TennCare Pharmacy Advisory Committee (PAC Meeting)
November 10, 2009

Members in Attendance:
David Collier, MD (TennCare), Chairman Alan Corley, DPh, Stanley Dowell, MD, Vice-Chair Jeri Fitzpatrick, MD, Edward Capparelli, MD, Lyn Govette, MPAS, PA-C, Lynn Knott, PharmD, Carol Minor, Nicole Woods, PharmD (TennCare), Roger Zoorob, MD

Non-members present from SXC: Leslie Pittman, PharmD, Robin Ramsey, PharmD,

INTRODUCTIONS
The meeting was called to order by Chairman Alan Corley. In review 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. The conflict of interest statement was read aloud. Dr. Corley stated no conflicts of interest had been disclosed. The members of the Committee introduced themselves.

MINUTES
The August 27, 2009 meeting minutes were reviewed.
- Motion made to approve the minutes.
- Motion seconded and carried.

TENNCARE UPDATE
Dr. David Collier gave this quarter’s TennCare update.
- TennCare MCO’s are now fully integrated.
- TennCare received high scores for the HEDIS/CAHPS report for 2009.
- University of Tennessee’s Center for Business and Economics Research conducts ongoing survey of TennCare recipients’ satisfaction with the TennCare program.
  - Enrollees reported 92% satisfaction with their coverage for 2009 timeframe.
- The CHOICES program
  - Phased implementation
    - Middle region: March 1, 2010
    - East & West regions: first of fiscal year 2011 (July 1, 2010)
  - Reorganization of Long Term Care (LTC) system
    - Simplified access
      - Will have single entry point to facilitate eligibility and enrollment
      - Public education & outreach will be provided
        - Assessment and screening will be granted along with information regarding referral for the program
        - Streamlined enrollment-expedited process
        - Comprehensive care coordination across acute care/LTC services
        - Integration of LTC services within existing system
        - Continuous quality improvement strategy across acute care/LTC services
  - Refocus LTC services
    - Increased utilization of Home & Community based services (HCBS)
- Critical Adult Care homes
  - Around the clock residential level II care for up to 5 disabled or elderly adults
    - Include specialized and/or skilled care for ventilators and traumatic brain injury patients
- Consumer (member) directed options include:
  - Personal care
  - Attendant care
  - Homemaker
  - In-Home respite
  - Companion care
  - Offer self directed care options-ability to hire non-traditional providers
  - Increased community based residential alternatives to nursing facilities
- Rebalance LTC funding
  - LTC funding will be part of global budget-funding will be streamlined
  - Monies follow person into appropriate, cost effective setting of their choice
  - Ability to serve more people with existing funds
  - Improved balance between expenditures for nursing facilities versus HCBS services.
- Care coordination
  - Comprehensive, continuous, holistic, and person-centered model of care
    - Member can maintain or improve physical or behavioral health status and/or functional abilities
    - Maximize member’s independence
    - Ensure member’s health, safety & welfare
- CHOICES integrated model will coordinate all Medicaid services for elderly & disabled
- Post-CHOICES implementation
  - Elderly & Disabled waiver terminates in respective regions
  - All waiver participants and nursing facility residents will be transitioned into CHOICES
  - All LTC services will be provided through CHOICES
    - LTC services will no longer be provided through current fee-for-service system. All payments will come through MCO’s.
  - Scheduling and authorization of services
    - Must be pre-authorized through MCO based on established Plan of Care
    - Scheduling based on member needs
      - Timeliness of service will be monitored
  - Electronic Visit Verification (EVV)
    - Required for CHOICES
    - Track provision of services
    - Facilitate timely payments
Increase ability to identify and resolve problems related to service gaps or delays in service

Visits will be tracked via logging in & out by phone

- TennCare budget presentation to the Governor will be November 18, 2009 at 4pm
- TennCare Legislative Oversight Committee meeting will be November 19, 2009
  - Webcast available: http://www.capitol.tn.gov/joint/committees/tenncare.html

Discussion

- Dr. Capparelli expressed concern that there was lots of paperwork involved with the new waiver and no reimbursement. He asked whether nursing home patients could end up stuck if the provider did not fill out the appropriate form. He also stated that for severely mentally and physically challenged patients, cutting 18 hrs of care per day to 24 hrs per week would result in insufficient care.

- Dr. Collier clarified the waiver versus limits on home health nursing. He explained that under the home health nursing limits, home services cannot cost more than nursing home care, and the MCOs must approve these services.

- Dr. Capparelli asked to what extent physicians have a say in the services approved. Dr. Collier stated that the physician needed to order the services, and that the MCOs could provide more specific information.

- Dr. Capparelli asked what would happen if a physician did not sign the proper forms. Dr. Collier stated that if the physician did not contract with the MCO, the provider would receive the non-network rate.

TENNCARE PHARMACY UPDATE

Dr. Nicole Woods gave this quarter’s TennCare Pharmacy update.

- H1N1 Influenza Update
  - At last PAC meeting in August, Tamiflu® and Relenza® clinical criteria were still in place. In late August, early September the State was beginning to experience H1N1 outbreaks.
  - In early September, an expedited queue was created in the call center to handle Tamiflu® and Relenza® requests in an expedited manner. Phone prompts were also created on the call center’s opening greeting to direct providers to line dedicated to Tamiflu® and Relenza® requests.
  - Based on CDC recommendations that children 5 years of age and younger were at high risk for complications from influenza, on September 3, 2009, the PA requirements for Tamiflu® and Relenza® were removed for children 5 years of age and younger.
  - The State’s cases of influenza continued to increase and on September 25, 2009, clinical criteria for Tamiflu® and Relenza® was removed to ease the administrative burden on clinics and ER’s caring for large numbers of TennCare recipients.
  - Claims for Tamiflu® and Relenza® will continue to be closely monitored and as more guidance from the CDC is available, TennCare will consider reinstating the clinical criteria for Tamiflu® and Relenza® once widespread flu activity has subsided.
  - Current claims for Tamiflu® and Relenza® are still at 4 to 6 times above the volume for a “typical” influenza season.
  - The H1N1 vaccine is now available and TennCare continues to encourage recipients to be vaccinated as appropriate.
The H1N1 vaccine and nasal spray are covered for all TennCare recipients and does not count towards monthly prescription limits.

Pharmacies that are registered H1N1 vaccine providers for 2009-2010 influenza seasons can submit claims for the H1N1 vaccine through the pharmacy point of sale (POS) system.

- The claim will adjudicate showing $0 cost for drug and a $10.25 dispensing fee which represents the administration fee
- Pharmacies initially were instructed to submit $0 for drug cost, due to system limitations, pharmacies must submit claim with $0.01 cost for vaccine. Messaging was placed to instruct pharmacies how to submit claims.

Discussion
- Dr. Capparelli asked if the quantity limits for Tamiflu® and Relenza® were in place and asked about the current limits. He reported hearing from other providers who believed there were no longer quantity limits when the PA requirements for Tamiflu® and Relenza® were removed.
  - Dr. Woods reported the quantity limits were still in place. She stated the initial quantity limits allowed for one course of therapy during a 6 month time period. However, due to the extenuating situation with this years’ influenza season current quantity limits were increased to allow for 2 courses of Tamiflu® or Relenza® during a 6 month time period. This change was implemented mid-October.
- Dr. Capparelli asked if the quantity limit information had been communicated to providers
  - Dr. Robin Ramsey stated the initial quantity limit information was included in the fax blast sent to providers when the clinical criteria requirements were removed for Tamiflu® and Relenza®. The updated quantity limits are currently posted on the web PDL.

Dr. Woods reported on the change in coverage of Zegerid® on PDL.
- Effective October 1, 2009, the manufacturer of Zegerid® decided to no longer participate in the federal rebate program. Therefore, Zegerid® become non-rebateable and no longer covered under the TennCare program.
- The current PAC recommendation states “that for provider choice, at least two proton-pump inhibitors (PPI) should be available.
- TennCare replaced Zegerid® with omeprazole as a preferred PPI. TennCare worked with SXC to have prior authorizations built for preferred PPI’s so providers would not have to make additional phone calls to switch Zegerid® users to another preferred product. The transition went smoothly with minimal disruption.

Discussion
- Dr. Capparelli asked if esomeprazole (Nexium®) and omeprazole were considered the same entity but different isomers or were the products considered different.
  - Dr. Woods stated the agents were considered different products because lack of response or intolerance to one does not necessarily indicate that the patient will not respond to the other.

Auto-Exemption (AE) Subcommittee meeting
- By law, the AE subcommittee is required to comply with the State’s open meeting law which requires the meeting agenda to be posted 7 days in advance of the meeting. Due to a miscommunication between the State and SXC the agenda was not posted prior to the meeting, therefore the scheduled meeting prior to the PAC meeting was cancelled.
• Dr. Woods proposed the AE subcommittee meeting be rescheduled in February 2010, unless the subcommittee members felt the meeting should be scheduled sooner.
  o The AE subcommittee members present (Dr. Corley, Dr. Capparelli, and Ms. Govette) stated agreement to postpone until day of February PAC meeting.

• Dr. Stanley Dowell asked Dr. Woods about the availability of the H1N1 vaccine for providers.
  o Dr. Woods stated she did not have exact amounts or estimated availability at this time. She stated to date, approximately 600,000 doses have been sent to Tennessee thus far, with more doses being shipped. **Dr. Woods stated she would get more information on H1N1 vaccine availability for Dr. Dowell and the committee.**

• Bolded follow up items from August minutes
  o Prior to the PBM vendor change, there was link from the TennCare website where providers could sign up for a list serve for information on TennCare changes. The committee had asked the State if the list serve was still available.
    • Dr. Woods reported the TennCare list serve was still available. Interested parties should go to [www.tn.gov/tenncare](http://www.tn.gov/tenncare) and click on “Providers” (left column), then “Pharmacy” (middle of page). There is an additional link to “Pharmacy Emailed news and updates” (middle of page) along with detailed instructions on how to sign up to receive mailings.
  o TennCare would survey oncologists for more information as to when Neumega® is used outside of the hospital setting.
    • Dr. Woods reported the State had reached out to one of the oncology specialists who had provided input for the oncology reviews, Dr. Jeffery Patton. Dr. Patton stated medical oncologists rarely use Neumega® however, gastroenterologists do use in the clinical setting of hepatitis C. He stated those practitioners are not generally set up to buy and bill medication and those patients do sometimes self administer. Dr. Woods stated based on Dr. Patton’s comments, Neumega® will remain under the pharmacy benefit at this time.
  o Inquiry by the committee was made as to whether other State Medicaid programs had restrictions on oncology agents.
    • Dr. Woods reported other Medicaid programs did have various restrictions in place for oncology agents, some program examples included Washington and Georgia.
      • Washington: all multisource brands, nilandron, Revlimid, Targretin, and Thalomid require prior authorization.
      • Georgia: requires prior authorization for selected anti-neoplastic drugs (includes bicalutamide, Sprycel®, Sutent®, Tarceva®, and Temodar®)

• Dr. Woods polled the committee members via email prior to meeting on two additional items.
  • A new IFN beta-1b product is now available, Extavia®. The product is identical to Betaseron® (same ingredients, strengths, and dosage forms).
The current PAC recommendation states: “all formulations of biologic modifiers be available for use”

Dr. Woods had asked the committee if the intent of the recommendation was “to have all unique (drug, strength, formulation) to be available” or for “all products to be available”. The latter would require the State to have identical products preferred regardless of cost to the State

Dr. Woods reported four PAC committee members responded via email stating the intent was “unique formulations”. They all agreed having one product was reasonable.

- Dr. Capparelli stated that the phrase “same strength and indications” should be included in order to be considered the same product.
- The committee verbalized agreement that the recommendation was intended to be unique agents and the State should make decision of which is more cost effective to the State.

The State received a letter from the AIDS Healthcare Foundation (AHF) regarding our current coverage of raltegravir. The letter suggested the State place raltegravir on prior authorization given its higher cost compared to other first line agents.

- When the Integrase Inhibitors were initially reviewed by PAC, raltegravir had not received a first line therapy indication and was FDA approved for salvage therapy only. SXC recommended raltegravir be subject to step therapy to reserve its use to treatment-experienced HIV patients. PAC accepted recommendation and asked that raltegravir be moved to preferred status with step therapy. PAC also recommended step therapy be removed if/when raltegravir received a first line indication.
- Dr. Woods stated she asked for Dr. Raffanti’s expert opinion on AHF’s letter.
  - Dr. Raffanti stated he discussed situation with ART conference group and their consensus was that even though the FDA approved raltegravir for naïve patients it is not in the current guidelines as a preferred choice. He stated they felt it was prudent to remind providers at this time there is little long term data on safety and efficacy in naïve treatment regimens and its significant price should make most providers reserve it for those naïve patients who cannot tolerate the NNRTI or PI based regimen alternatives. Dr. Raffanti stated it would be reasonable to restrict its use for naïve patients in this situation.

- Dr. Woods reported all of the committee’s responses via email stated the State should follow Dr. Raffanti’s recommendation and current practice guidelines.
- The committee verbalized agreement with the emailed opinions.

**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 November 10, 2009 PAC review packet at: https://tnm.providerportal.sxc.com/rxclaim/TNM/Pcommittee.htm

Analgesics

Non Steroidal Anti-Inflammatory Agents (NSAIDs)

NSAIDs are widely used to treat mild to moderate pain as well as acute and chronic inflammatory conditions. The American College of Rheumatology, the ACP and APS all recommend NSAIDs as first line therapy options for mild to moderate pain. Currently available treatment guidelines do not give preference to one NSAID over another, but do recommend caution and close monitoring of patients for efficacy and safety. Specifically, ketorolac is used only for short term management of moderately severe post-surgical pain, and it has been associated with an increased risk of severe adverse effects, specifically a black box warning for GI bleeding, renal failure, effects on platelets, and use in labor, delivery, and nursing. Due to these safety concerns, it is recommended that ketorolac therapy be reserved to no more than 5 days of therapy. With the exception of ketorolac, all other NSAID agents have been demonstrated to be similar in efficacy and adverse effects, and can be considered therapeutic alternatives. In order to ensure adequate prescriber choice, it is recommended that at least 5 NSAID agents be available for use. There is no evidence to demonstrate that topical NSAID agents are more effective than oral agents; however the topical agents can be useful in patients with difficulty swallowing or with poor absorption. Therefore, it is recommended that topical NSAID agents be available to those with swallowing or absorption difficulties. Given its misoprostol component, Arthrotec® is associated with fewer gastroduodenal ulcers than diclofenac alone; therefore it is recommended that Arthrotec® be available for those at high risk for GI ulcers.

Discussion

- Dr. Capparelli stated he felt meloxicam should be an agent that is available in this category. He stated meloxicam should be available because of its increased cyclooxygenase II activity and decreased gastrointestinal effects compared to traditional NSAIDs, additionally, meloxicam can be dosed daily.
- Dr. Corley stated a phrase addressing liquid formulations being available should also be included in the recommendation.
- Dr. Zorob asked if the 5 agents that would be available would include meloxicam and Arthrotec® or would be in addition to.
- Dr. Capparelli asked why only 5 agents were included in the recommendation. He stated that if the general rule was to offer half of the available agents then more agents could be included to be available in this category.
  - Dr. Pittman stated that was the general suggested rule however when classes had numerous agents available, the recommended number available was not always exactly half of available agents.
- Dr. Dowell motioned that seven agents be made available and the agents would include meloxicam to be available as well as wording added to address liquid formulations.
- Motion was seconded and approved.
Proposed Clinical Criteria for Arthrotec®
- PA approval not required for patients ≥ 60 years old.

Discussion
- Dr. Capparelli stated the phrase “For patients < 60 who are at high risk for GI side effects” should be added as a patient population who would be eligible for Arthrotec®
- Motion made to accept clinical criteria for Arthrotec® with proposed changes to add wording for patients < 60
- Motion seconded and carried.

Proposed Clinical Criteria for Flector® & Voltaren® gel
- Approval will be granted for the following conditions:
  - Patient has failed an adequate trial of ORAL generic diclofenac AND at least 1 other preferred NSAID (to equal a total of at least 2 preferreds), OR
  - Patient is unable to swallow/absorb PO medications

Discussion
- Dr. Capparelli asked if patient would have to try and fail oral diclofenac in order to be approved for Flector® & Voltaren® gel.
  - Dr. Pittman stated the patient must try and fail the generic in order to be approved for a brand name agent
- Dr. Capparelli asked about what would happen in the scenario of a patient who could not tolerate or had other contraindications to other PO NSAID medications, besides diclofenac.
  - Dr. Ramsey stated the patient could be approved for Flector® & Voltaren® gel if they had a contraindication or intolerance to oral NSAIDs.
- Dr. Capparelli recommended that bullet point be added to clinical criteria to address “contraindication or intolerance to oral NSAIDs”
- Motion made to accept clinical criteria with proposed addition
- Motion seconded and carried.

Step Therapy (ST) for Meloxicam
- Mobic® requires prior authorization for anyone < 60 years of age.
  - For patients < 60 years: Prescriptions for Mobic® can be approved for those patients that have had a therapeutic trial of one month of at least 2 traditional NSAID medications or are at risk of a GI bleed as noted by one of the following contraindications:
    - History of PUD (peptic ulcer disease)/GI bleed
    - GERD (gastroesophageal reflux disease) due to conventional NSAIDS
    - Patient on anticoagulants (warfarin/heparin/LMWH)
    - Patient on corticosteroids
    - Hx of platelet dysfunction or coagulopathy
    - Patient on methotrexate

Discussion
- SXC proposed to remove ST for meloxicam
- Motion made to accept SXC’s recommendation to remove ST
- Motion seconded and carried

Quantity Limits
- Motion made to accept QL
• Motion seconded and approved

**COX-II Inhibitors**

⇒ Celecoxib is an NSAID agent that is more selective for cyclooxygenase-2 (COX-2) and has demonstrated a lower incidence of GI adverse effects as well as a lesser effect on platelet aggregation than other non-selective NSAIDs. Current clinical guidelines, with the exception of those from the American College of Rheumatology Subcommittee on Osteoarthritis, all consistently recommend the NSAID class as a first line therapy option for mild to moderate pain and do not give preference to one NSAID or COX-II agent over another. The American College of Rheumatology Subcommittee on Osteoarthritis recommends use of COX-II inhibitors in patients at increased risk of severe GI adverse events. Clinical studies have demonstrated that COX-II inhibitors are as effective as traditional NSAID agents in regards to treatment of pain and inflammatory conditions, but offer a more favorable gastrointestinal side effect profile. However, due to ongoing safety concerns of increased risk of cardiovascular events the use of celecoxib should be limited to patients who are at high risk of gastrointestinal side effects or to patients who cannot tolerate traditional NSAIDs. Therefore, it is recommended that celecoxib be available for use but be subject to step therapy criteria.

**Discussion**

- Dr. Capparelli stated he had reviewed 2 additional meta analyses that did not demonstrate celecoxib caused increased cardiovascular risk. He stated he was not able to review the American Heart Association’s statement on use of COX-II inhibitors but felt the current data did not support the recommendation that included statement of “ongoing safety concerns of cardiovascular events”
  - Dr. Ramsey stated the current data is not clear, there are some studies as Dr. Capparelli referenced that do not show increased cardiovascular risk and there are other studies that continue to question its potential cardiovascular effects.
- Dr. Capparelli stated the cardiovascular risk data is seen only at higher dosing of celecoxib (>400mg daily)
- Dr. Capparelli recommended removing the sentence from the recommendation and re-stating as “Therefore, the use of celecoxib should be limited to patients who are at high risk of gastrointestinal side effects or to patients who cannot tolerate traditional NSAIDs”.
- Motion made to accept recommendation with proposed changes
- Motion seconded and carried.

**Proposed Step Therapy for Celebrex®**

- All COX II inhibitors require prior authorization for anyone < 60 years of age.
- For patients < 60 years: Prescriptions for COX-II inhibitors can be approved for those patients that have had an adequate trial of one month of at least two traditional NSAID medications or are at risk of a GI bleed as noted by ANY one of the following contraindications:
  - History of PUD (peptic ulcer disease)/GI bleed
  - GERD (gastroesophageal reflux disease) due to conventional NSAIDS
  - Patient on anticoagulants (warfarin/heparin/LMWH)
  - Patient on corticosteroids
  - Hx of platelet dysfunction or coagulopathy
  - Patient on methotrexate
• Celebrex® for moderate to severe pain: Doses should be kept to \(\leq 200\text{mg per day}\)

**Discussion**

• Dr. Capparelli stated the first bullet point should be re-phrased to mimic the wording in the Arthrotec® clinical criteria “PA approval not required for patients \(> 60\) years old”

• Dr. Capparelli stated adding clopidogrel users and possibly chronic aspirin users to the criteria for increased risk of GI bleed should also be discussed.
  
  o Dr. Roger Zorob stated agreement that clopidogrel users should be added. He also stated chronic aspirin users are at risk but risk is lower.
  
  o Lynn Govette stated the clopidogrel users should be added to the statement regarding “patients on anticoagulants”

• Dr. Capparelli motioned to accept the clinical criteria provided that first bullet point be re-worded to mimic Arthrotec® phrasing and that use of clopidogrel be added as a risk factor for GI bleeds. **Dr. Capparelli asked if SXC would further investigate the concomitant use of aspirin with COX-II inhibitors versus traditional NSAIDs and bring information back to committee for discussion as to whether chronic aspirin users should be added to the COX-II inhibitor criteria.**

• Dr. Woods asked the committee if a bullet point addressing familial adenomatous polyposis (FAP) should also be included.
  
  o Dr. Capparelli stated no because the FAP dosing is at the level where cardiovascular risk is questionable.

• Motion made to accept clinical criteria with proposed changes.
• Motion seconded and carried.

**Quantity Limits**

• Motion made to accept quantity limits
• Motion seconded and carried.

**Non Narcotic Analgesics**

⇒ Tramadol is a centrally acting synthetic opioid analgesic. Tramadol is a unique analgesic in that it possesses both opiate and noradrenergic qualities. Tramadol plays a role in the treatment of both acute and chronic pain. When compared to opiate agents, tramadol may be better tolerated, have lesser side effects and may have a lower potential for abuse and psychological/physical dependence when used short term. However, cases of abuse and dependence have occurred and patients should be monitored closely for efficacy and misuse, especially in the setting of long term use. Current clinical guidelines consistently recommend use of tramadol when treatment with APAP and NSAIDs are not adequate or contraindicated. Clinical trials have demonstrated efficacy in treating pain due to a number of etiologies Therefore, it is recommended that at least one tramadol-containing analgesic be available for use.

**Discussion**

• Dr. Capparelli stated if “one-tramadol” containing analgesic be available then the agent could potentially be tramadol-acetaminophen. He stated the combination product’s indication is technically for short term use only. Dr. Capparelli recommended that the recommendation be re-phrased to state “at least one generic tramadol product be available for use”

• Motion made to accept recommendation with proposed change in phrasing.
• Motion seconded and carried.

**Quantity Limits**
Motion made to accept QL
Motion seconded and carried

**Short Acting Narcotics**

Opioid agents are a primary class of drugs used in pain management with short acting opioid agents playing an important role in the treatment of acute pain and breakthrough pain in patients with chronic pain. With the exception of trials involving propoxyphene, clinical trials have consistently demonstrated the efficacy of short acting opioid agents, and studies comparing the various short acting opioids have demonstrated that no one single agent is definitively superior over the other agents in the class. The short acting opioids are similar in their adverse effects and many of the adverse effects subside with continued dosing as tolerance builds. Currently available clinical guidelines recommend use of the short acting opioid agents for acute pain and chronic breakthrough pain. The guidelines recommend monitoring patients closely for efficacy, misuse and adverse effects, but do not recommend one agent over another. Therefore, it is recommended that at least 2 unique single agent short acting opioids and at least 2 unique combinations of short acting opioids be available for use.

**Discussion**

- Dr. Capparelli stated for single agent products one should be oxycodone and for combination products agents should include hydrocodone/acetaminophen (APAP) and oxycodone/APAP. Dr. Capparelli stated the tapentadol still had potential for addiction and may have less side effects but not enough data available yet.
- Dr. Corley stated a phrase for liquid formulations should also be included in the recommendation. Specifically, Dr. Corley stated codeine, morphine, and hydrocodone/APAP.
  - Dr. Capparelli stated the codeine/APAP elixir is used for controlling coughing and other respiratory symptoms.
  - Dr. Corley stated liquid morphine was widely used for cancer and hospice patients and the liquid hydrocodone/APAP was utilized for children post procedures and injuries.
- Dr. Corley inquired about the branded products listed as preferred in the drug listing.
  - Dr. Pittman explained the products were either priced as generics or there were significant rebates in place.
- Dr. Zorob asked for clarification regarding propoxyphene. He asked why the agent was preferred when the data was not consistent and some experts believed it was no more efficacious than APAP.
- Dr. Capparelli stated there were over 15,000 scripts for propoxyphene last quarter. He stated the significant safety concerns with other agents gives a place for the drug even though its efficacy is not as established. He stated many of his patients therapeutically responded to propoxyphene.
- Dr. Knott stated the CNS effects of propoxyphene in the elderly were horrible. She stated at her facility they transition all patients off propoxyphene through tapering to acetaminophen. She stated there were very few documented failures with the approach.
- Dr. Zorob stated he generally does not use propoxyphene in his patients.
- Dr. Capparelli stated it is generally a last resort but he did feel it has a place in therapy.
• Motion made to accept recommendation with change to include oxycodone in single agents, hydrocodone/APAP and oxycodone/APAP in the combination agents and to include language for liquid formulations that would include codeine, hydrocodone/APAP and morphine.

• Motion seconded and carried.

Quantity Limits

Discussion
• Dr. Capparelli asked why the codeine limits were set higher than oxycodone and hydrocodone products.
  o Dr. Ramsey stated the codeine was coded according to maximum dosing range.

• Dr. Capparelli stated he recommended for the 60mg single and combination products the quantity limits be set at 6 tablets per day.

• Dr. Corley noted in the packet quantity limit table, in the propoxyphene/APAP listing the 10/500mg listing should actually be 10/650mg.

• Motion made to accept the quantity limits with the proposed change to the 60mg codeine products to 6 tablets per day

• Motion seconded and carried.

Gastrointestinal Agents

Chloride Channel Activators

⇒ Lubiprostone is the only chloride channel activator available. In clinical trials, it has demonstrated efficacy in the treatment of chronic idiopathic constipation as well as constipation predominant irritable bowel syndrome (IBS) in women. However, lubiprostone has not been directly compared to conventional treatments such as dietary management and laxatives which are recommended as first-line treatment for constipation and therefore it is typically reserved for patients in whom other approaches have been unsuccessful. Current clinical guidelines include lubiprostone as a treatment option when therapy with dietary management and laxatives has been unsuccessful. Therefore, it is recommended that lubiprostone be available for use subject to clinical criteria.

Discussion
• Dr. Capparelli asked if approval was granted for things other than idiopathic constipation
  o Dr. Ramsey stated no, the only approvable indications were for idiopathic constipation and constipation-dependent IBS

• Dr. Capparelli asked if there were any issues with electrolyte or chloride balance with the use of lubiprostone
  o Dr. Ramsey stated she was not aware of any reports

• Ms. Govette asked for clarification that the IBS indication was for women only.
  o Dr. Ramsey stated yes the IBS indication was for women only.

• Motion made to accept the recommendation

• Motion seconded and carried.

Proposed Clinical Criteria for Amitiza®

• Approval for Amitiza® will be granted upon documentation of:
  - Diagnosis of idiopathic chronic constipation or constipation-predominate irritable bowel syndrome (IBS) AND
- Trial and failure of at least TWO other laxatives (bulk, osmotic, or stimulant)

Discussion
- Dr. Capparelli recommended adding phrase “in women” with the IBS indication for the published criteria
- Motion made to accept the clinical criteria.
- Motion seconded and carried.

Quantity Limits
- Motion made to accept quantity limits
- Dr. Capparelli asked if the dose should be diagnosis
  - Dr. Pittman stated the higher dose was for idiopathic constipation rather than IBS.
- Dr. Capparelli asked why the dosing was different for the indications.
  - Dr. Ramsey stated she was not sure why there was a difference
- Motion seconded and carried

Laxatives
⇒ Laxatives are used for the treatment of constipation, for bowel preparation prior to gastrointestinal procedures and for the prevention and treatment of hepatic encephalopathy. Lactulose, polyethylene glycol (PEG), and sodium phosphate (NaP) monobasic and dibasic formulations are the prescription laxatives available. Current clinical guidelines include lactulose and polyethylene glycol for treatment of constipation when dietary management fails. Additionally, lactulose is also recommended for the treatment of hepatic encephalopathy. Sodium phosphate (NaP) regimens are comparable in efficacy to PEG regimens for bowel preparation but NaP has demonstrated more severe systemic adverse effects and it is not recommended for use in patients with renal or liver insufficiency, congestive heart failure, or liver failure. Therefore, it is recommended that lactulose and polyethylene glycol be available for use.

Discussion
- Motion made to accept recommendation
- Motion seconded and carried.

Dermatological Agents

Agents for Genital Warts
⇒ Imiquimod, podofilox, and sinecatechins are FDA-approved for the topical treatment of external genital warts. Imiquimod is also indicated for the treatment of AK and superficial BCC. Current clinical guidelines from the CDC for the treatment of genital warts do not recommend any one regimen over another; however sinecatechins is not discussed in the guideline, as it was approved after publication, and its place in the pharmacotherapeutic management of genital and perianal warts is unknown. The use of imiquimod for the treatment of AK and superficial BCC is addressed in national and international treatment guidelines and it is recommended as a treatment option for both disease states. Therefore, it is recommended that at least one agent for the treatment of genital warts be available for use. Additionally, due to its role in the treatment of AK and BCC, it is recommended that imiquimod be available for use.

Discussion
• Dr. Capparelli asked if utilization data could show indications for usage
  o Dr. Pittman stated that information was not available
• Dr. Capparelli stated he experienced a high drop out rate with use of podofilox compared to imiquimod. He stated the podofilox was more irritating to the skin and due to the nature of genital warts it was more difficult to separate treatment areas from non-treatment areas.
• Dr. Capparelli motioned to accept recommendation
• Motion seconded and carried.

Emollients
⇒ Emollients increase hydration of the skin to maintain the skin’s barrier properties and prevent irritation. Current clinical guidelines recommend these agents as standard therapy for many skin conditions, such as seborrheic dermatitis and atopic dermatitis. Guidelines do not recommend one topical emollient over another; however, ammonium lactate is currently the only FDA-approved emollient. Therefore, it is recommended at least ammonium lactate be available for use.

Discussion
• Ms Govette asked for clarification regarding the guidelines statement of use of emollients in the care of contact dermatitis as secondary prevention strategy. Ms Govette asked why it would be considered secondary prevention if the primary treatment goal would include avoiding the irritant
  o Dr. Woods stated there might be situations where individual could not avoid the irritant and the emollient was used to prevent dermatologic reaction. She gave the example of a teacher with reaction to chalk.
• Dr. Capparelli asked whether there was any data available related to use of lactic acid and lactic acid with vitamin E where there is impaired skin integrity and any information as to whether the vitamin E added any benefit to the lactic acid.
  o Dr. Pittman stated there was no information available because the products are not approved by FDA. She stated the agents are non-FDA approved marketed prescription drugs.
• Dr. Capparelli asked why the agents were listed as preferred if they are not FDA-approved
  o Dr. Pittman stated the agents were listed because they are available and are generally thought to be equivalent to ammonium lactate. She stated ammonium lactate and lactic acid are group together in the same category in the SXC claim system.
• Dr. Capparelli noted the utilization for the lactic acid and the lactic acid with vitamin E was both low. He stated he was not sure that covering non-FDA approved medications was appropriate.
  o Dr. Woods stated historically, the other agents that have been covered were older agents that simply had not gone through the approval process
• Ms. Govette noted the agents here were steroid sparing which would be useful characteristic for pediatric population.
• Dr. Capparelli motioned to accept recommendation
• Motion seconded and carried.

Topical Steroids
Topical corticosteroids are utilized for symptomatic relief and treatment of both acute and chronic inflammatory dermatoses. Topical steroids are the standard of care for the treatment of atopic dermatitis and psoriasis, according to guidelines from the AAD. Currently available clinical guidelines do not differentiate between agents or dosage forms. Results from clinical trials demonstrate that there is no one topical corticosteroid agent that is more efficacious than another in the class. Additionally, clinical trials evaluating the different dosage forms did not consistently demonstrate that a specific dosage form is more efficacious than another. All agents in this class can be considered therapeutic alternatives to the other agents in the same potency group. It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

Discussion
- Dr. Capparelli asked if all generics would be preferred and all brands non-preferred.
  - Dr. Pittman stated there were a few selected generics that would be non-preferred due to price.
- Motion made to accept recommendation
- Motion seconded and carried.

Enzyme Prep & Wound Healing Agents
⇒ There are currently two enzyme prep and wound healing products available in the United States, becaplermin, and collagenase. Currently only becaplermin and collagenase are approved by the FDA, and the agency has proposed that all topical products containing papain be withdrawn from the market due to a lack of substantial evidence supporting their effectiveness. Although the agents in this class have typically been shown to be efficacious when compared to placebo, no guideline currently recommends one agent over another. It is recommended at least one agent in this class indicated for the debridement of necrotic tissue in dermal ulcers and severe burns be available for use. Additionally, becaplermin is only FDA-approved for use in lower extremity diabetic ulcers and efficacy has not been established for the treatment of pressure ulcers and venous stasis ulcers; therefore, it is recommended its use be restricted to treatment of lower extremity diabetic ulcers.

Discussion
- Dr. Capparelli asked for clarification as to why the study referenced showed that papain was more effective than collagenase when the papain products are no longer available.
  - Dr. Pittman stated the FDA stated there was a lack of substantial evidence demonstrating efficacy.
  - Dr. Pittman stated the study did show significantly less necrotic tissue with the papain versus the collagenase however, the results did not correlate with overall wound healing.
- Dr. Capparelli stated the recommendation should include two agents be available.
  - Dr. Pittman clarified stating the recommendation states one agent be for dermal ulcers and severe burns and additionally, becaplermin be available for lower extremity diabetic ulcers and venous stasis ulcers.
- Dr. Capparelli stated the becaplermin is used for a variety of ulcers and it should not be restricted.
  - Dr. Woods stated there is currently no evidence to support its use in other types of ulcers and its cost is significant. She stated clinical criteria would be appropriate in this scenario.
• Motion made to accept recommendation
• Motion seconded and carried.

Proposed Clinical Criteria for Regranex®
• Regranex® will be approved only for patients having a diagnosis of lower extremity diabetic ulcers.

Discussion
• Motion made to accept recommendation
• Motion seconded and carried.

Oral Retinoids
⇒ Acitretin and isotretinoin are oral retinoids that are currently approved for the treatment of psoriasis and severe recalcitrant nodular acne vulgaris, respectively. Clinical trials have demonstrated the efficacy of both medications for their approved indications. Guidelines from the AAD state that the combination of a topical retinoid and antimicrobial agent is the preferred treatment approach for the majority of patients with acne vulgaris and recommend isotretinoin be reserved for use in moderate nodular and severe recalcitrant nodular acne vulgaris. AAD guidelines for the treatment of psoriasis recommend topical corticosteroids as the cornerstone of treatment for the majority of patients with psoriasis. Acitretin is recommended for use in combination with phototherapy or biologics for treatment of psoriasis. Additionally, acitretin is the treatment of choice in HIV-positive patients with severe psoriasis due to its lack of significant immunosuppression. Despite their proven efficacy, the use of oral retinoids is limited by their adverse events, including teratogenicity which is described in a black box warning; therefore, it is recommended that all agents in this category be subject to clinical criteria to minimize adverse effects and fetal exposure to the drugs.

Discussion
• Dr. Capparelli stated there was not a need for additional criteria if the iPledge program was in place and mandatory
  o Dr. Pittman stated Dr. Capparelli was correct, the iPledge program ensures the safety concerns related to fetal exposure are thoroughly addressed.
  o Dr. Woods noted the difference for Soriatane® was the agent does not have a pre-existing safety program in place
• Dr. Capparelli stated it would be more complete to include the iPledge phone number and website on the public documents
• Dr. Capparelli motioned to accept recommendation
• Motion seconded and carried.

Proposed Clinical Criteria for Isotretinoin
• Patients will be approved for isotretinoin if both the patient and physician have registered with the iPledge program.
  (Registration with the program helps to ensure appropriate counseling has been provided to the patient and proper procedures have been followed with regards to the risks of use in women of child-bearing age).

Discussion
• Motion made to accept the clinical criteria for Isotretinoin provided the phone number and website for iPledge are included in the public documents
Motion seconded and carried

Proposed Clinical Criteria for Soriatane®
- Soriatane® will be approved only for patients meeting ALL of the following criteria:
  - Recipient has a diagnosis of severe psoriasis (covering at least 10-20% of body surface area).
  - Recipient has tried and failed, or had an intolerance or contraindication to, ALL of the following:
    - Topical corticosteroids
    - Topical antipsoriatrics (i.e., Dovonex®, Tazorac®, anthralin, Taclonex®)
    - Phototherapy (UVB, PUVA, etc.), if available to the patient within their geographic area.
  - If the recipient is female:
    - Must have had TWO negative urine or serum pregnancy tests (one performed during the first 5 days of the menstrual period immediately preceding the beginning of Soriatane® therapy).
    - Must have committed to use 2 effective forms of contraception simultaneously, unless absolute abstinence is chosen, or the patient has undergone a hysterectomy or bilateral tubal ligation, or is clearly postmenopausal. The 2 selected forms of contraception must be initiated at least 1 month prior to starting Soriatane® and continued for 3 years after discontinuing the drug.
    - Must have read and signed a Patient Agreement/Informed Consent for Female Patients form.
  - Recipient must NOT have impaired liver or kidney function, or abnormally elevated lipid levels.
  - Recipient must NOT be receiving concomitant methotrexate (due to risk of hepatitis) or tetracyclines (due to risk of increased intracranial pressure).

Discussion
- Dr. Capparelli asked if further definition of “abnormally elevated lipid levels” should be defined. He stated abnormal lipid levels could be interpreted as different values and did not think the call center should have to interpret the values
  - Dr. Pittman stated she would check on how the call center was instructed to handle the criteria question
  - Dr. Pittman stated the call center asks the doctor to determine if the lipid levels are elevated.
  - Dr. Pittman stated she would anticipate the levels are triglycerides due to the inclusion in the adverse effects.
- Dr. Woods stated her experience with dermatologists prescribing has been positive and thorough
- Dr. Capparelli stated he would be concerned with specialists having to manage abnormal values outside their area of practice. He also stated the range for lipid values is constantly changing and difficult to know what upper limit should be.
  - Dr. Pittman stated the phrase may have been made vague intentionally because the recommendations do change frequently.
- Dr. Woods stated this may be an item that we can further investigate and bring back to the committee if necessary. Dr. Woods stated that SXC will investigate and report back to the committee
- Motion made to accept clinical criteria
- Motion seconded and carried.
Quantity Limits
• Motion made to accept QL
• Motion seconded and carried

Topical Retinoids
⇒ Topical retinoids are indicated for treatment of acne vulgaris and current guidelines from the AAD state that the combination of a topical retinoid and antimicrobial agent is the preferred treatment approach for the majority of patients with acne vulgaris. In studies comparing the agents, no one agent was consistently more efficacious than any other and clinical guidelines do not distinguish between the agents in this class for the treatment of acne vulgaris. Tazarotene is the only topical retinoid agent FDA-approved for the treatment of psoriasis. Clinical trials have demonstrated its efficacy alone as well as in combination with other antipsoriatic agents. Current AAD guidelines recommend the use of tazarotene as an adjunct to topical corticosteroids which are the cornerstone of therapy. Therefore, it is recommended at least two topical retinoids be available for use, one of which should be tazarotene. In order to prevent use of topical retinoids for the mitigation of fine wrinkles, it is recommended that the topical retinoids be subject to clinical criteria to ensure medical necessity.

Discussion
• Dr. Capparelli stated tazarotene is specifically mentioned in the recommendation however the majority of utilization is with the tretinoin product
  o Dr. Pittman stated the recommendation was worded to ensure that a product be available that is indicated for the use in psoriasis. She stated the other products are interchangeable therefore the tazarotene is needed plus one additional agent.
• Dr. Capparelli stated he did not understand why tretinoin would not be included specifically in the recommendation since that is where the majority of the utilization is and because the product is an inexpensive generic.
  o Dr. Pittman stated there is no clinical difference between the tazarotene and adapalene and it is necessary to include the tazarotene specifically due to its indication for psoriasis
  o Dr. Woods stated she did not anticipate the generic tretinoin becoming not available. She stated clinically there was no difference between tretinoin and adapalene and therefore no reason that one should be available over the other
• Dr. Capparelli stated he was concerned that if tretinoin were to become non-preferred the majority of prescribers would have to then call for prior authorization.
  o Dr. Pittman stated all agents require prior authorization at POS if recipient is over age 30 regardless of preferred or non-preferred status.
• Ms. Govette asked about the combination product Epiduo®. She noted the clinical guidelines include topical retinoid and benzoyl peroxide as a first line treatment option. She asked if the combination should also be available.
  o Dr. Woods stated no because the individual agents are available separately. She stated if the cost of the combination product were to change significantly, the State may not want to have as preferred. She stated the majority of the utilization is in the pediatric population.
• Dr. Capparelli stated he was concerned for prescribers if tretinoin were to be not available.
Dr. Pittman stated she understood his concern but clinically there is no difference between the tretinoin and adapalene to have to have one over the other.

- Dr. Capparelli stated there were also specific concerns in other classes of agents such as growth hormone and certain insulins where products were considered no different clinically but prescribers were very concerned about having to change patients’ therapy.
  - Dr. Woods stated the concerns raised with growth hormone were centered around the injection devices for the medications and physicians were concerned about patients having to learn different techniques. Dr. Woods stated there were adequate mechanisms in place to notify physicians and pharmacies if a large change such as tretinoin moving to non-preferred were to occur.

- Dr. Capparelli motioned to accept the recommendation provided it was changed to state “it is recommended at least two topical retinoids be available for use” additionally “it is recommended that at least tretinoin and tazarotene be available”

- Motion seconded and carried.

**Step therapy for Tretinoin**

- For a diagnosis of acne, keratosis follicularis or actinic keratosis:
  - Recipients less than 31 years old will be approved.
  - Recipients 31 years of age and older will be approved as follows:
    - For a diagnosis of keratosis follicularis (or Darier’s disease) - approved for 12 months.
    - For a diagnosis of actinic keratosis for the prevention of future lesions - approved for 12 months.
  - A diagnosis of acne vulgaris-approved

**Discussions**

- Dr. Capparelli asked about the statement made during the presentation that the agents were not approved in patients less than 12 years old.
  - Dr. Pittman stated the combination products are not FDA approved in children less than 12 year old but the other products have not been studied in children less than 12 years old.

- Ms Govette made motion to approve the recommendation

- Motion seconded and carried.

**Step therapy for Tazorac®**

- For a diagnosis of psoriasis, will be approved if the recipient has had a failure of, intolerance to, or contraindication to, at least one topical steroid.

- For a diagnosis of acne, keratosis follicularis, or actinic keratosis:
  - Recipients less than 31 years old will be approved.
  - Recipients 31 years of age and older will be approved as follows:
    - For a diagnosis of keratosis follicularis - approved for 12 months.
    - For a diagnosis of actinic keratosis for the prevention of future lesions - approved for 12 months.
  - For a diagnosis of acne vulgaris-approved

**Discussions**

- Motion made to accept step therapy for Tazorac®

- Motion seconded and carried.
• Dr. Woods asked SXC to review claims in this category to determine utilization in children less than 12 years old.

**Topical Keratolytic Agents**

⇒ Topical keratolytic agents, such as salicylic acid and urea, are effective and safe therapies for a number of skin conditions such as seborrheic dermatitis, psoriasis, warts, corns, and calluses. These agents can be used alone or in combination with other topical therapies, including corticosteroids. These topical agents are generally well tolerated, with associated side effects limited to local skin reactions. Additionally, no significant drug interactions have been reported. The agents within this class have been used safely and effectively for many years; however, there is limited data available evaluating the efficacy of these products for their approved indications. It is recommended that at least one topical keratolytic agent be available for use.

**Discussion**

• Dr. Corley stated the recommendation should state at least one urea product and one salicylic acid product be available for use since there are two separate categories being addressed.
• Dr. Capparelli stated agreement with Dr. Corley
• Motion made to accept recommendation with proposed changes
• Motion seconded and carried.

**Topical Anesthetics**

⇒ The topical anesthetics include medications for a variety of indications. With the exception of lidocaine patches, they are often used to alleviate itching and pain caused by insect bites, minor burns, sunburns, atopic dermatitis, or eczema. Additionally, these agents are commonly used to provide an anesthetic effect during minor surgical procedures and diagnostic tests. The variety of products, dosage forms, and indications present makes direct, head-to-head comparisons of these agents difficult. Additionally, clinical guidelines for the use of topical anesthetics are lacking; therefore, it is difficult to determine therapeutic alternatives in this category. Based on their FDA-approved indications and place in therapy, it is thought that all topical anesthetics (with the exception of lidocaine patches) are similar in safety and efficacy. Therefore, it is recommended at least one topical anesthetic be available for use. The topical lidocaine patch has a unique indication for the treatment of pain associated with postherpetic neuralgia. Guidelines from the American Academy of Neurology (AAN) recommend the use of topical lidocaine, as well as oral medications such as tricyclic antidepressants, gabapentin, pregabalin, and opioids, for the treatment of pain associated with PHN, but do not indicate that topical lidocaine patches are recommended over oral therapies. In addition, there are no head-to-head trials evaluating lidocaine patches against the oral medications that are also indicated for the treatment of pain associated with PHN. Due to their high cost and limited indications, it is recommended that topical lidocaine patches be subject to clinical criteria in order to ensure appropriate use.

**Discussion**

• Dr. Capparelli motioned to accept recommendation
• Motion seconded and carried.

**Clinical Criteria for Lidoderm®**
• Lidoderm® will be approved for patients with a diagnosis of neuropathic pain who have had a failure of, contraindication to, or intolerance of at least one agent in ALL of the following classes:
  o Tricyclic antidepressants
  o Anticonvulsants

Discussion
• Dr. Capparelli stated tricyclic antidepressants are commonly used for neuropathic pain. However, he stated his experience with patients struggling with neuropathic pain has been the individuals are not always emotionally stable due to their constant state of pain. He stated these patients have higher tendency to overdose with medications and the overdose with tricyclic antidepressant can be deadly. Dr. Capparelli stated many prescribers are moving away from utilizing the tricyclics because of the increased risk associated with potential overdose. Dr. Capparelli stated he was concerned about requiring patients to step through tricyclic therapy.
• Dr. Fitzpatrick stated the tricyclic antidepressants are not as widely used as they once were. She stated the agents are still used for a variety of indications but she stated agreement that the tricyclics do carry significant risks in the scenario of overdose.
• Dr. Capparelli recommended to rephrase criteria to state must have tried and failed one of the following classes of agents instead of having to try and fail both classes.
• Dr. Pittman suggested the anticonvulsant agents be listed out separately and the criteria could be adjusted to require trial and failure of two of the three agents in the two categories (gabapentin, pregabalin, or tricyclic antidepressant)
• Dr. Corley stated agreement the tricyclic antidepressant should not be a mandatory requirement. He also observed the guidelines include other categories of agents for treatment (such as opiates) that are not included in the criteria.
• Dr. Fitzpatrick stated agreement with Dr. Pittman’s suggestion of listing the agents out separately and the criteria could be adjusted to require trial and failure of two of the three agents in the two categories (gabapentin, pregabalin, or tricyclic antidepressant)
• Motion made to accept criteria with change in phrasing to state “must try and fail 2 agents from among the following classes”
• Motion seconded and carried.

Topical Antineoplastic Agents
  ⇒ The topical antineoplastics are a diverse group of agents with different indications including treatment of AIDS-related Kaposi’s sarcoma, cutaneous T cell lymphomas, actinic keratosis, and basal cell carcinoma. Clinical trial data demonstrate efficacy of agents with respect to unique indications, and current clinical guidelines include use of alitretinoin, bexarotene, diclofenac 3% gel, and various formulations of fluorouracil in treatment options, however no single agent has been recommended over another. Therefore it is recommended that at least one agent for each unique indication be available for use.

Discussion
• Dr. Capparelli stated the diclofenac gel and the flurouracil are both indicated for the treatment of actinic keratosis. He stated the cost information should be evaluated further and only one agent be available.
• Motion made to accept recommendation provided the cost information is further investigated
• Motion seconded and carried.
REVIEW OF AUGUST PAC MEETING DECISIONS
SXC reviewed TennCare’s decisions from the August 27th 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 Committee’s recommendations are as follows:

Page 6, Monoclonal Antibodies. PAC recommended updating Synagis criteria to reflect the current American Academy of Pediatrics Treatment guidelines for RSV in high risk infants. TennCare accepted PAC’s recommendation. To allow providers & pharmacies time to process prior authorization requests and to have adequate time for drug shipments to be made for start of RSV season, November 1, 2009, TennCare will allow prior authorization requests to begin on October 15, 2009.

SPEAKERS FOR PUBLIC TESTIMONY

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<td>Scott Breakstone</td>
<td>PharmaDerm</td>
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<td>Andrea Williams, RPh</td>
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An announcement: Next PAC meeting will be Thursday, February 18, 2010 at the Cool Springs Marriott.

Meeting Adjourned.