individual agents and failed for compliance or other issues, the combination product would be approved.
  o Concern was voiced from the Committee that since the Duoneb® product is listed as a non-preferred agent patients would be required to use the individual agents which would count as two scripts toward the five script limit.
  o Dr. Hawkins informed the Committee that albuterol nebulized solution has been on the Auto-Exemption list since the asthma category was added, and ipratropium nebulized solution was added to the Auto-Exemption list within the last few weeks.
  o Concern was voiced from the Committee that there may be confusion in the call center as to whether the criteria applies to Combivent® or Duoneb® since the word “nebulizer” is not in the title of the criteria.
  o Motion was made and seconded to approve the criteria as presented by First Health with the phrase “nebulized solution” added in the title.
  o Motion carried.
• Quantity Limits discussion:
  o Motion to approve the recommended quantity limits as proposed.
  o Motion seconded and carried.

Respiratory Agents, Leukotriene Modifiers:
⇒ According to the NHLBI, inhaled corticosteroids are the cornerstone of treatment for asthma. Leukotriene modifiers (LTRA) should be considered as a potential alternative or add-on therapy for those patients with persistent asthma. Guidelines indicate that leukotriene modifiers can be used as controller medications in the treatment of asthma particularly for those ages four and under. For patients ages five and older, the preferred adjunctive therapy to inhaled corticosteroids is a long-acting inhaled beta agonist (rather than a leukotriene modifier). Leukotriene modifiers are beneficial in the treatment of allergic rhinitis (AR), but should be considered second line medications after trial and failure of topical nasal steroids and minimally sedating antihistamines.

• Discussion:
  o Concern was expressed from the committee regarding the high utilization of these agents. It was pointed out there were 56,000 inhaled SABA prescriptions, only 20,000 prescriptions for ICS and 54,000 prescriptions for Singulair® in the fourth quarter despite clinical criteria being in place. While the Committee acknowledges there are cases where use of Singulair® for AR is appropriate, for example, when antihistamines are intolerable or contraindicated, they felt this agent is being over-utilized in the TennCare population.
  o Dr. Hawkins informed the Committee that the utilization is of concern to the Bureau and First Health as well. The current criteria allows for automatic approval in recipients ages 21 and under regardless of indication. First Health is recommending a change to the clinical criteria, specifically for allergic rhinitis, in an effort to decrease utilization.
  o The Committee questioned whether Singulair® usage has been broken down according to age of recipient.
Dr. Woods stated that the Bureau and the Drug Utilization Review (DUR) board have looked at both the age and indication break down and she believed the majority of the utilization was in patients under the age of 21. In patients under 21, approximately 50% of utilization was for allergic rhinitis.

Dr. Clifford pointed out that with the introduction of Singulair granules®, it is now being used in much younger patients.

Motion was made and seconded to accept the recommendation as presented by First Health.

- Discussion ensued about the place of LTRAs in the asthma guidelines according to age. It was noted that LTRAs are listed as a controller medication option in all children, not just those ages four and under.

- Motion was amended to approve the recommendation as presented by First Health with the deletion of the phrase “particularly for those ages four and under. For patients aged five and older, the preferred adjunctive therapy to inhaled corticosteroids is a long-acting beta agonist (rather than a leukotriene modifier).”

- Motion seconded and carried.

- Quantity Limits discussion:
  - Motion to approve the recommendation as proposed.
  - Motion seconded and carried.

- Step Therapy for Singulair® discussion:
  - Concern was expressed from the Committee regarding patient populations in which non-sedating antihistamines or nasal steroids would not be appropriate.
    - Dr. Clifford recommended changing criteria for allergic rhinitis from “non-sedating antihistamines and a nasal steroid” to “non-sedating antihistamines or a nasal steroid” due to the difficulty of getting pediatric patients to cooperate with nasal steroids.
    - Dr. Capparelli stated he had concerns with requiring use of non-sedating antihistamines in adults with poorly controlled hypertension or benign prostatic hyperplasia (BPH). A trial of antihistamines in these patients would not be appropriate and he suggested adding “or intolerance to” to the allergic rhinitis criteria.
  - Motion was made to approve the clinical criteria with the addition of the phrase “or intolerance to” to the allergic rhinitis criteria.
    - Dr. Powers asked if the criteria for allergic rhinitis should read “non-sedating antihistamine and/or nasal steroid.”
    - Dr. Hawkins clarified that the current allergic rhinitis guidelines recommend using a nasal steroid or an oral antihistamine as first line therapy, then proceed to combination therapy if first line therapy was unsuccessful. The intent of the proposed criteria was to ensure patients had tried combination therapy before proceeding to Singulair®.
    - Dr. Woods further clarified that our current criteria for allergic rhinitis for adults require both a nasal steroid and an oral antihistamine.
    - Dr. Capparelli expressed concern that there are certain groups of patients in which use of both agents is not possible due to a contraindication. He suggested adding “or intolerant to one of the agents.”
    - Dr. Woods clarified that if a patient was intolerant to one of the agents, they would still have try and fail the other agent. She suggested adding “intolerance to or contraindication to” to the allergic rhinitis criteria.
Motion was amended to approve the step therapy criteria as presented with the addition of the phrase “or intolerance to or contraindication to” to the allergic rhinitis criteria.

Motion was seconded and carried.

The Committee recommended an auto-look back for this category to decrease the number of prior authorizations required.

-Lunch Break-

**Respiratory Agents, Anti-Asthma Monoclonal Antibodies:**

⇒ Omalizumab is used in allergic asthma because it limits the release of the mediators of the allergic response. Omalizumab has been shown to reduce asthma related symptoms and improve quality of life in patients with severe persistent allergic asthma. It is recommended that omalizumab be available for patients with moderate or severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with the combination of an inhaled corticosteroid and a long acting beta agonist.

- Discussion:
  - Motion was made and seconded to approve the recommendation as presented by First Health.
  - Motion carried.

- Clinical Criteria for Xolair® discussion:
  - Dr. Hawkins noted this is a situation where the initial PA would be approved for 6 months only and subsequent PA renewals would be granted upon verification of marked clinical improvement.
  - Concern was expressed from the Committee that terminology “Step 5 asthma” is included in the Clinical Criteria which may pose some confusion due to the recent changing of severity terminology in the NHLBI guidelines.
    ▪ Dr. Hawkins clarified that the terminology “moderate to severe persistent” is also included to avoid confusion.
  - Concern was expressed from the Committee that age is not part of the proposed clinical criteria, but merely a note in the criteria.
    ▪ Dr. Hawkins clarified that this is a change to the current criteria which state patients must be older than 12 years of age for approval. The note is intended to be a caution to the physician only.
    ▪ Dr. Capparelli expressed concern that most providers do not access the clinical criteria documents and therefore, will not know about this note. He proposed if there is a significant safety issue in this patient population, perhaps something further needs to be in place to restrict use.
    ▪ Dr. Hawkins clarified the intent of the proposed criteria was not to be denied based on age. This agent is not contraindicated in patients less than 12 years of age, but it has not been studied.
  - Motion was made and seconded to approve the clinical criteria as presented by First Health.
    ▪ Dr. Capparelli again expressed concern about whether language needs to be included in the criteria regarding the caution in patients under the age of 12 years old.
- Dr. Hawkins recommended we incorporate this caution into the script from the call center to alert providers that there are no studies in patients < 12 years of age.
  - Motion carried.

**Respiratory Agents, Anti-Viral Monoclonal Antibodies:**

⇒ Palivizumab is effective as a preventative therapy against severe viral lower respiratory tract infection in pediatric patients at high risk for Respiratory Syncytial Virus (RSV). The American Academy of Pediatrics (AAP) has very specific recommendations about the patient population that has been shown to benefit from palivizumab therapy. Therefore, it is recommended that palivizumab be available for use during RSV season in patients who meet the high-risk criteria set forward by the AAP.

- Discussion:
  - The Committee questioned whether the clinical criteria should be included in the recommendation.
    - Dr. Hawkins and Dr. Woods noted that it is our general policy to keep the two components separate in the event the current guidelines were to change. This would also prevent us from having to bring the entire class back to PAC if the guidelines were to change.
      - Motion was made to accept the recommendation as presented by First Health.
      - Motion seconded and carried.
  - Clinical Criteria for Synagis® discussion:
    - Dr. Hawkins noted the clinical criteria mimic the AAP guidelines with the addition of tobacco smoke as an environmental air pollutant and the addition of low birth weight as a risk factor.
    - Motion was made and seconded to approve the Clinical Criteria as presented by First Health.
    - Motion carried.

**Central Nervous System Agents, Antihyperkinesis Agents:**

⇒ The stimulants and atomoxetine are approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), while the stimulants are also approved for the treatment of narcolepsy. Current treatment guidelines from the AAP place stimulants as first line therapy for ADHD. Although FDA-approved indications vary regarding age of treatment, all of the stimulants have similar efficacy and adverse event rates, and current guidelines make no differentiation between the available agents, formulations, or dosage forms. Therefore, all of the stimulants can be considered therapeutic alternatives to one another, though extended release agents may be preferred in some settings due to difficulties with multiple daily dosing. As stated in the AAP guidelines, it is reasonable to switch to another stimulant agent if there is an inadequate response or intolerable adverse reaction to a single agent. In order to allow for patient and prescriber preference, it is recommended that at least two distinct stimulant agents be available, one of which should be an extended release formulation. Based on available clinical trials, atomoxetine can be considered a second line agent behind the stimulants for the treatment of ADHD; however, given its low abuse potential, atomoxetine has utility in cases of suspected drug abuse; therefore, its use should be reserved for these instances.

For the treatment of narcolepsy, modafinil, amphetamine, methamphetamine, dextroamphetamine, and methylphenidate are all reasonable treatment alternatives. The current literature indicates that modafinil may be better tolerated than traditional stimulants for the
treatment of excessive daytime sleepiness. In addition, the European Federation of Neurological Societies (EFNS) recommends modafinil as first line therapy for narcolepsy. Therefore, modafinil should be available for use in hypersomnia with clinical criteria to restrict its use to approved indications only.

- Discussion:
  - Dr. Fitzpatrick stated that she had spoken with other practitioners and they were very pleased to have Concerta® as preferred. She noted that clinically practitioners were seeing that Vyvanse® truly has a longer duration of action than Concerta® and Adderall XR®. Many other extended release products do not last the full 12 hours and it becomes necessary to add an immediate release product at the end of the day. Vyvanse® also has a decreased abuse potential because it is a prodrug and does not become active until ingested. This makes providers feel more comfortable in populations where they are concerned about potential abuse. The cost seems to be similar to the other agents in the class as well and may be less expensive if an immediate release product is not needed at the end of the day.
  - Dr. Fitzpatrick had also spoken with other practitioners from the field of mental health about Strattera®. She notes that Strattera® does not have the same efficacy as seen with other stimulants; however, the abuse potential is less. This agent is also very useful in children who do not tolerate a stimulant due to anxiety or moodiness and in patients with Tourette’s syndrome or other tic disorders which can be worsened by stimulants.
  - Dr. Fitzpatrick also asked that we possibly incorporate an auto look-back to prevent PAs if these agents are not going to be preferred. The PA process is very time consuming.
  - Dr. Clifford agreed that Vyvanse® indeed lasts longer and requested that this item be preferred.
  - Dr. Fitzpatrick stated that she was hearing Vyvanse® is not priced higher than the other agents and asked why Vyvanse® would not be added to the PDL if it’s not a cost issue.
    - Mr. Beshara stated that, if in a stable contract environment, it would be added as a preferred agent. However, if a new contract is put into place, this item would have to be re-evaluated.
  - Dr. Capparelli stated that sending pills to school poses a real convenience problem due to additional paperwork and depending on school nurses for proper administration. As he understands it, the abuse potential of Vyvanse® is lessened due to the decreased buzz. He also noted that the abuse potential is less because addicts have not discovered how to abuse the drug as of yet since it has to be activated first. He stated that we needed either Vyvanse® or Strattera® as preferred.
  - Dr. Fitzpatrick pointed out that Vyvanse® is indeed more efficacious than Strattera® in the opinion of psychiatrists; however, there was still a population of patients who would benefit from Strattera® and not just those who are prone to abuse (e.g., patients with tic disorders). She suggested incorporating an automatic look-back for a stimulant in order to allow automatic PA approval.
  - Dr. Pittman asked if there was a case where Strattera® would be used first line.
    - Dr. Fitzpatrick stated that she did not usually use Strattera® first; however, there are some cases where Strattera® would be used first-line including drug abuse related issues and tic disorders.
Mr. Beshara asked if there was any literature to support better efficacy/safety for either Vyvanse® or Strattera® to be added to the recommendation. He further stated that the Bureau was generally very conservative in their stance on new products due to safety concerns not always being present at the time of initial drug launch.

- Dr. Fitzpatrick agreed that most studies do not recommend one agent over another. However she does note that parents are seeing Vyvanse® lasts longer even into the early homework hours. She notes that this may prevent the need for additional stimulants.

- Dr. Capparelli noted that there was already a fair market share for an agent that was very new to the market. He noted that the Committee voted to have an agent with less abuse potential added to the PDL at the last review of this class, and Strattera® was the only option at that time. If Vyvanse® is as effective with less abuse potential, it would fulfill the requirements.

- Ms. Govette pointed out that she used Strattera® for new adult patients that claim to have Attention Deficit Disorder (ADD)/ADHD because of its lesser potential to be abused since there is no testing scale for the diagnosis of adult ADD/ADHD. Since Vyvanse® is not indicated for adults, Strattera® has been her agent of choice for situations such as these.

- Mr. Beshara stated we would create a PA fax form for Strattera® to help make the PA process less cumbersome.

- Dr. Capparelli stated he still has problems with tracking patients down after the PA has been approved. It would be much simpler to be able to give the patient a prescription and not worry about the PA process.

- Dr. Fitzpatrick motioned that we accept the recommendation with moving Vyvanse® to preferred on the PDL. She also asked that a look back be implemented and a fax form be developed for Strattera® to make the PA process easier.

- Dr. Pittman asked if we needed to reword the recommendation.
  - Dr. Capparelli stated that it appeared that Vyvanse® had similar effectiveness and longer duration of action compared to the other agents. He asked that we have Vyvanse® as one of the preferred agents. For Strattera®, he stated that the recommendation should not only include the use in abuse situations, but allow for its use in tic disorders as well.
  - Dr. Fitzpatrick asked if moving Vyvanse® to preferred would cause Adderall® XR to be moved to non-preferred leading to disruption for those who are already stable.
    - Mr. Beshara stated that was a possibility, but disruption to the current users would be considered.
  - Dr. Fitzpatrick asked why the recommendation required the only two agents be preferred.
    - Dr. Woods stated that it was usual policy to require that about half of the unique agents be available. It was conveyed that the recommendation could be reworded to require at least 3 agents.

- Dr. Capparelli pointed out that utilization of immediate release products is very low in comparison to extended release.
  - Dr. Pittman pointed out that she understood the immediate release products were usually used in very young children.
  - Dr. Fitzpatrick agreed, however she noted that she also used these products for instances where extended release preparations wore off
too early and in anorexic patients. She stated that the extended release preparations are usually started first line.

- Dr. Capparelli asked if the extended and immediate release products would be considered a therapeutic duplication.
  - It was noted that these agents do not deny for therapeutic duplication.
- Dr. Clifford noted that by adding Vyvanse® to the formulary it may save money due to decreasing the need for a second dose of an immediate release product. He also made the point that everyone reacts differently to any given medication. He stated that sometimes he will start out with an agent due to family history of success with a given agent. He asked that we have Strattera® preferred as well.
  - Mr. Beshara responded that he understood the request to have Vyvanse® available as preferred if it is considered a superior agent due to its long duration of action; however, he made the point Strattera® was an inferior agent with regards to efficacy. He argued that it should be subject to criteria to allow for its use in appropriate patients.
- Dr. Fitzpatrick made the comment that the proposed criteria for Strattera® did not allow for its use in those with tic disorder.
  - Mr. Beshara stated we could look at the criteria, but he still struggled with placing an inferior agent as preferred.
  - Dr. Pittman suggested we add these specific patient populations to the criteria.
- Ms. Govette stated that she fills out the PA and sends it to the pharmacy along with the prescription, so the pharmacy can fax it in to help prevent communication issues.
- Mr. Beshara asked the Committee when they would use Strattera® over Vyvanse®.
  - Dr. Fitzpatrick stated she would use it in cases of intolerance to stimulants manifested by agitation, obsession, moodiness, and aggression, or in patients with tics or tic disorders such as Tourette’s.
- Dr. Woods asked if we could address all of the concerns in the recommendation if we required three distinct agents be available, one of which should be Vyvanse®. Then have the last sentence state that either Strattera® or Vyvanse® be available for those with abuse potential and Strattera® be available for those with tic disorders.
- Dr. Capparelli made the point that Strattera® was so different from the stimulants it made sense to recommend that both Strattera® and Vyvanse® be preferred agents due to different utilizations.
- Dr. Capparelli motioned that we accept the recommendation with the following changes:
  - Strike the phrase, "in some settings"
  - Recommend at least 3 distinct agents be preferred, at least one of which should be an extended release formulation.
  - Delete the phrase, “therefore its use should be reserved for these instances”
  - Add both Strattera® and Vyvanse® as preferred and unrestricted since they have unique indications and uses.
- Motion was seconded and carried.
- Mr. Beshara asked the committee what they would expect the market share to be if Strattera® were unrestricted.
Dr. Fitzpatrick did not expect the utilization to go up due to its lower efficacy.

Dr. Capparelli stated he would be flabbergasted if it went above 10%. He thought it would only make it easier for those who needed Strattera® to get it.

Both Dr. Fitzpatrick and Dr. Capparelli stated that they did expect the Vyvanse® market share to increase, though, given that some of the Adderall® XR market share would move to Vyvanse®.

Dr. Pittman asked if the committee had used Daytrana® specifically in instances of difficulty sleeping. She asked if it was common to prescribe Daytrana® in these instances so that the patch could be removed early to allow for ease in falling asleep.

Dr. Fitzpatrick stated that this may be a concern in a very small number of patients; however, she used this product more frequently in those who were unable to swallow. She asked what TennCare was hearing as reasons for approving Daytrana® and if this was a common complaint.

Dr. Woods clarified that she had only heard this complaint from one physician.

Dr. Hawkins verified that these types of cases are not coming through reconsiderations.

• Quantity Limits discussion:
  o Dr. Fitzpatrick brought up the issue that Concerta® now had an FDA approved indication for 72 mg daily in adolescents, and she asked that we adjust the quantity limits of the 36 mg strength to 2/day to allow for this dose without a PA.
  o Motion was made to approve the quantity limits with the exception of the 36 mg Concerta® being changed to 2 per day.
  o Motion seconded and carried.

• Clinical Criteria for Provigil® discussion:
  o Dr. Fitzpatrick asked if we could create a PA fax form for this product, as well.
    ▪ Dr. Hawkins stated this was not currently in the pipeline, but it could be added if needed.
  o Dr. Capparelli requested that we have the PA fax forms linked to the criteria.
  o Dr. Fitzpatrick expressed agreement with the proposed criteria, stating that for ADHD other agents would be tried before Provigil; however, this agent may be tried first for sleep disorders.
  o Dr. Capparelli noted that this drug has been life changing for his patients with sleep disorders.
  o Motion to accept the criteria as written.
  o Motion seconded and carried.

• Clinical Criteria for Strattera® discussion:
  o Dr. Powers asked if we should discuss the criteria for Strattera® since the committee wanted it removed.
  o Mr. Beshara asked that the criteria be discussed, in case Strattera® remained non-preferred on the PDL.
  o Dr. Powers and Dr. Capparelli asked that we modify the criteria to add tic disorders/ Tourette's syndrome.
  o Dr. Capparelli asked if this agent would be approved only for college students or for adults as well.
Dr. Hawkins clarified that the agent would be approved regardless of age if there is abuse potential with the patient or patient’s family, as well as for use in college.

- Dr. Pittman clarified that this would only be approved for those with ADHD/ADD.
- Dr. Fitzpatrick requested that we have a PA fax form for this agent if it was not made preferred.
- Motion to amend the criteria as follows: Strattera will be approved (without prior trial and failure of a stimulant) if one of the following is met:
  - For a question of substance abuse with the patient or patient’s family
  - For use while in college
  - For Tic disorders/Tourette’s syndrome

Motion seconded and carried.

Central Nervous System Agents, 5-HT₁ Receptor Agonists:

⇒ Triptans are approved for the acute treatment of migraine attacks with or without aura in adults, and they are recommended as possible alternatives to non-steroidal anti-inflammatory drugs (NSAIDs). Although available data shows mixed results, and the onset of action may vary slightly among agents, all of the triptans have similar efficacy and safety. However, it is reasonable to switch to another triptan if there is an inadequate pain response or intolerable adverse reaction to a single agent. Therefore, it is recommended that at least two distinct triptans be available. In order to ensure patient and provider choice, it is recommended that at least one non-oral dosage form be available for patients with migraines associated with nausea.

- Discussion:
  - Dr. Clifford asked how we would define adults.
    - Dr. Woods clarified that we were only referring to FDA-approval, not recommending any sort of age limit for this class.
  - Dr. Capparelli pointed out that the nasal sprays don’t seem to be as effective as tablets or injectables. He asked if patients would be able to receive both a different oral agent and injectable Imitrex®. He stated that other triptans should not be used within 24 hours of the Imitrex injection.
    - Dr. Pittman stated that it would hit as a therapeutic duplication.
    - Dr. Woods stated she was not sure this edit was turned on, but we could find out.
  - Dr. Capparelli also stated that we needed to have the Imitrex® injectable kit as preferred due to the vision impairment often accompanied with a migraine. It would be almost impossible for a patient to see to draw a dose out of a multiuse vial.
  - Dr. Corley noted that he was not aware that the Imitrex® even came in a vial. He stated he has only dispensed the kit.
  - A motion was made that the recommendation be amended to include at least one oral agent, at least one nasal formulation, and at least one injectable kit.
    - Motion seconded and carried.

- Quantity Limits discussion:
  - Dr. Corley motioned to approve the quantity limits as proposed.
  - Motion seconded and carried.

Central Nervous System Agents, Serotonin Noradrenaline Reuptake Inhibitor (SNRIs):

⇒ The SNRIs, duloxetine and venlafaxine, are FDA-approved for the treatment of generalized anxiety disorder and major depressive disorder (MDD). Duloxetine is also approved for the
management of diabetic peripheral neuropathic pain (DPNP). Venlafaxine carries an additional FDA-approved indication for the treatment of social anxiety disorder. Current National Institute for Clinical Excellence (NICE) guidelines for the management of depression recommend Selective Serotonin Reuptake Inhibitor (SSRIs) as first line therapy for the treatment of depression, with SNRIs and tricyclic antidepressant (TCAs) as second line therapy. The primary role of SNRIs is as an alternative in patients with MDD who have responded poorly to other agents. For the treatment of anxiety disorders, current guidelines recommend SSRIs as first line therapy, with the SNRIs and TCAs as second line options. Due to the lack of comparative trials and mixed results from meta-analyses, it is unclear whether any significant clinical differences exist between the available SNRIs for the treatment of MDD or anxiety disorders. However, the guidelines do not distinguish between the available SNRIs for either of these indications. For the treatment of DPNP, current guidelines place duloxetine as a first-tier agent.

Based on this information, venlafaxine and duloxetine can be considered therapeutic alternatives to one another for the treatment of MDD and anxiety disorders. It is recommended at least one SNRI be available with step therapy to restrict its use to patients who have responded poorly to SSRIs. Additionally, it is recommended that duloxetine be available for use in the treatment of DPNP.

- **Discussion:**
  - Dr. Fitzpatrick expressed agreement with the recommendation. She pointed out that sometimes a SNRI will be used first line if there is a family history of doing well with SNRIs rather than a SSRI; however, this is rare. A SSRI is commonly started first.
  - Dr. Zoorob motioned to accept the recommendation of First Health.
  - Motion seconded and carried.
- **Quantity Limits discussion:**
  - Dr. Fitzpatrick asked whether a 150mg and a 75 mg tablet could be used if a 225 mg daily dose was needed.
    - Dr. Pittman confirmed that two strengths could be used together and that there were edits in place to prevent that from counting as 2 scripts.
  - Ms. Govette motioned to approve the quantity limits as proposed.
  - Motion seconded and carried.
- **Class Step Therapy discussion:**
  - Dr. Fitzpatrick asked for clarification on what was meant by “maximum tolerated dose” and whether this was left up to the prescriber.
    - Mr. Beshara noted that prior to this edit some prescribers would switch from a low dose of an SSRI to an SNRI without ever increasing the SSRI dose.
    - It was pointed out that this was simply a question being asked by the call center and there was not a definite SSRI dose required for approval.
  - Dr. Powers cautioned that lower doses were commonly used in geriatric patients and side effects, often gastrointestinal (GI) side effects, were the reason to switch to a SNRI.
  - A motion was made to accept the recommendation of First Health.
  - Motion seconded and carried.
- **Clinical Criteria for Cymbalta® discussion:**
Dr. Capparelli asked if this could be done as an automatic look-back so that the PA would be approved if diabetic medications were on the patient’s profile.

- Dr. Hawkins stated she would look into adding an ICD-9 override.
- Dr. Capparelli asked if all pharmacists were aware of how to do an ICD-9 override.
- Dr. Hawkins stated that TennCare and First Health were looking at ways to educate the provider community about how to submit ICD-9 codes with claims. There is actually a seminar going on now through UT to educate pharmacists about this override. Also there is a possibility of adding educational material to the website.

Dr. Fitzpatrick asked if there was a list of ICD-9 override codes on the website.

- Dr. Hawkins confirmed there was a list posted to the web.

Dr. Woods stated that an educational initiative for the prescribers was in the works through the DUR program and a fax blast to the pharmacies was possible.

Dr. Powers asked about the use of Cymbalta® for non-diabetic neuropathic pain and chronic pain syndrome. He stated that it may be reasonable to add Cymbalta® for those who are inadequately controlled on a narcotic plus an agent for neuropathic pain such as gabapentin.

Dr. Fitzpatrick asked if we could approve Cymbalta® for those with chronic pain syndrome and depression. She stated that often the patient would have already tried a SSRI.

Dr. Hawkins asked the Committee if we should open the criteria to allow for use in non-diabetic neuropathic pain after trial and failure of 2 agents commonly used to treat neuropathic pain. She further suggested that a third bullet point could include concomitant diagnoses of pain and depression.

Dr. Capparelli expressed his concern over actually putting this proposed criteria into effect as there are limited studies and no FDA-approved indication. He stated that the Committee always tried to stick pretty closely to guidelines and literature. He stated that while valid he thought we should wait until there was more literature to support this.

Dr. Hawkins stated she felt comfortable allowing Cymbalta® use for non-diabetic neuropathic pain after trial and failure of two other agents as there are not many other treatment options. She asked if this should be internal criteria or published to the medical community.

Dr. Capparelli stated he thought it would be wise if these criteria were kept internal. When more literature to support this practice was published, this could be made part of the criteria.

Dr. Fitzpatrick motioned to add 2 more bullet points to the approval criteria:

- Non-diabetic neuropathic pain that had failed to be controlled on 2 other agents commonly used for neuropathic pain.
- Concurrent depression and neuropathic pain

Motion seconded and carried with Dr. Capparelli abstaining from the vote.

**Analgesics, Long-Acting Narcotics:**

⇒ According to current treatment guidelines, opioid analgesics are the mainstay of treatment for moderate to severe pain. When used properly, long acting narcotics provide a decrease in administration frequency, longer periods of consistent pain control and a lower incidence of adverse effects than short-acting narcotics. However, these benefits come with greater abuse potential. There are no data to suggest that any one agent is superior to another; however, morphine is generally the agent most commonly used. Therefore, it is recommended that at least long-acting morphine be available. Methadone has utility in patients with allergy to other
opioid analgesics, but it has a long half-life and is associated with significant risks including respiratory depression and cardiac arrhythmias. For this reason, methadone should be subject to clinical criteria restricting its use to patients who have tried and failed, or have a contraindication or intolerance to long-acting morphine. Furthermore, given concerns regarding fentanyl’s abuse potential and the risk of respiratory distress and overdose, fentanyl should be reserved for those who are opioid tolerant and unable to take (or absorb) oral opioids.

- Discussion:
  - Dr. Capparelli noted that there are very few physicians who actually prescribe methadone and those that do have a long waiting list. He stated that, in general, methadone is not a first choice agent among prescribers.
  - Dr. Capparelli also expressed concern that the agents on the preferred list are all morphine sulfate, which limits the choice of prescribers. He pointed out that there are issues in patients with chronic pain who develop tolerance to these agents and need to switch to an alternative agent but there are no other alternative agents available as preferred.
    - Dr. Hawkins pointed out that currently methadone is a preferred agent; however, this poses an issue when patients fail morphine sulfate and providers call the call center who tell them the other preferred product is methadone. Per our general PA criteria, patients currently have to try and fail two different agents prior to getting approval for a non-preferred agent. The proposed PDL listing (containing only extended-release morphine) would require trial and failure of only one preferred agent prior to getting approval for a non-preferred agent. She asked the Committee to comment if there was a reason they wouldn’t use morphine first-line, and if so, which product would they recommend to put on the preferred list.
    - Dr. Capparelli acknowledged that this is a difficult situation and different patients respond to different agents, though oxycodone and fentanyl are the two most commonly used alternative agents. He recommended that at least one other unique agent be available as preferred. Dr. Powers concurred with this opinion.
    - Dr. Hawkins acknowledged that she agreed with this statement; however, trying to determine which agent to select as preferred is difficult due to the high abuse potential with both of these alternative agents.
    - Dr. Capparelli suggested that Opana ER® may be an option, since currently the abuse potential is low.
      - Dr. Woods asked for input on the abuse potential of Opana ER® from the Committee.
      - The Committee stated they have little experience with this product.
    - Dr. Woods suggested adding one additional unique agent be available as preferred.
      - Dr. Hawkins expressed concern that this takes us back to requiring trial and failure of two preferred agents prior to approval of a non-preferred agent.
    - Dr. Capparelli suggested that one morphine product, one oxycodone product and one fentanyl product be available to provide flexibility to providers both for tolerance and to rotate between agents. Dr.
Powers concurred that this recommendation is consistent with usual prescribing patterns for these agents.

- Motion was made to accept the recommendation as presented by First Health with the addition that at least three unique agents be available.
- Motion seconded and carried.

**REVIEW OF MAY PAC MEETING DECISIONS**

First Health reviewed TennCare’s decisions from the November 8, 2007 PAC meeting. In the interest of time, decisions were presented only for those classes in which TennCare did not accept the Committee’s recommendations. The classes where TennCare’s decisions differed from the recommendations of the Committee are as follows:

- **Respiratory Agents: Minimally Sedating Antihistamines (Page #7)**
  - PAC: Asked that TennCare consider adding a 2nd agent once it becomes cost effective to do so.
  - TennCare will add generic over-the-counter (OTC) cetirizine as preferred at the end of the month.

- **Respiratory Agents: Intranasal Steroids (Page #10-11)**
  - PAC: Recommended that fluticasone be added as a necessary agent due to market share numbers prior to its move to non-preferred.
  - TennCare: Because the current guidelines do not differentiate between intranasal steroids and the PAC did not provide clinical rational for the superiority of fluticasone, the recommendation will not be amended. However, fluticasone will be moved to preferred once contracting issues are evaluated based on the award of the new contract for a PBM vendor.

- **Respiratory Agents: Nasal Antihistamines (Page #13)**
  - PAC: Asked that the quantity limit for Astelin® nasal spray be reevaluated.
  - TennCare: Azelastine is supplied in a 17 mg bottle providing 100 metered sprays. The maximum daily dose is 8 sprays/day or 240 sprays/month. The quantity limit of 3 bottles will remain in place based on the maximum daily dose.

- **Respiratory Agents: Non-narcotic Antitussives (Page #15)**
  - PAC: Suggested that the second sentence (stating benzonatate not be used in children < 10 years of age) be removed, and that the recommendation be revised to require that at least one agent be available.
  - TennCare: Upon further investigation into this class, it was discovered that benzonatate is currently considered (and has historically been categorized as) a non-covered cough and cold product (PA required for children). However, the state has agreed to begin to cover benzonatate unrestricted for those over the age of 10. For recipients age 10 and under, benzonatate will be subject to PA criteria due to safety concerns regarding the risk of choking. It was also discovered that the one available prescription dextromethorphan product is now obsolete; therefore, dextromethorphan will be removed from this category. OTC dextromethorphan will continue to be covered for children.

- **Respiratory Agents: Non-narcotic Antitussives Criteria (Page #16)**
  - PAC: Had recommended that there not be criteria around benzonatate.
  - TennCare: Decided to implement the following criteria for benzonatate:
Benzonatate will be approved for children ≤ 10 if the prescriber verifies the following:
1) the patient has no trouble swallowing capsules whole AND;
2) the physician is aware that, if chewed, benzonatate may cause numbness of the mouth, tongue, throat, and esophagus, increasing the risk of choking.

- **PAC:** Requested that a statement be added clarifying that benzonatate will be approved for children older than 10 and adults without a PA.

- **Central Nervous System Agents: Topamax® Criteria (Page #30)**
  - **PAC:** Approved the proposed criteria, with the added recommendation that pregnancy be included as a reason for not trying a beta-blocker and amitriptyline for migraine prophylaxis.
  - **TennCare:** Propranolol, amitriptyline, and topiramate are all considered pregnancy category C and current guidelines do not recommend topiramate over the other agents for use during pregnancy. All agents have mixed safety data in pregnancy, including case reports of adverse effects, as well as reports of safe use during pregnancy. TennCare recognizes that there are certain situations where topiramate would be preferred over the other migraine prophylactic agents; however, there are also situations where propranolol or amitriptyline may be preferential over topiramate in pregnancy. For these reasons, the criteria were revised to allow use of topiramate when there are concerns over using a beta-blocker or amitriptyline in pregnant patients.
  - **Dr. Capparelli** agreed that the FDA approved pregnancy category was the same for all the migraine prophylactic agents; however, he stated that the experts he spoke with used Topamax® as the preferred agent. He asked that we remove the word “select” from the phrase, “in select pregnant women.”
SPEAKERS FOR PUBLIC TESTIMONY

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Meeting Adjourned.