Members in Attendance:
Melvin Blevins, MD, David Collier, MD (TennCare), Chairman Alan Corley, DPh, Stanley Dowell, MD, Vice-Chair Jeri Fitzpatrick, MD, Lyn Govette, MPAS, PA-C, James Johns, MD, Ernest Jones, MD, Carol Minor, Joel Phares, MD, Chris Schwerdt, PharmD, Eleanor Twigg, PharmD, Nicole Woods, PharmD (TennCare)
Non-members present from SXC: Leslie Pittman, PharmD, Tracey Lovett, PharmD.
Excused Absences: Edward Capparelli, MD, Shana Bush, PharmD

INTRODUCTIONS
The meeting was called to order by Chairman Alan Corley. Dr. Corley stated that committee members are volunteers, appointed according to public act (TCA 71-5-2401) establishing the Pharmacy Advisory Committee (PAC) and have signed both confidentiality and conflict of interest statements. Dr. Corley stated no conflicts of interest had been disclosed. Dr. Corley informed the committee that a few members have rotated off the committee and the following replacements were made: Dr. Ernest Jones will replace Dr. Roger Zoorob, Dr. Chris Schwerdt will replace our long-term pharmacy committee member Dr. Lynn Knott and our managed care pharmacist committee member Dr. Shana Bush will replace Dr. Terry Shea. Dr. Corley thanked the outgoing committee members for their service and welcomed our new members. Committee members were asked to sign and return new conflict of interest statements for the 2012 year. The members of the Committee introduced themselves.

PAC MINUTES
The November 8, 2011 PAC meeting minutes were reviewed.
- Dr. Melvin Blevins motioned to approve the minutes as presented.
- Motion seconded and carried.

TENNCARE UPDATE
Dr. David Collier gave this quarter’s TennCare update.
- The FY 2013 Budget- Previously each TennCare department was asked to present a 5% reduction budget. However, this 5% reduction was not needed. The TennCare budget proposed was amended by the Governor and the update provided today will review those amendments.
  - Provider Rate Reduction: currently there is legislation pending (HB 2383/SB2245) that restores 1.75% of the January 1, 2012 rate reduction of 4.25% resulting in a 2.5% reduction. If this legislation passes it will be retroactive to 1/1/12. The FY 2012 provider rate reduction was restored by 1.75% for a total 7.75% reduction versus the 9.5% proposed reduction. The proposed plan is to use recurrent funds to prevent an increase in the provider rate reduction for FY 2013.
  - Providers that will be affected by the provider rate reduction include nursing homes, ICFs/MR (intermediate care facilities for persons with mental retardation), MCO administrative rates, transportation providers, Lab and x-ray providers, dentists, PACE (Program of All-inclusive Care for the elderly) and Home Health providers (excludes HCBS providers).
  - Perinatal Grant (Regional Perinatal Centers): There was a big concern regarding this proposed cut as the grant helped to reduce neonatal
mortality. However, this grant was continued for FY 2012 as a result of non-recurring funds. In FY 2013 this grant will be funded with recurring funds.

- **OB reimbursement:** TennCare proposed a flat rate reimbursement for any type of delivery. The Governor approved a higher reimbursement rate with the use of non-recurring funds that allowed for a vaginal rate +17% reimbursement for deliveries instead of the +5% increased reimbursement rate proposed by TennCare. For FY 2013 the delivery rate reimbursement will be slightly lower at vaginal rate +10% and will be funded with recurring funds. Hopefully, this will result in performance of C-sections only when medically necessary.

- **Emergency Department Physician Reimbursement:** TennCare proposed a reduction in the reimbursement to a level (approx. $27). The Governor approved the contract rate or $50, whichever is less and this would use non-recurring funds for FY2012. In FY2013 the reimbursement rate will range from $27 to $50 with the use of non-recurring funds as well. This reimbursement rate will be re-evaluated in FY2014.

- **Supplemental grants:** The grants to Med/Metro/Jellico are continued.

- **TNAAP contract:** For FY2012 this service was not funded. However, for FY2013 the contract will be restored with non-recurring funds ($100,000).

- **Miscellaneous proposed reductions not in budget:** Other proposed reductions not included in the Governor’s budget which will not be implemented include:
  - Eliminate hospice support services for adults
  - 1.25% provider rate reduction
  - Eliminate adult allergy medication coverage
  - Mental health provider rate reduction
  - Co-pay for non-pregnant adults for some services.
  - Co-pay for non-emergent transportation

- **Reductions:**
  - **Long Term Care Services:** This is now referred to as Long-Term services & supports. Tennessee has typically had a more liberal approach regarding the requirements for LTC compared to surrounding states. Previously only 1 ADL deficiency was required. However, more stringent requirements for long term care will be implemented. The change requirements for nursing facility care include:
    - Deficiencies in 3-4 ADLs to qualify for nursing
    - Two major groups classified as:
      - Choices Group 1-Nursing home care recipients
      - Choices Group 2- Home care recipients (HCBS)
        - Adults 65 years of age and older
        - OR adults 21 years of age and older who have impairments/physical disabilities
      - A new group: Choices Group 3 will require:
        - Deficiency in 1-3 ADLs
        - Will not be eligible for residential care, but allowed to receive HCBS (home care based services)
This change will allow TennCare to provide services to those in need without being too liberal regarding nursing home services.

HCBS-will have a reduced rate that involves a blended rate of homemaker and personal assistant.

- Limit Retroactive Eligibility Payments to MCO: As it stands now regarding retroactive eligibility, if retroactive eligibility was approved for the past 2 years. TennCare would pay 2 years of full capitation rate to the MCO. Going forward, TennCare will only pay full capitation for no more than 12 months of retroactive eligibility and only claims received for services rendered prior to 12 months will be paid.

- Hospital Acquired /Preventable Medical Conditions:  
  
  - TennCare will follow Medicare’s lead and will not reimburse for these types of conditions.

- TennCare Standard Spend Down (SSD): Opened last Tuesday, February 21, 2012. This was the 4th time enrollment has been opened. This program is possible through an amendment to the TennCare waiver which allows a limited number of persons otherwise not eligible for Medicaid.
  
  - SSD serves a limited number of people who are not otherwise eligible for Medicaid, but are aged, blind, disabled (as determined by social security), or the caretaker relative of a Medicaid eligible child and who have enough unreimbursed medical bills to allow them to “spend down” their income to the State’s Medically Needy Income Standard (MNIS).
  
  - This service will continue into next year as well.

- EHR (Electronic Health Records) Provider Incentive Program: This is a federally funded program administered by the state.
  
  - As of February 17, 2012:
    - $21,349,173 paid to 1,011 eligible professionals
    - Approximately $15,893,583 paid to 19 eligible hospitals
    - Total amount paid $37,242,756.58

- John B. Lawsuit: lawsuit addresses the adequacy of services provided by TennCare for children under the age of 21. Judge Wiseman issued a ruling on February 14, 2012. The ruling stated:
  
  - That the state is in substantial compliance with all binding provisions of the consent decree.
  
  - Judge Wiseman vacated the consent decree, dissolved all injunctive relief and dismissed the case.
  
  - The state is pleased with outcome of the case.
  
  - Plaintiffs in the case intend to appeal, which is required to be filed within 30 days of the ruling.

- ICD-10 Implementation:
  
  - January 1, 2012, a federal mandate requires health plans, clearinghouses, and providers to use new standards when electronically conducting certain health care administrative transactions. This requirement for the 5010 version standards went live 1/1/12.
  
  - ICD-10 implementation was scheduled for October 1, 2013. However, CMS is considering a delay pending further evaluation as a result of concerns from the AMA (American Medical Association) regarding the burden on physicians to meet the deadline. No information has been
given as to whether a delay will be granted at this time. Therefore, TennCare has been working and continues to work toward the deadline requirements for the ICD-10 implementation as previously set until further information is received.

TENNCARE PHARMACY UPDATE
Dr. Nicole Woods gave this quarter's TennCare Pharmacy update.

- **New NCPDP D.0 Claim Standard format**: The new NCPDP D.0 claim standard format went into effect January 1, 2012. This new claim standard format replaces the previously accepted NCPDP 5.1 claim format. Overall, the transition to the new format went very smoothly.
  - Pharmacies received a provider notice informing them of the changes that will be needed to move to this new format via a D.0 Payer Specification sheet which provided the technical information required to process claims.
  - Pharmacies were given a transition period during the month of December in which both the 5.1 and D.0 formats were allowed so pharmacies could properly migrate to the new format and minimize any obstruction for members receiving medications at the beginning of the year. Pharmacies that wanted to test submission of claims in the new format were encouraged to contact SXC to arrange a testing time.
  - At this time all pharmacy claims must be submitted in the new D.0 claim standard format.

- **Pharmacy Budget Reductions**: In FY2013 the proposed budget item regarding implementing a more aggressive MAC (maximum allowable cost) was postponed due to non-recurring funds.
  - This budget item is scheduled for FY2013 unless additional funds are identified.

- **Proposed FY2013 Budget Items**:
  - Enhanced Third Party Liability (TPL) - TennCare proposed an enhanced third party liability collection from the pharmacies. In July 2011, a POS (point of sale) coordination of benefits (COB) edit was implemented. This COB edit identified members who were known to have primary insurance and required that the pharmacy submit the claim to the primary insurance first with TennCare being the payer of last resort. It’s anticipated that this edit will continue into the next budget year and will continue to provide savings for the state.
  - Enhanced Specialty Pharmacy Contract Strategy - This enhanced contract strategy would equate to deeper discounts on certain specialty drugs and the possibility of having fewer specialty pharmacies within the network.
  - Elimination of Prescription Allergy Medications for Adults - TennCare proposed to the Governor elimination of prescription allergy medications for Adult members.
  - The last 2 proposed budget items were not included in the Governor’s final budget proposal.

- **Suboxone/Subutex Tapering**: One of the items proposed last year was the implementation of a quantity limit for buprenorphine products which would allow up to 16 mg/day for up to 6 months. Following this 6 month time period, the member
would need to be tapered down to a quantity limit of 8mg/day beginning March 1, 2012.

- The first group of buprenorphine users is set to hit the new limit on March 1, 2012 and these patients will be required to be down to a max dose of 8mg/day at that time. To assist providers with this taper, multiple provider notices were faxed to targeted prescribers informing them of the new quantity limit including a list of patients that were receiving greater than 8mg/day and encouraging providers to taper their patients down to the new quantity limit. All our Suboxone providers have been informed of those patients that will need to be tapered down to 8mg/day and are currently in the process of tapering those patients. After March 1, 2012, those patients that have reached the 6 month limit will no longer be able to receive more than 8mg/day of buprenorphine products from the TennCare Pharmacy program. Patients will be required to pay out-of-pocket for quantities that exceed the buprenorphine quantity limit.

- Lastly, the Pharmacy Program will experience a change in leadership effective March 14, 2012. Dr. Woods informed the Pharmacy Advisory Committee (PAC) that she would be leaving TennCare to explore a new job opportunity. Dr. Woods thanked the committee for their hard work and for making the last 6 years so pleasant. Dr. Woods stated that she has enjoyed working for TennCare and with PAC and will definitely miss working with everyone. At this time a new Pharmacy Director has yet to be named. However, interviews are currently being conducted and she expressed confidence that a highly capable person will be selected to fill the position. In regards to PAC, the leadership change will not impact the PAC process. PAC will continue to function as it has in the past few years. Dr. Woods stated that this has been a difficult decision to make, but feels overall the change will be a positive move. Dr. Woods thanked the committee for the beautiful flowers. On behalf of the committee, Dr. Corley thanked Dr. Woods for all her hard work and stated she would truly be missed.

- Dr. Collier informed the committee that TennCare will present the budget to the legislature on March 12th & 13th and this presentation will be broadcasted via webcast if anyone is interested in viewing.

- Dr. Corley made a comment regarding the proposed MAC pricing changes. Dr. Corley stated that through the efforts of pharmacists across the state and the PAC committee, generic utilization has increased another 2% this year from 82% to 84%. Every 1% shift in generic utilization is approximately 24-25 million dollars that is being saved. As a result of the 2% increase in generic utilization, the state is receiving a 50 million dollar cost savings. Yet the state is still looking to cut generic reimbursement, which is viewed as a negative incentive to what is being achieved. Dr. Wood stated she understood his position on the matter.

**MISCELLANEOUS AGENDA ITEMS**

- **Suboxone PA Request Form:** Dr. Woods informed the committee that a few weeks ago an email had been sent out regarding the Suboxone PA fax form. A few suggestions were given regarding Suboxone PA fax form. Additionally, concerns were raised regarding buprenorphine clinical criteria. As a result of these proposed changes being outside of what the PAC committee initially approved, a few items were being brought back today for review and to obtain input from the committee. There are primarily 2 changes that will need to be reviewed:
- The current Suboxone prior authorization criteria requires the prescriber to check the CSD (controlled substance database) within the past 30 days of request.
- The problem with this 30 day time frame involves concerns where the member is doctor shopping and receiving other controlled substances from other providers within the last 30 days and the Suboxone provider is unaware as the CSD has not been checked recently.
  - 1) The Proposed Change: Require the prescriber to have checked the CSD on the day of the PA request to ensure the provider has the most up to date information.
- Dr. Dowell asked what type of challenges the proposed change will place on the provider requesting the PA.
  - Dr. Woods stated that from the current feedback received from the providers such as pain management providers, is that they typically make an effort to check the CSD at the time the request is being made and the patient is actually in the office. Dr. Woods stated that the pharmacy program has worked with some providers who needed assistance getting set-up with the CSD. In the majority of these cases the providers were set-up and given a password within the same day. The process to pull information from the CSD is fairly simple. If the provider has their unique password, the patient’s name and date of birth, then the patient’s profile can be accessed.
  - Dr. Pittman also stated that one concern regarding the CSD involves an inherent lag in reporting to the CSD, so the information may not be current if checked within the past 30 days. For example a claim filled 2 weeks ago, may not appear in the CSD until a week or so later. Dr. Dowell inquired as to how long the lag time for reporting information took. Dr. Lovett stated it could be approximately 2 weeks. Dr. Corley stated that in some instances it may be longer than 2 weeks depending on the pharmacy. Pharmacies are required to report every few weeks. Dr. Pittman stated that this is an issue. If we allow the provider to check within the last 30 days and the lag time to report is 2 weeks or more, then the information viewed within the past 30 days is not the most current information—it could possibly show information that has not been updated in the past 2 months. Dr. Blevins commented that pain management providers typically check this database on a daily basis and use the database as a component or part of everyday practice when evaluating the patient, he stated he saw no concerns nor objected with the proposed changed. Dr. Blevins stated the proposed change was definitely appropriate and would protect both the patient and provider.
    - Dr. Blevins motioned to approve the proposed change item 1.
    - Lyn Govette seconded the motion
    - Motion carried
- The current Suboxone prior authorization criteria requests that the last controlled substance reflected on the CSD report is provided. This limited information does not allow TennCare to determine if the member is receiving concomitant opioids in addition to Suboxone.
  - 2) The Proposed Change: would expand this request to request the last 5 controlled substances reflected on the CSD report.
Dr. Woods also stated that this would additionally assist the call center pharmacists reviewing the requests to give them a better idea if concomitant use is taking place. Dr. Pittman clarified that the call center does not have access to the CSD.

- Dr. Blevins stated that this proposed change could be another safety factor by implementing control mechanisms which could prevent concomitant use that could potentially be harmful to the patient.
- Dr. Jones stated that this would be helpful. Dr. Jones stated that he has found concomitant use of Suboxone® and another narcotic agent following urine/blood screenings. He stated the patient will come to the office with Suboxone in the system and are currently receiving another prescribed drug. However, the patient may not provide this information upon consultation. Dr. Jones stated that checking the CSD allows verification that the patient is using the drug as intended.

Dr. Corley inquired as to whether there was additional information available on legislation requesting expanded access for providers who are not actively dispensing medications. Dr. Corley asked if this legislation was passed would it apply to TennCare.

- Dr. Woods stated that her current reading of the proposed legislation has that it would not allow access to TennCare but expands the access to allow law enforcement personnel and some additional healthcare workers. The concern is that current law only allows access to actively dispensing providers. Therefore, this law does not provide access for our call center personnel. There are only 4 people within TennCare who actually have access and 1 of them is a pharmacist who actively works with lock-ins and Re-reviews.

Lyn Govette stated that the proposed change is to request the last 5 controlled substances from the requesting provider to ensure that concomitant use is not occurring.

Dr. Phares warned against opening access to the CSD to preserve privacy rights. As the CSD contains vital personal information. Dr. Blevins agreed with Dr. Phares and felt there should be limits in place.

Dr. Collier stated that providers are held accountable and could possibly be fined for using the database for means other than actively treating the patient.

Dr. Woods stated that any wording that would open access would be limited to professionally licensed healthcare providers (i.e. pharmacists, dentists, physicians).

- Dr. Blevins motioned to approve the proposed change item 2.
- Dr. Jones seconded the motion.
- Motion carried

- **Kalydeco® (ivacaftor):** Dr. Lovett gave a brief overview of ivacaftor, an oral agent for the treatment of CF (cystic fibrosis), specifically for patients with a G551D mutation.
  - **Proposed Interim Criteria:**
    - Lab documentation confirming G551D mutation
    - Patient has received a baseline liver functioning test
    - Quantity limit of 2/day
    - Lyn Govette motioned to approve the proposed interim criteria.
    - Dr. Blevins seconded the motion.
AE SUBCOMMITTEE
Dr. Leslie Pittman reported to the PAC committee there were 4 additions of new drugs to existing categories on the Auto-Exemption (AE) List for 4Q2011. These 4 additions included Erwinaze™, Jakafi™, Erivedge™, and Inlyta®. Dr. Pittman gave a brief overview of the Auto-exemption list and the rules of the AE subcommittee.

- AE list is a list of drugs that will not count toward the patient’s script limits
- The AE subcommittee reviews new drugs for addition to the list. The AE list has standing drug categories. New drug agents added to already existing drug categories on the AE list do not require the PAC committee to approve. Removal of drug agents from the AE list requires approval from the committee. If a new category is added to the AE list, it can be added. However, the new drug category must obtain PAC’s approval by the next meeting.

  - Dr. Johns asked if clinical criteria was in place for Erwinase® as a result of the agent’s high cost. Dr. Pittman thought the recommendation for oral anti-neoplasotics was to allow availability for all unique agents in that category.
    - Dr. Woods clarified why this ruling was put in place. Utilization review of this class showed the agents were being used appropriately. Another concern involved patients not receiving their medications due to the agent requiring a PA and the prescriber being unaware of the PA status. Additionally, the guidelines for oncology agents change fairly quickly and since oncology specialists are the primary prescribers of these agents, it was felt allowing availability of these agents would ensure patients that truly needed the agents would receive the drug without barriers.

DRUG CLASS REVIEWS

The drug class review section of the meeting consisted of an SXC 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 a vote on the recommendation and any proposed restrictions.

For the purpose of the minutes, the section below reflects SXC’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 SXC, please refer to the February 23, 2012 PAC review packet at: https://tnm.providerportal.sxc.com/rxclaim/TNM/PAC%20packet%20022312.pdf

Anti-Infective Agents

Penicillins

- The penicillin agents are indicated to treat a variety of infections. Clinical trials have generally demonstrated safety and efficacy of these agents based on their respective indications. Clinical guidelines recommend penicillins as first-line agents for certain strains of community acquired pneumonia, otitis media, group A β-hemolytic
streptococcal pharyngitis, bacterial sinusitis, and minor skin and soft tissue infections. An extended formulation of amoxicillin is available and clinical trials have shown its effectiveness in group A streptococcal pharyngitis. However, these trials have not shown that the extended release amoxicillin is superior to other agents in the class and safety and efficacy has not been established in pediatric patients less than 12 years of age. Additionally, given the differences in the subclasses of penicillins such as inactivation by beta-lactamase and spectrum of activity, at least one agent in each of the subclasses should be available. Therefore, it is recommended that at least 3 oral penicillin agents are available for use. Additionally, due to high utilization in the pediatric population, at least one liquid formulation should be available.

Discussion:

- Lyn Govette inquired as to why a liquid formulation was not specifically listed in the drug listing similar to the other classes.
  - Dr. Lovett clarified that when a specific liquid formulation is not listed it typically is allowed if the general drug name is listed as a preferred agent in the drug category listing.
- Dr. Johns asked if the specific oral subclasses could be added to the recommendation. Additionally, asked if the recommendation could state at least 1 liquid formulation is available for each subclass of penicillins, if available.
  - Dr. Lovett stated that the subclasses and if available, a liquid formulation of each subclass could be added to the recommendation as requested.
  - Dr. Johns motioned to approve the recommendation with the following modifications:
    - List the 3 specific subclasses
    - At least 1 liquid formulation for each subclass be available
  - Dr. Jones seconded the motion.
  - Motion carried.

1st Generation Cephalosporins

Cephalosporins are grouped into generations based on their spectrum of activity. The first generation cephalosporins include cefadroxil and cephalexin. The first generation cephalosporins are active against gram-positive aerobes and typically have poor activity against gram-negative organisms. However, there is some susceptibility to some strains of Escherichia coli (E.coli), Klebsiella pneumoniae, Proteus mirabilis and Shigella. Overall, the first generation cephalosporins have demonstrated efficacy for their respective indications. Comparison within the class has failed to consistently demonstrate “superiority” of one agent over the other for the treatment of respiratory tract infections, skin and soft tissue infections or urinary tract infections; however, given that cephalexin is the only agent approved for bone and joint infections and cefadroxil is the only agent approved for pharyngitis and tonsillitis, it is recommended that both cefadroxil and cephalexin are available for use.

Discussion:

- Dr. Johns asked if a liquid formulation could be available for both as well. However, he suggested if there is a significant cost difference, then perhaps the same clinical criteria proposed for Zithromax® could be applied to the liquid formulations if necessary.
  - Dr. Pittman stated that typically when the strengths or liquid formulation are split out from the other agents, it usually involves a significant cost difference compared to the other agents or formulations.
• Dr. Johns motioned to approve the recommendation with the modification of adding a sentence that states an oral suspension be available for each agent.
• Motion seconded and carried.

2nd Generation Cephalosporins

- The second generation cephalosporins are used to treat a variety of infections including skin and skin structure, genitourinary tract and respiratory tract infections. Second generation cephalosporins have greater activity against Haemophilus influenza (H. flu) compared to the first generation cephalosporins and exhibit enhanced activity against gram-negative bacteria in vitro. Treatment guidelines identify second generation cephalosporins as treatment options for community acquired pneumonia and alternative agents for patients with a non-type 1 penicillin allergy for the treatment of pharyngitis. Clinical trials comparing the oral second generation cephalosporins to each other do not consistently favor one agent over another. However, clinical guidelines recommend cefuroxime as an alternative agent for otitis media in penicillin allergic patients. Also there are differences in spectrum of activity and FDA indications within the class. Therefore, it’s recommended that at least 2 second generation cephalosporins should be available, one of which should include cefuroxime. Additionally, a liquid formulation should be available for the pediatric population.

Discussion:
• Lyn Govette motioned to approve the recommendation as presented.
• Motion seconded and carried.

3rd Generation Cephalosporins

- Cephalosporins are grouped into generations based on their spectrum of activity. The third generation cephalosporins include cefdinir, ceftitorin, cefixime, cefpodoxime and ceftibuten. The third generation cephalosporins are active against streptococci, Haemophilus influenza and Moraxella catarrhalis and are more active against gram-negative bacilli compared to other cephalosporins. However, they are not as active against susceptible strains of staphylococci compared to first generation cephalosporins. Treatment guidelines identify third generation cephalosporins as alternative empiric agents for the treatment of community acquired pneumonia, and as treatment options for infections due to Enterobacteriaceae. These agents are also considered alternative agents for the treatment of otitis media in patients with non-type 1 penicillin allergies. Additionally guidelines recommend 3rd generation cephalosporins as an alternative agent in patients with COPD and mild exacerbations with no risk of poor outcome. In the treatment of lower respiratory tract infections including community acquired pneumonia, no consistently significant differences were observed when compared with agents within the class. Therefore it is recommended that at least 3 third generation cephalosporin agents are available that will allow for full antibacterial coverage within the class. Additionally, a liquid formulation should be available for the pediatric population.

Discussion:
• Dr. Woods read comments to the committee received from Dr. Capparelli regarding the 3rd generation cephalosporins.
Dr. Capparelli’s comments stated that cefditoren works well for upper respiratory infections in children and is usually utilized after amoxicillin or cephalexin. Dr. Capparelli agreed with the recommendation and did not feel there were significant differences between the 3 branded agents that required one agent to be preferred over another.

- Dr. Blevins motioned to approve the recommendation.
- Motion seconded by Lyn Govette.
- Motion carried.

**Tetracyclines**

- The tetracyclines are FDA approved for use in various infectious diseases based on their activity against certain microorganisms. They work by inhibiting bacterial protein synthesis. These agents may be considered therapeutic alternatives to one another, as clinical trials have not exhibited any clinically significant differences within the class. However, minocycline and doxycycline may possess some advantages which may contribute to their high utilization, such as once to twice daily dosing as a result of longer elimination half-lives compared to the other agents within the class. Doxycycline may cause less photosensitivity and binds calcium to a lesser extent compared to tetracycline. Given that demeclocycline is the preferred alternative pharmacological treatment for chronic SIADH, it should be accessible for this subgroup of patients. Therefore it is recommended that at least doxycycline be available, with demeclocycline available for patients with SIADH. Doxycycline hyclate 20mg tablet has a sole indication for use as an adjunct in patients with adult periodontitis. Additionally, minocycline extended release formulation is only FDA approved for the treatment of non-nodular moderate to severe acne vulgaris with inflammatory lesions in patients 12 years of age or older. Therefore both doxycycline hyclate 20mg tablets and the minocycline extended release formulation should be subject to clinical criteria to ensure their appropriate use.

**Discussion:**
- Lyn Govette motioned to approve recommendation as presented.
- Motion seconded and carried.

**Clinical Criteria for demeclocycline:**

| Will be approved without requiring previous trials of preferred agents if being used for the treatment of SIADH |

**Discussion:**
- Dr. Blevins motioned to approve clinical criteria for demeclocycline.
- Dr. Jones seconded the motion
- Motion carried.

**Clinical Criteria for doxycycline hyclate 20mg (Periostat®):**
Will be approved when BOTH of the following conditions are met:

- When used as an adjunct to scaling and root planing to promote attachment level gain and reduce pocket depth for adult periodontitis.
- In patients with any of the following:
  - Multiple sites unresponsive to mechanical debridement
  - Acute infections
  - Medically compromised patients
  - Tissue-invasive organisms and ongoing disease progression

Discussion:
- Dr. Blevins motioned to accept the clinical criteria presented.
- Motion seconded and carried.

**Clinical Criteria for minocycline ER (Solodyn®):**

Will be approved if ALL of the following are true:

- Diagnosis is for the treatment of non-nodular moderate to severe acne vulgaris with inflammatory lesions.
- Recipient has failed, has an intolerance, contraindication or adverse reaction to at least two of the following topical agents:
  - Metronidazole (Metrogel®)
  - Azelaic acid (Azelex®, Finacea®)
  - Erythromycin (A/T/S® solution, gel)
  - Clindamycin (Cleocin T®)
  - Topical keratolytic agents (such as benzoyl peroxide, salicylic acid preparations)
- Recipient requires long-term therapy with an oral tetracycline
- Recipient must be less than 21 years old

Discussion:
- Dr. Jones motioned to accept clinical criteria presented.
- Dr. Dowell seconded the motion
- Motion carried.

**Quantity Limits:**

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<tr>
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<td>1/day</td>
</tr>
<tr>
<td>Periostat®</td>
<td>2/day</td>
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<tr>
<td>Solodyn®</td>
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Discussion:
- Dr. Blevins motioned to accept clinical criteria presented.
- Motion seconded and carried.

**Macrolides**

- The macrolide antibiotics are used to treat a variety of infections caused by susceptible organisms including but not limited to upper and lower respiratory tract infections, skin and skin structure infections, sexually transmitted diseases, Helicobacter pylori infection and duodenal ulcer disease, listeriosis, diphtheria, pertussis and intestinal amebiasis. Treatment guidelines recommend the use of
macrolide antibiotics (excluding fidaxomicin) as the preferred empiric treatment for community acquired pneumonia in otherwise healthy patients and they are primary treatment options for various skin and soft tissue infections, various sexually transmitted diseases, and pertussis as well as primary and secondary prophylaxis and treatment of Mycobacterium avium Complex disease. Overall, the macrolide antibiotics have demonstrated efficacy for their respective indications and available head-to-head studies do not consistently demonstrate the “superiority” of one macrolide over another. However, due to varying indications and spectrums of activity, it is recommended erythromycin, azithromycin and clarithromycin should be available.

Fidaxomicin is the newest agent approved in the macrolide class and is a narrow-spectrum agent approved for the treatment of Clostridium difficile-associated diarrhea. For the treatment of Clostridium difficile diarrhea, fidaxomicin was shown to be non-inferior to vancomycin though it was also shown to have significantly lower rates of recurrence and higher rates of global cure. Current guidelines recommend metronidazole as the treatment of choice for the initial episode of mild to moderate C difficile infection, with oral vancomycin reserved for the treatment of severe C difficile infection. Due to its narrow-spectrum of activity and lack of endorsement by current clinical guidelines, it is recommended fidaxomicin should be subject to clinical criteria.

Discussion:
- Dr. Johns recommended that a statement should be included regarding availability of an oral suspension for all 3 recommended agents. Dr. Woods asked if clarification should be added stating an oral suspension for the 3 recommended agents be available specifically for pediatric patients and patients unable to swallow.
- Dr. Johns motioned to approve the recommendation with the modification of allowing an oral suspension available for the 3 recommended agents for pediatric patients and patients unable to swallow.
- Motion seconded and carried.

**Clinical Criteria for azithromycin suspension**
- No PA required for 11 years old & younger.
- All others: Will be approved for patients unable to swallow tablets.

Discussion:
- Dr. Woods read comments from Dr. Capparelli that stated that the age requirement should be set at 15 & younger versus the proposed 11 & younger, as he has several 11 to 15 year old children who have difficulty swallowing.
  - Dr. Woods informed the board that if a child fell in this category they could go through the PA process to obtain the liquid formulation.
- Dr. Blevins felt the age limit of 11 & younger was appropriate and if the liquid formulation was needed beyond this age then the PA process is available to that subset of patients and motioned to approve the clinical criteria as presented.
- Motion seconded and carried.

**Clinical Criteria for Dificid®**
Dificid® will be approved for recipients meeting the following criteria:

- Diagnosis of Clostridium difficile (C. diff) associated diarrhea
- Trial and failure of oral vancomycin within the past 30 days

**NOTE:** Individuals started on Dificid® therapy in the hospital will be approved for this agent following hospital discharge in order to allow for completion of the course of therapy.

**Discussion:**

- Dr. Jones asked if patients were started on therapy in the hospital would continuation of the drug following hospital discharge require a PA.
  - Dr. Pittman stated that it would require a prior authorization (PA). However, the first question included in the criteria asks if the patient was started on therapy in the hospital. If so then it would be approved.
  - Dr. Corley asked whether a pharmacist could obtain the PA if this information was known. Dr. Pittman stated that if the pharmacist has this information, then yes a pharmacist could indeed request a PA.

- Dr. Blevins motioned to approve the criteria as presented.
- Dr. Phares seconded the motion
- Motion carried.

**Quantity Limits:**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>azithromycin powder for susp (Zithromax® powder for susp)</td>
<td>2g per Rx</td>
</tr>
<tr>
<td>azithromycin 250 mg tablets (Zithromax®)</td>
<td>12 per Rx</td>
</tr>
<tr>
<td>azithromycin 600 mg tablets (Zithromax 600®)</td>
<td>8/month</td>
</tr>
<tr>
<td>Clarithromycin ER (Biaxin XL®)</td>
<td>2/day</td>
</tr>
<tr>
<td><strong>Dificid®</strong></td>
<td>2/day</td>
</tr>
<tr>
<td>Zmax® 2 gm</td>
<td>2g per Rx</td>
</tr>
</tbody>
</table>

**Discussion:**

- Dr. Blevins made a motion to approve the quantity limits.
- Motion seconded and carried.

**Ketolides**

- Telithromycin is FDA approved to treat community acquired pneumonia due to Streptococcus pneumoniae, including multi-drug resistant isolates, Haemophilus influenza, Moraxella catarrhalis, Chlamydia pneumoniae and Mycoplasma pneumoniae. Clinical trial demonstrate efficacy in clinical and bacteriologic response, including the treatment of erythromycin-resistant S pneumoniae and penicillin-resistant S pneumoniae. However, no significant differences were observed in clinical or bacteriologic response rates when comparing 10 days of therapy with either telithromycin or clarithromycin. Telithromycin is associated with significant safety risks, including hepatotoxicity, prompting the FDA to conclude that the risks of therapy outweigh the benefits in the treatment of minor illnesses. Currently clinical guidelines for the treatment of community-acquired pneumonia recommend a macrolide for the treatment of most patients with respiratory quinolones recommended in regions with a high rate of macrolide-resistant S pneumoniae, or for
patients with comorbidities. In patients with mild to moderate community acquired pneumonia, telithromycin should be reserved for patients failing other antimicrobial agents. Due to its significant safety concerns as well as place in therapy it is recommended telithromycin should be subject to step therapy.

Discussion:

- Dr. Blevins agreed with the recommendation and stated this is an agent that took off with a bang. However, its use quickly fizzled as a result of the safety hazards. Therefore given there are other agents that are much safer, he agreed that guidelines should be in place to use this as a last-line agent.
- Dr. Blevins motioned to approve the recommendation as presented.
- Dr. Jones motioned to accept the recommendation as presented.
- Motion carried.

**Step Therapy for Ketek®:**

Approved for treatment of community-acquired pneumonia in patients with previous trial (within 28 days) and failure of *at least TWO of the following*: a penicillin, cephalosporin, sulfonamide, advanced macrolide, quinolone, or doxycycline.

Discussion:

- Comments read from Dr. Capparelli stated that he agreed with the recommendation; however he also suggested in addition to “trial and failure”, “intolerance” should also be added as well.
  - Dr. Woods stated that intolerance was intentionally left off to ensure this agent was used as a last line agent. Dr. Pittman stated that adding intolerance would possibly allow the patient to have really only tried 1 agent (i.e. penicillin allergic pt.) making the agent a second-line agent choice.
  - Dr. Dowell suggested adding the note that if the agent was started in the hospital, approval will be allowed for completion of therapy following hospital discharge.
- Dr. Dowell motioned to approve the recommendation with the modification to add the note: if the agent is started in the hospital, approval will be allowed for completion of therapy following hospital discharge.
- Motion seconded and carried.
- Dr. Pittman also pointed out that there were no claims processed for this agent for 4Q2011 and recommending moving this category to the low utilization status.
- Motion made to move to the low utilization category.
- Motion seconded and carried.

**Oral Glycopeptides**

- Oral vancomycin is FDA-approved for the treatment of enterocolitis due to *Staphylococcus aureus* or *Clostridium difficile* pseudomembranous colitis. Clinical trials have demonstrated the similar efficacy between vancomycin and metronidazole in the treatment of mild *C difficile* pseudomembranous colitis. Current guidelines recommend metronidazole as the treatment of choice for the initial episode of mild to moderate *C difficile* infection with oral vancomycin reserved for the treatment of severe *C difficile* infection. Due to concerns regarding the emergence of resistance, it is recommended oral vancomycin should be subject to clinical criteria to ensure appropriate use.
Discussion
- Lyn Govette motioned to accept the recommendation.
- Motion seconded and carried.

<table>
<thead>
<tr>
<th>Clinical Criteria for Vancocin™:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval will be granted for individuals meeting <strong>ALL</strong> of the following <strong>criteria</strong>:</td>
</tr>
<tr>
<td>- Diagnosis of <em>enterocolitis caused by Staphylococcus aureus</em>, OR</td>
</tr>
<tr>
<td>- Diagnosis of <em>pseudomembranous colitis caused by C. difficile</em> colitis, AND trial and failure of, contraindication, adverse reaction or drug-drug interaction to oral metronidazole unless there is a contraindication, adverse reaction, or drug to drug interaction that would preclude its use.</td>
</tr>
</tbody>
</table>

The following is a common list (not all inclusive) of reasons why metronidazole may not be appropriate:
- Recipient is either pregnant or a child under the age of 10
- Recipient is severely ill
- Recipient is receiving an alcohol related compound (interaction with metronidazole)
- Recipient is allergic to metronidazole
- The organism is resistant to metronidazole
- There is evidence suggesting the diarrhea is caused by Staphylococcus aureus
- The recipient failed metronidazole in the past
- The diarrhea is suspected recurrent *C. difficile* colitis

Discussion:
- Dr. Blevins commented that for an 85 year old with mild *C. diff*, he typically will go with vancomycin.
  - Dr. Pittman stated that for mild *C. diff* both metronidazole and vancomycin have similar cure rates. However, in severe disease vancomycin has a better cure rate versus metronidazole.
  - Dr. Woods asked if these were patients that tended to have recurrent *C. diff*. Dr. Blevins stated yes it was usually recurrent *C. diff*. Dr. Pittman stated patients with recurrent *C. diff* would qualify for vancomycin.
- Dr. Johns suggested a note regarding if therapy had been started in hospital, approval will be allowed following discharge for completion of therapy.
  - Dr. Pittman stated that several appeals are received and denied for providers requesting oral vancomycin for a patient that was started on IV vancomycin in the hospital. Therefore, she expressed concern with adding this note, as the provider may feel that the oral agent which is not absorbed systemically should be approved if the patient received IV vancomycin.
  - The committee recommended that the note specify that if the patient received the agent orally in the hospital, then approval of the oral agent following hospital discharge will be allowed.
- The committee asked where the age limit of 10 for not using metronidazole came from and asked if that should be researched and modified if needed. Dr. Johns stated that he talked with Vanderbilt infectious disease providers and they had no problem with the age limit.
- Dr. Blevins motioned to approve the recommendation with the modification that a note is placed stating that if the patient is started on oral vancomycin in the hospital, then oral vancomycin will be approved following discharge.
- Motion seconded and carried.
**Lincosamides**

- Clindamycin is the only orally available lincosamide and is FDA approved to treat serious respiratory tract, skin and skin structure infections caused by susceptible bacteria, as well as serious infections caused by susceptible anaerobic bacteria. Clindamycin has shown efficacy for its approved indications; however it also carries a black box warning regarding its association with potentially fatal colitis. As such, it should be reserved for serious infections where less toxic antibiotics are inappropriate. Current clinical guidelines recommend clindamycin as initial or alternative therapy in a number of infections including, but not limited to, community acquired pneumonia, acute otitis media, sinusitis, and various types of skin and skin structure infections. Lincosamides are generally reserved for anaerobic coverage or situations when penicillin should not be used, such as patients with penicillin allergies and/or resistant organisms. Given their role in the treatment of various infections, particularly in patients with penicillin allergy, it is recommended oral clindamycin, including the pediatric dosage form, should be available for use.

**Discussion:**
- Dr. Corley asked the State to review the net/net cost for clindamycin 150mg versus the 300mg strength. Dr. Corley stated that the cost for clindamycin 150mg capsules is approximately $0.21/unit while the 300mg strength capsules are $0.70/unit. As a result he does not carry the 300mg strength due to the cost.
  - Dr. Woods stated they would review the cost and if the cost is significantly different they may consider moving the 300mg strength to non-preferred. The Board was asked if there was any concern with primarily using the 150mg.
  - Dr. Phares stated that clindamycin is a preferred agent in penicillin allergic patients for endocarditis prophylaxis. The dose is 600mg which would require more capsules to be taken if the 150mg strength is used, but if the cost savings is significant then he didn’t think it would be a major concern.
- Dr. Blevins motioned to approve the recommendation.
- Motion seconded and carried.

<table>
<thead>
<tr>
<th>Clinical Criteria for Cleocin Pediatric® (clindamycin pediatric solution)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No PA required for 11 years old &amp; younger.</td>
</tr>
<tr>
<td>• All others: Will be approved for patients unable to swallow tablets.</td>
</tr>
</tbody>
</table>

**Discussion:**
- Dr. Blevins motioned to approve the clinical criteria.
- Dr. Jones seconded the motion.
- Motion carried.

**Oxazolidinones**

- The only drug contained in the oxazolidinone class is linezolid. It is indicated for skin and skin structure infections, pneumonia and vancomycin-resistant Enterococcus infections. Linezolid is effective against methicillin-resistant Staphylococcus aureus (MRSA) and multi-drug resistant Streptococcus pneumoniae. Linezolid has demonstrated similar efficacy compared to other agents used for the same FDA-approved indications. To minimize the emergence of resistance, guidelines recommend reserving linezolid use for infections caused by methicillin-resistant
Staphylococcus aureus or ampicillin- and vancomycin-resistant Enterococcus faecalis/faecium. Therefore, it is recommended linezolid be subject to clinical criteria to ensure judicious use.

Discussion:
- Dr. Johns asked for clarification as to how the liquid approval would be handled due to the non-preferred status. Dr. Pittman stated it would only be approved based on the same proposed clinical criteria required for the tablets.
- Lyn Govette motioned to accept the recommendation as presented.
- Motion seconded and carried.

**Clinical Criteria for Zyvox®:**

<table>
<thead>
<tr>
<th>For oral therapy, the patient must have been diagnosed as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Vancomycin Resistant <em>Enterococcus faecium</em> infections, OR</td>
</tr>
<tr>
<td>• Vancomycin Resistant <em>Enterococcus faecalis</em> infections, OR</td>
</tr>
<tr>
<td>• Healthcare-associated Methicillin-Resistant <em>Staph aureus</em> (MRSA) infections or community-acquired MRSA with poly-resistance.</td>
</tr>
</tbody>
</table>

**Note:** The patient must have culture documentation of diagnoses. Individuals started on Zyvox® therapy in the hospital will be approved for the agent following hospital discharge in order to allow for completion of the course of therapy.

Discussion:
- Dr. Jones motioned to accept the clinical criteria as presented.
- Motion seconded and carried.

**Quantity Limits:**

| Zyvox® | Oral: 2 tabs/day or 60mL/day |

Discussion:
- Lyn Govette motioned to accept the quantity limits as presented.
- Motion seconded and carried.

**Oral Aminoglycosides**

- Neomycin is the only agent in the oral aminoglycosides class. Efficacy of neomycin as an adjunct treatment for the prophylaxis of surgical infections and hepatic encephalopathy has been demonstrated in clinical trials, although systemic absorption may lead to toxic reactions, such as neurotoxicity, ototoxicity and nephrotoxicity. For prophylaxis of surgical infections, guidelines recommend oral neomycin with oral erythromycin along with mechanical bowel preparation as a treatment option for use prior to colorectal surgery. Oral neomycin is recommended as a second line option for hepatic encephalopathy in patients that do not respond adequately to lactulose. Therefore, it is recommended oral neomycin should be available for use.

Discussion:
- Dr. Blevins made the motion to accept the recommendation as presented
- Dr. Jones seconded the motion
- Motion carried.

**Oral Nitroimidazoles**
Metronidazole and tinidazole are antiprotozoal drugs that belong to the nitroimidazole class of antibiotics. All of the nitroimidazoles are considered effective agents for the management of various protozoal infections such as intestinal amebiasis, giardiasis, and trichomoniasis. Metronidazole has additional coverage for bacterial infections caused by susceptible gram negative anaerobes. Additionally, clinical guidelines recommend metronidazole as a first line agent for the treatment of mild to moderate Clostridium difficile. Although, tinidazole has a longer duration of action and better side effect profile, both agents are considered equally effective. Tinidazole is the only nitroimidazole FDA approved to treat giardiasis; however, clinical data has not established one agent as being superior over another, and guidelines recommend use of both agents. Therefore it is recommended that at least metronidazole is available for use.

Discussion
- Dr. Jones motioned to accept the recommendation.
- Dr. Blevins seconded the motion.
- Motion carried.

**Non-Absorbable Rifamycin**

Rifaximin is the only nonabsorbable, broad-spectrum antibiotic FDA approved for the treatment of traveler’s diarrhea caused by noninvasive strains of E. coli and reduction in risk of overt hepatic encephalopathy recurrence in adult patients. Clinical guidelines list rifaximin as an alternative option for traveler’s diarrhea and specify antibiotics should be reserved as second-line agents for hepatic encephalopathy. Additionally, long-term clinical trial data beyond 6 months is not available. Therefore, it is recommended that rifaximin be subject to clinical criteria to ensure appropriate use.

Discussion
- Dr. Blevins motioned to approve the recommendation.
- Dr. Phares seconded the motion.
- Motion carried.

**Clinical Criteria for Xifaxan®**

Authorized if being used for ONE of the following:
- Treatment of traveler’s diarrhea caused by non-invasive strains of *Escherichia coli* (*E. coli*) that cannot be treated with another agent such as a fluoroquinolone or azithromycin.
- Treatment of hepatic encephalopathy for patients who do not adequately respond to lactulose.

Discussion:

- Lyn Govette motioned to approve the recommendation with modifications that the wording, trial/failure, contraindication, intolerance, drug-drug interaction could replace “cannot be treated”.
- Dr. Blevins seconded the motion.
- Motion carried.

The Committee was dismissed for Lunch break.
Attendance after lunch: all committee members returned.

**Sulfonamides**

- The sulfonamide antibiotics represent a group of agents whose coverage encompasses a wide variety of aerobic gram-positive and gram-negative bacteria, and are FDA-approved for the treatment of various infections. The development of widespread resistance to sulfonamide antibiotics has led to the majority of treatment guidelines for their FDA-approved indications listing the sulfonamide antibiotics as alternative treatments. However, the SMZ/TMP combination is still recommended first line in the treatment of urinary tract infections and in the treatment and prevention of *Pneumocystis carinii* pneumonia in patients infected with HIV. Sulfadiazine is recommended in combination with first line therapies pyrimethamine and leucovorin for the treatment of *Toxoplasma gondii* encephalitis. Due to its place as first-line therapy for the treatment of specified infections, it is recommended at least the combination SMZ/TMP should be available for use. Additionally, sulfadiazine should be available for the treatment of *Toxoplasma gondii* encephalitis.

**Discussion:**
- Dr. Johns made a motion to accept the recommendation with modification that a liquid formulation of SMZ/TMP is available.
- Motion seconded and carried.

**Clinical Criteria for sulfadiazine:**

<table>
<thead>
<tr>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadiazine will be approved for the treatment of <em>Toxoplasma gondii</em> encephalitis in combination with pyrimethamine.</td>
</tr>
</tbody>
</table>

**Discussion:**
- Motion made to accept the clinical criteria as presented.
- Motion seconded and carried.

**Oral Nitrofurans**

- Nitrofurantoin is the only agent in the nitrofuran class; however, it is available as nitrofurantoin suspension, nitrofurantoin macrocrystalline and nitrofurantoin monohydrate/macrocystalline. All formulations of nitrofurantoin are indicated for the treatment of urinary tract infections. Nitrofurantoin and nitrofurantoin macrocrystalline are also indicated for prophylaxis in patients with frequent UTIs; however, nitrofurantoin monohydrate/macrocystalline is indicated only for acute treatment. Clinical trials have demonstrated efficacy of all formulations of nitrofurantoin and have shown them to be similar to other agents used for the treatment of urinary tract infections. Additionally, current clinical guidelines from ACoG and IDSA recommend nitrofurantoin macrocrystals and nitrofurantoin monohydrate/macrocystals as treatment options for acute, uncomplicated UTIs. Due to its indication for both treatment and prophylaxis of UTIs, it is recommended at least nitrofurantoin macrocrystalline should be available for use. Additionally, nitrofurantoin suspension should be available for use in the pediatric population as well as for those with difficulty swallowing.

**Discussion**
• Lyn Govette motioned to approve the recommendation as presented.
• Dr. Dowell seconded the motion.
• Motion carried.

**Clinical Criteria for nitrofurantoin suspension:**
- No PA required for 11 years old & younger.
- All others: Will be approved for patients unable to swallow tablets.

Discussion:
- Motion made to accept the clinical criteria.
- Motion seconded and carried.

**Miscellaneous Agents for UTI**
- Fosfomycin is FDA-approved for single-dose therapy of uncomplicated UTIs (acute cystitis) in women due to susceptible strains of Escherichia coli and Enterococcus faecalis. Current clinical guidelines recommend fosfomycin as a treatment option for uncomplicated urinary tract infections, along with SMX/TMP, nitrofurantoin and quinolones; however, SMX/TMP is generally considered the preferred agent for treatment. In general, no significant differences were observed in clinical trials comparing treatment with fosfomycin and other agents used to treat uncomplicated urinary tract infections. Therefore, due to its higher relative cost, it is recommended fosfomycin should be subject to clinical criteria restricting its use to patients who are not candidates for other less costly treatment options.

Discussion
- Dr. Blevins stated that with so many other agents available and given that the drug is rarely used in clinical practice he agreed with the agent being placed on PA status.
- Dr. Jones commented that this agent would primarily be used in nursing home patients who have failed other treatments, but continue to have recurrent UTI (urinary tract infections).
- Dr. Blevins motioned to approve the recommendation.
- Motion seconded and carried.

**Clinical Criteria for Monurol®:**
- Will be authorized if the recipient is pregnant and has a urinary tract infection, OR, the recipient has a previous failure, contraindication, intolerance or resistance to at least 2 of the following agents: or previous failure with sulfamethoxazole/trimethoprim, or is infected with an organism resistant to sulfamethoxazole/trimethoprim.
  - Sulfamethoxazole/trimethoprim
  - Quinolones
  - Nitrofurantoin

Discussion:
- Dr. Blevins motioned to accept the clinical criteria.
- Motion seconded and carried.

**Quantity Limits:**
- Monurol®: 1 packet (3 g) per course of therapy
Discussion:

- Dr. Blevins stated the quantity limits were appropriate and motioned to approve the quantity limits as presented.
- Dr. Jones seconded the motion.
- Motion carried.
- Dr. Pittman stated that this category met requirements and made the recommendation to move this category to the low utilization category. Committee agreed.
- Motion made to move to the low utilization category.
- Motion seconded and carried.

**Methenamine & Combinations**

- The primary role of methenamine is for prophylaxis or suppression of urinary tract infections (UTIs), especially when long term therapy is considered necessary. The combination methenamine products are utilized primarily for relief of symptoms associated with urinary tract infections. Clinical trials demonstrate that methenamine single entity antibiotics are safe and effective for the prevention of urinary tract infections. There is limited clinical information regarding the place in therapy of these agents; however, the American College of Obstetricians and Gynecologists guideline on the treatment of urinary tract infections in nonpregnant women note that methenamine salts (hippurate and mandelate) have long been used for the prevention of urinary tract infections. All agents in this class can be considered therapeutic alternatives. Therefore, it is recommended at least one methenamine single agent product and one methenamine combination product should be available for use.

Discussion:
- Dr. Jones motioned to accept the recommendation as presented.
- Dr. Phares seconded the motion.
- Motion carried.

**Antifungals for Oropharyngeal Candidiasis**

- All of the agents in the class are FDA-approved for the treatment of oropharyngeal candidiasis. Clotrimazole is also approved to prevent oropharyngeal candidiasis in immunocompromised patients. Data from head-to-head clinical trials does not consistently demonstrate superiority of one agent over another in this class. Current IDSA treatment guidelines recommend clotrimazole troches, nystatin suspension or fluconazole for the treatment of oropharyngeal candidiasis. Of the agents in this class only nystatin is approved for use in children of all ages. Therefore, it is recommended at least two antifungals for the treatment of oropharyngeal candidiasis should be available for use, one of which should be nystatin suspension due to its use in children.

Discussion
- Dr. Blevins motioned to accept the recommendation.
- Dr. Johns seconded the motion.
Motion carried.

**Oral Antifungals for Systemic Infections**

- The oral antifungal agents are FDA-approved to treat a wide variety of infections, including but not limited to aspergillosis, blastomycosis and histoplasmosis, candidiasis, cryptococcal infections and dermatophyte infections. Clinical trials demonstrate efficacy within the FDA-approved indications and current clinical guidelines recommend the use of various oral antifungal agents as first- or second-line treatment options for various infections. Due to the relative safety and efficacy of fluconazole, ketoconazole, and griseofulvin in the treatment of fungal infections, it is recommended these agents should be available. Itraconazole, posaconazole and voriconazole are all effective for their respective FDA-approved indications; however, these agents are associated with significant adverse events and/or have very specific FDA-approved indications; therefore, these agents should be subject to clinical criteria. Due to the emergence of resistance, flucytosine is only indicated to be given in combination with amphotericin B; therefore, this agent should be subject to clinical criteria.

**Discussion**

- Dr. Blevins motioned to accept the recommendation.
- Lyn Govette seconded the motion.
- Motion carried.

### Clinical Criteria for flucytosine/Ancobon®

| Individuals started on flucytosine therapy in the hospital will be approved for this agent following hospital discharge in order to allow for completion of the course of therapy. |

**Discussion:**

- Lyn Govette motioned to approve the clinical criteria.
- Motion seconded and carried.

### Clinical Criteria for Noxafil®

| Noxafil® will be approved if used for ANY of the following: |
| As indicated for the prophylaxis of invasive *Aspergillus* and/or *Candida* in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoetic stem cell transplant (HSCT) recipients with Graft versus Host Disease (GVHD) or recipients with hematologic malignancies (leukemia, lymphoma, myelodysplastic syndromes) with prolonged neutropenia from chemotherapy |
| Treatment of *Fusariosis* disease |
| Treatment of *Zygomycetes* disease |
| Treatment of other fungal infections or molds that are refractory or resistant to, or in patient who have a contraindication or intolerance to itraconazole or voriconazole, or in patients who are intolerant to these medicinal products |

**Note:** If started as an inpatient hospital regimen and this is a continuation of therapy, via home health or in a nursing home, then the drug is approvable.

**Discussion:**
• Dr. Blevins motioned to accept the clinical criteria.
• Motion seconded and carried.

<table>
<thead>
<tr>
<th>Clinical Criteria for voriconazole/Vfend®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voriconazole will be approved for the following diagnoses:</td>
</tr>
<tr>
<td>• Treatment of invasive aspergillosis</td>
</tr>
<tr>
<td>• Serious fungal infections caused by <em>S. apiospermum</em> and <em>Fusarium</em> species including <em>F. solani</em></td>
</tr>
<tr>
<td>• Part of standard anti-fungal regimen in febrile neutropenic patients</td>
</tr>
<tr>
<td>• Other fungal infections that are refractory or resistant to other oral triazole agents (i.e. fluconazole, ketoconazole, itraconazole)</td>
</tr>
<tr>
<td><strong>Note:</strong> If started as an inpatient hospital regimen and this is a continuation of therapy, then the drug is approvable.</td>
</tr>
</tbody>
</table>

Discussion:
• Motion made to accept the recommendation as presented
• Motion seconded and carried.

<table>
<thead>
<tr>
<th>Quantity Limits:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole (Diflucan) 150 mg</td>
</tr>
</tbody>
</table>

Discussion:
• Dr. Schwerdt stated there are situations where voriconazole may be prescribed as 1 tablet daily for 3 days, then weekly for a specified time in patients with recurrent infections. Will the PA process allow this quantity limit?
  o Dr. Pittman stated that if the committee felt this was a rational or appropriate dosing they could review the quantity limit. Dr. Woods stated that the quantity limit was primarily set to prevent stockpiling.
  o Dr. Blevins stated that this dosing is rare and it would be appropriate to obtain through PA.
  o Dr. Pittman stated it would be available through the normal quantity limit clinical criteria.
• Lyn Govette motioned to accept the clinical criteria as presented.
• Motion seconded and carried.

**Oral Antifungals for Onychomycosis**

➢ The two oral agents currently FDA approved for the treatment of onychomycosis are terbinafine and itraconazole. Clinical trials demonstrate the clinical superiority of terbinafine compared to itraconazole and clinical guidelines consider terbinafine first-line therapy for the treatment of onychomycosis. Therefore, terbinafine can be considered a superior agent within this class. However, treatment for onychomycosis should be commenced only when mycological infection has been confirmed; therefore, all agents in this class should be subject to clinical criteria. In addition, because onychomycosis can be considered cosmetic in many cases, and cosmetic agents are excluded from coverage through the TennCare program, it is recommended that agents in this class be approved for onychomycosis only when an individual’s health could be compromised without treatment.

Discussion
- Dr. Woods stated that comments received from Dr. Capparelli were in agreement with the recommendation.
- Dr. Blevins motioned to accept the recommendation.
- Motion seconded and carried.

<table>
<thead>
<tr>
<th>Clinical Criteria for terbinafine (Lamisil®, Terbinex®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Terbinafine will not be approved for cosmetic use.</td>
</tr>
<tr>
<td>- Terbinafine will be authorized for the treatment of nail fungal infections (onychomycosis) if the following are present:</td>
</tr>
<tr>
<td>- Positive diagnostic microbiological or histological test (i.e. KOH preparation, periodic acid Schiff (PAS) stain, or lab culture), AND</td>
</tr>
<tr>
<td>- Underlying disease (i.e. diabetes, peripheral vascular disease, poor circulation, immunocompromised recipients)</td>
</tr>
<tr>
<td>- Terbinafine granules will be authorized for the treatment of tinea capitis.</td>
</tr>
</tbody>
</table>

Discussion:
- Lyn Govette asked if the greater than 4 years of age should be included in the clinical criteria. Dr. Pittman stated that is indeed FDA approved for patients 4 years of age and older. However, the age restriction was not included.
  - Dr. Woods asked if there was a safety issue with the use in children below this age. Dr. Pittman stated that due to the nature of the medications there could be possible safety concerns with this age group.
  - **Dr. Pittman stated they could review this and add this information to the clinical criteria, if needed.**
- Dr. Jones asked for clarification on how to differentiate cosmetic use in a diabetic patient.
  - Dr. Woods stated that this would be a concern for patients who may have an underlying condition in which progression of onychomycosis could pose a major risk. Dr. Woods stated that patients would qualify under the underlying disease bullet point.
  - Dr. Jones wanted to ensure that call center personnel would be cognizant of such concerns. Dr. Pittman stated that the call center criteria specifically ask if the patient has diabetes, peripheral vascular disease, poor circulation or are immunocompromised. Any of these diagnoses along with positive lab documentation will be approved.
- Comments received from Dr. Capparelli stated that many providers were good at diagnosing nail fungal infections on physical evaluation. Dr. Capparelli felt the lab documentation results were a barrier to care. However, Dr. Woods stated that Dr. Capparelli was under the impression that requesting lab documentation was new. Dr. Pittman stated that positive lab documentation was not new and was previously in place. Additionally, clinical literature has shown that over 50% of the lab tests come back negative indicating the condition is not truly a nail fungal infection.
- Dr. Blevins approved the clinical criteria presented.
- Motion seconded and carried.

| Clinical Criteria for itraconazole (Sporanox®) |
Itraconazole is unrestricted for Blastomycosis, Histoplasmosis, Aspergillosis, Cryptococcosis, Coccidiomycosis, febrile neutropenia, oropharyngeal/esophageal candidiasis, Candida krusei infections, and any other systemic fungal infection.

Also unrestricted for prevention of histoplasmosis or any other invasive fungal infection (including cryptococcosis, coccidiomycosis) in HIV or immunocompromised patients.

For onychomycosis will be authorized if ALL of the following are true:
- Positive diagnostic microbiological or histological test (including KOH preparation, periodic acid Schiff (PAS) stain, or lab culture), AND
- Underlying disease (i.e. diabetes, peripheral vascular disease, poor circulation, immunocompromised recipients, etc.), AND
- Recipient has tried and failed or has an intolerance or contra-indication to terbinafine.

Discussion:
- Dr. Johns asked for clarification as to how this agent will be listed on the PDL.
  - Dr. Pittman stated that all the oral antifungals are listed under one category on the PDL. The agents were just broken out for the purposes of reviewing the agents.
- Dr. Johns motioned to approve the clinical criteria.
  - Motion seconded and carried.

**Quantity Limits:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>itraconazole</td>
<td>4/day</td>
</tr>
<tr>
<td>Lamisil®</td>
<td>4/day</td>
</tr>
<tr>
<td>Sporanox®</td>
<td>4/day</td>
</tr>
<tr>
<td>terbinafine</td>
<td>84/year</td>
</tr>
<tr>
<td>Terbinex®</td>
<td>2 kits/year</td>
</tr>
</tbody>
</table>

Discussion:
- Dr. Corley asked why there was a difference in the quantity limits for terbinafine and Lamisil®. Dr. Pittman referred the question to Dr. Woods as this is the current quantity limit in place.
  - Dr. Woods was unsure why they had two different quantity limits and stated it was possibly just an error. Dr. Corley asked if the presented recommendation would be 4/day for both products.
- Dr. Jones motioned to accept the quantity limits with the modification to the terbinafine quantity limit of 4/day.
  - Motion seconded and carried.

**Clinical Criteria for Topical Agents used for Onychomycosis**

Ciclopirox 8% solution:
- As a result of clinical data showing that terbinafine is much more effective than topical agents, Dr. Pittman reviewed the proposed clinical criteria for topical agents used for onychomycosis. The proposed clinical criteria is essentially the same criteria used for itraconazole for onychomycosis.
Clinical Criteria for ciclopirox 8% (Penlac, Pedipirox4 Kit, ciclopirox kit 8%, CNL8 nail kit)

- For onychomycosis will be authorized if **ALL** of the following are true:
  - Positive diagnostic microbiological or histological test (i.e. KOH preparation, periodic acid Schiff (PAS) stain, or lab culture), AND
  - Underlying disease (i.e. diabetes, peripheral vascular disease, poor circulation, immunocompromised recipients), AND
  - Recipient has tried and failed or has an intolerance or contraindication to terbinafine.

Discussion:
- Dr. Blevins commented that the topical agents are not effective for onychomycosis.
  - Dr. Pittman agreed they were not effective and given the cost of terbinafine has decreased; the topical agents are actually more expensive.
- Dr. Jones motioned to approve the clinical criteria as presented.
- Motion seconded and carried.

REVIEW OF NOVEMBER PAC MEETING DECISIONS

SXC reviewed TennCare’s decisions from the November 8, 2011 meeting. In the interest of time, decisions were presented only for those classes in which TennCare did not accept the Committee’s recommendations.

- Dr. Corley and Dr. Pittman explained to the new committee members that the Grayed-Out packet consisted of the decisions that the PAC members voted on at the last meeting and the response of TennCare regarding those decisions as well as any item that required follow-up.
- Page 5: Committee asked for Twinject® to move to a non-preferred status due to cost. Upon further research the cost of Twinject® reflected on the cost utilization does not accurately reflect the net-net cost as a result of federal rebates, therefore Twinject® will remain preferred.
- Page 9: Quantity limits on sumatriptan nasal and Imitrex® nasal were presented with different quantity limits, so committee asked for research on the quantity limits. The quantity limits were researched and found to be presented incorrectly. The quantity limit should have reflected 6 units per month. Additionally, Treximet® is available as a package of 9, therefore quantity limits were changed to 9 tablets/month to avoid confusion. The QL (quantity limit) for Sumavel was inadvertently left off the list in error and will be listed with a QL of 4/month for consistency.
- Page 33: Following the meeting it was found that the max dose of nifedipine ER is 120mg daily, therefore the quantity limit for the 60mg tablets will be 2/day to prevent patient from having to use 2 different strengths.
- Page 43: TennCare accepted PAC’s recommendation with the additional clarification added regarding the outcomes data available for dabigatran.
  - Dr. Capparelli submitted comments that including the 110mg dose was pointless as this dose is not available in the US. Dr. Woods stated that information was included to accurately reflect the outcomes data of the RE-LY trial. Dr. Woods stated the committee could opt to remove this statement from the recommendation, since this dose is not available in the US or they could leave the statement in for completeness of the RE-LY trial outcomes.
Dr. Phares made a comment regarding a study in the February 12th Lancet publication which exhibited no increase in bleeding and would be glad to send this information out to any committee member that would like a copy.

The committee felt that the statement could remain for future reference.

- Page 44: TennCare accepted PACs recommendation with modifications regarding the suggestion to include a bullet point that “Xarelto will not be approved for concurrent use with amiodarone, dronedarone or non-DHP calcium channel blockers”. Given that the interaction between Xarelto and these agents is moderate and coadministration is not contraindicated, this statement will be incorporated into the criteria as a note.

- Page 52-53: TennCare disagreed with PAC’s recommendation regarding pitavastatin associated with a lower incidence of myalgia. At this time there is insufficient evidence to conclude this agent has a lower incidence. Rates of myalgia reported for pitavastatin ranged from 1.08% to 4.1% (data from Clinical Lipidology, 2010 and Livalo® package insert) with rates for simvastatin and atorvastatin ranging from 0.9% to 3.7% and 2.7% to 8.4% respectively (data from package inserts). TennCare will continue to monitor the data and if data supports lower rates, TennCare will reconsider the requested criteria change.

- Page 62: PAC approved the quantity limits presented by SXC, but requested increasing the QL on all other strengths to 1.5mg per day to allow titration up to the higher strength without having to fill a different script. TennCare accepted PAC’s recommendation including the increase of the QL for all other strengths to 1.5/day. However, to avoid the perception that the tablets may be split, the QL will be posted as a per 30 day QL.

- There were no requests for public testimony.

Next Meeting will be May 24, 2012
Dr. Corley thanked Dr. Woods for her service and wished her well on behalf of the committee.
Meeting Adjourned.