TennCare Pharmacy Advisory Committee (PAC Meeting)  
February 18, 2010

Members in Attendance:  
Yasmine Ali, MD, Melvin Blevins, MD, David Collier, MD (TennCare), Chairman Alan Corley, DPh, Stanley Dowell, MD, Vice-Chair Jeri Fitzpatrick, MD, Lyn Govette, MPAS, PA-C, Lynn Knott, PharmD, Carol Minor, Terry Shea, PharmD, Eleanor Twigg, PharmD, 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 conflict of interest statements. Dr. Corley stated no conflicts of interest had been disclosed. The members of the Committee introduced themselves.

MINUTES  
The November 10, 2009 meeting minutes were reviewed.
• Dr. Melvin Blevins motioned to approve the minutes.
• Motion seconded and carried.

AUTO EXEMPTION SUBCOMMITTEE  
Dr. Corley reported the first meeting of the Auto Exemption (AE) Subcommittee was held this morning prior to the regularly scheduled PAC meeting. The AE Subcommittee was formed as a result of legislation passed in 2009. Dr. Corley reported the subcommittee adopted governing rules for additions and deletions of agents from the AE list. He reported the subcommittee will meet as needed. Dr. Corley stated the Subcommittee meeting minutes will be available as part of the public record.

TENNCARE UPDATE  
Dr. David Collier gave this quarter’s TennCare update.
• The Long-Term Care (LTC) Community Choices Act is scheduled to go live in middle TN on March 1st.
  o TennCare has been meeting regularly with MCO’s and providers to ensure a smooth transition.
  o The LTC Community Choices Act is scheduled to be active in the west and eastern regions on July 1, 2010.
    ▪ If TennCare has to implement the proposed limits on medical services, this may delay the roll out to west and eastern regions.
• eHealth Initiative
  o The State has received approximately 2.7 million dollars from the federal government to fund the program and continue working towards electronic health records.
  o It is anticipated that physicians will be eligible to receive incentive payments if they choose to participate in the eHealth program.
  o The federal funds are a part of the Hitech act to encourage development and use of electronic medical records.
Additionally, QSource, Tennessee’s external quality assurance program also received funding to open a regional resource center in Nashville to assist professionals in developing eHealth technology in their practices.

TennCare Budget
- The Governor presented his budget proposal on February 1, 2010.
- The Governor approved all of TennCare’s proposed budget cuts that were presented in November 2009.
  - Proposed limitations for adult members include:
    - Limitation to 8 office visits per year
    - Limitation to 8 lab/x-ray services per year
    - Limitation to 8 outpatient procedures per year
    - Limitation to $10,000.00 for hospital services per year
    - Elimination of rehabilitation services (physical therapy, occupational therapy and speech therapy)
  - TennCare also proposed eliminating hospice care coverage and some grants for prenatal programs; however the Governor did not submit those eliminations as part of the budget proposal.
- The limitations proposed and reductions in services are a result of the continuing revenue shortfalls.
- TennCare was asked last year to reduce the budget by approximately 15%, some of the reductions and cuts were not implemented because of the American Recovery and Reinvestment Act (ARRA) funds. The funds are scheduled to expire in December 2010. Additionally, TennCare has also been asked to make further budget reductions beyond the initial 15% reduction, for the 2010 budget.
- The Tennessee Hospital Association has proposed plans to help offset the proposed reductions in service coverage. This is an on-going discussion and plans have not been approved or finalized yet.
- For the time being, TennCare will proceed with necessary processes and preparations to implement limitations and reductions in service coverage on July 1, 2010. A required letter outlining the proposed changes was sent to the Center for Medicare and Medicaid Services (CMS) on February 3, 2010.

Discussion
- Dr. Blevins expressed concern over the possible limitation to eight visits per year. He stated the limitation would place primary care physicians in a precarious position of balancing care of complicated patients with specialist visits and regular office visits. He stated primary care physicians would be forced to provide care outside their scope of practice.
  - Dr. Collier expressed understanding of Dr. Blevins concerns. Dr. Collier stated in previous years the Bureau had considered similar reductions in services and at the time a list of certain medical conditions was created to be exempt from the reductions. Dr. Collier reported that a similar list was being created at this time as well. The list has not been finalized but certain medical conditions were being taken into consideration.
  - Dr. Collier stated laboratory services were considered per day of occurrence; a practitioner could plan and schedule more than one
Dr. Blevins stated the reductions and limitations on services and reimbursements could directly impact the viability of some hospital institutions, especially intensive care units and tertiary facilities.

Dr. Stanley Dowell asked how the Governor’s proposals for budget cuts would impact the PAC committee. Dr. Dowell asked whether the PAC committee’s recommendations for changes to formulary could potentially impact a member’s need for office visits and other related services.

- Dr. Collier stated he was not aware of any direct changes or impact to the current Pharmacy Advisory Committee. He stated the formation of the committee along with the implementation of a preferred drug list several years ago and specific criteria for agents on the PDL resulted in significant cost savings to the State.

- Dr. Woods stated that the grandfathering was always considered when implementing PDL changes. In addition, the majority of the formulary changes made are in categories where the PAC has voted that all agents are considered therapeutic equivalents; therefore changes may not require a visit to the physician – a new prescription can just be called in for a preferred product. She stated that she did not anticipate any change in the PAC process with the new limitations being proposed.

Dr. Jerri Fitzpatrick asked if the proposed limitations in services and visits would include mental health patients.

- Dr. Fitzpatrick stated the proposed changes should be factored into all discussions regarding formulary changes. She stated formulary changes in the mental health population would impact office visits and other related services. She expressed concern about the impact the proposed changes will have on patient care.
  - Dr. Collier confirmed that the proposed changes would include behavioral health. Dr. Collier clarified the proposed limitations would not impact members under the age of 21, pregnant women, or patient in the waiver-based programs.

Ms. Carol Minor asked when the limitations for office visits and related services would begin and when would the decision be finalized.

- Dr. Collier stated the decision process is on-going right now however the State is required to notify affected individuals a minimum of 30 days prior to any changes. He stated if the proposed budget changes are finalized for a July 1, 2010 implementation, the decision would have to be finalized no later than June 1, 2010.
  - Dr. Collier stated a list of possible “exemptions” for certain medical conditions/laboratory services was being considered and complied at this time. He stated the intent of all of the budget changes was to try to impact the least number of individuals in capturing cost savings.
TENNCARE PHARMACY UPDATE
Dr. Nicole Woods gave this quarter’s TennCare Pharmacy update.

- TennCare Pharmacy Budget
  - The pharmacy department has been asked to reduce its budget by 9.7 million state dollars which equals roughly 28.5 million total dollars. After pharmacy reform several years ago, the pharmacy program is managed fairly tightly and identifying additional areas for savings is difficult.
  - Two primary proposals have been made to identify additional potential cost savings.
    - Creation of a four dollar generic list:
      - Many pharmacies offer certain generics at a cost of four dollars per month supply. With so many places offering these drugs for $4, it is difficult to argue that TennCare should pay more than four dollars for these types of medications. Currently, TennCare usually does not pay more than four dollars for ingredient costs of these prescriptions; however with the addition of dispensing fees the overall cost is often greater than four dollars.
      - The proposal would implement a specific type of MAC price on drugs listed on TennCare’s $4 list. The MAC would be set such that the pharmacy would receive one dollar for a 30 day supply plus a three dollar dispensing fee to equal a total four dollar cost. The MAC price is set on a per unit basis, so for members who receive a larger quantity the pharmacy would be reimbursed slightly more.
      - A tentative list has been created, however the list has not been finalized.
      - The same MAC dispute process would be in place for the four dollar MAC pricing.
    - Adopt more aggressive MAC pricing:
      - Current MAC averages 79% off of AWP; the proposal would increase this to 82% off of AWP.
  - Dr. Shea asked if TennCare was currently receiving four dollar costs from pharmacies who are utilizing a four dollar generic list.
    - Dr. Woods stated TennCare performs periodic spot checking on the four dollar lists. She stated to date the checks have shown a four dollar price being submitted for the usual and customary price. She stated that there is not currently a way to prevent these claims from being submitted with a price over four dollars; however the proposed four dollar list for TennCare would help to ensure that pharmacies were not pay more than $4 for these claims.

- UT Pharmacy Continuing Education Updates
Continuing Education seminars across the State will start in the upcoming weekend for pharmacists.

TennCare will participate as a speaker to help address common issues with claims processing and PDL items such as clinical criteria and step therapy requirements.

- Dr. Dowell asked if TennCare had considered offering 90-supply as a cost saving measure.
  - Dr. Woods stated the idea had been discussed in the past but due to the high turnover rate in the Medicaid population, this is not considered a good option for the State.

**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 18, 2010 PAC review packet at: [https://tnm.providerportal.sxc.com/rxclaim/TNM/Pcommittee.htm](https://tnm.providerportal.sxc.com/rxclaim/TNM/Pcommittee.htm)

**Immunologic Agents**

**Immunomodulators**

Immunomodulators interfere with pro-inflammatory cytokines released by lymphocytes involved in the pathophysiology of several chronic inflammatory diseases, including rheumatoid arthritis (RA), plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and Crohn’s disease with each agent being FDA approved for all or some of these indications. In general, currently available clinical guidelines do not recommend the immunomodulators as first line therapy. Clinical guidelines do not distinguish between agents in this class, except to conclude that anakinra is not recommended for the treatment of RA. Head-to-head trial data in this class is limited and it is therefore difficult to determine therapeutic equivalence within this class. However, due to its modest efficacy compared to anti-TNF agents, anakinra can be considered an inferior agent in this class and should therefore be a non-preferred agent. All other agents can be considered therapeutic alternatives within their approved FDA indications. It is recommended that at least two immunomodulators be available for use and at least one agent for each FDA-approved indication should be available. Additionally, due to the risk of significant adverse events associated with these agents, including an increased risk of potentially life-threatening infections, it is recommended that all agents in this class be subject to clinical criteria. In addition, to prevent misuse, all agents in the category should be subject to quantity limits.

**Discussion**

- Dr. Woods read Dr. Edward Capparelli’s comments he’d submitted in his absence. Dr. Capparelli stated the choice of two immunomodulators was
reasonable. He stated the delivery device for Cimzia as well as the other autoclick pen device seemed easy to use for individuals with visual acuity or manual dexterity problems. Dr. Capparelli stated he did not believe utilization of 976 claims justified clinical criteria; he recommended that the criteria should be removed and the category tracked for inappropriate use.

- Dr. Leslie Pittman stated the reason for lower claim volume was due to the current criteria being in place.
- Dr. Woods stated the call center data demonstrated up to 33% of claims in the category were denied for prior authorizations. She stated historically, when clinical guidelines were clear in recommendations for second line therapy, clinical criteria was placed to help ensure appropriate use.
- Dr. Blevins stated the agents in this category were effective, but expensive and do carry significant side effects, and are categorized as second line therapy.
- Dr. Shea stated agreement clinical criteria should remain in place.
- Dr. Woods stated that selected quantity limits in this category had been adjusted to account for overuse identified through retrospective claims review.
- Dr. Shea motioned to accept recommendation.
- Motion seconded and carried.

Proposed Clinical Criteria:

(Italized/strikethrough wording indicates changes from current criteria):

<table>
<thead>
<tr>
<th>Clinical Criteria: Immunomodulators</th>
</tr>
</thead>
<tbody>
<tr>
<td>For a diagnosis of <strong>Ankylosing Spondylitis:</strong></td>
</tr>
<tr>
<td>• Enbrel®, or Humira® will be approved for patients who have failed an adequate trial of TWO NSAIDs (unless contraindicated). Note: Recipients will have to try and fail (or have an intolerance or contraindication to) Enbrel® AND Humira® prior to receiving approval for Simponi®.</td>
</tr>
<tr>
<td>For a diagnosis of <strong>Crohn's disease:</strong></td>
</tr>
<tr>
<td>• Humira® or Cimzia® will be approved for patients who have tried and failed a corticosteroid OR an immunosuppressive agent. Note: Recipients will have to try and fail (or have an intolerance or contraindication to) Humira® prior to receiving approval for Cimzia®.</td>
</tr>
<tr>
<td>For a diagnosis of <strong>Juvenile Rheumatoid Arthritis (JRA)</strong> or <strong>Juvenile Idiopathic Arthritis:</strong></td>
</tr>
<tr>
<td>• Enbrel®, or Humira® will be approved for patients who have tried and failed (or have an intolerance or contraindication to) methotrexate.</td>
</tr>
<tr>
<td>For a diagnosis of <strong>Plaque Psoriasis:</strong></td>
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<tr>
<td>Enbrel®, Humira® or Stelara® will be approved for patients meeting the following criteria:</td>
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<tr>
<td>• Diagnosis of chronic, moderate to severe plaque psoriasis</td>
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<tr>
<td>• Treatment failure with at least 2 topical treatments (corticosteroids, calcipotriene, coal tar, tazarotene, anthralin) AND at least one oral treatment (Soriatane®, methotrexate, cyclosporine), unless contraindicated Length of authorization: Initial PA of 6 months, and yearly thereafter if medication is well tolerated. For continuation of therapy after the initial PA, a 50% reduction of total Psoriasis Area Severity Index (PASI) score must be achieved. Note: Recipients will have to try and fail (or have an intolerance or contraindication to) Enbrel® AND Humira® prior to receiving approval for Stelara®.</td>
</tr>
<tr>
<td>For a diagnosis of <strong>Psoriatic Arthritis:</strong></td>
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<tr>
<td>• Enbrel®, Humira®, or Simponi® will be approved for patients who have failed an adequate trial of methotrexate (unless contraindicated) Note: Recipients will have to will have to try and fail (or have an intolerance or contraindication to) Enbrel® AND Humira® prior to receiving approval for Simponi®.</td>
</tr>
</tbody>
</table>
For a diagnosis of Rheumatoid Arthritis:

Enbrel®, Humira®, Kineret®, Cimzia® or Simponi® will be approved for patients meeting the following criteria:

- Patient must have failed or been intolerant to therapy with glucocorticoids (unless absolutely contraindicated by severe brittle diabetes, severe osteoporosis, etc.) AND at least methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease) AND one other DMARD. For recipients who have a contraindication to methotrexate, another only one DMARD must be tried and failed.

Note: Recipients will have to try and fail (or have an intolerance or contraindication to) Enbrel® AND Humira® prior to receiving approval for Kineret®, Cimzia® or Simponi®.

Discussion

- Ms. Govette asked what the rationale was for changing some of the criteria.
  - Dr. Pittman stated for the Crohn’s Disease diagnosis there were currently no step therapy requirements in place; she stated the guidelines were clear in establishing immunomodulators’ place in the therapy and the changes reflected the guidelines’ recommendations.
  - Dr. Pittman stated the changes in the rheumatoid arthritis diagnosis removed the requirement for glucocorticoids and methotrexate. She stated the requirement would include methotrexate and one other DMARD.

- Dr. Blevins motioned to accept the clinical criteria.
  - Motioned seconded and carried.

Proposed Quantity Limits

<table>
<thead>
<tr>
<th>Quantity Limits</th>
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<tbody>
<tr>
<td>Cimzia®</td>
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<tr>
<td>2ml/month</td>
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<tr>
<td>Enbrel®</td>
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<tr>
<td>25 mg: 8 doses/month</td>
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<tr>
<td>50 mg: 4 doses/month</td>
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<tr>
<td>Humira®</td>
</tr>
<tr>
<td>4 syringes/28 days</td>
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<tr>
<td>Humira® Crohn’s Starter Pack</td>
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<tr>
<td>6 syringes/28 days</td>
</tr>
<tr>
<td>Kineret®</td>
</tr>
<tr>
<td>30 doses/month (billing units = 0.67 mL)</td>
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<tr>
<td>Simponi®</td>
</tr>
<tr>
<td>0.5 mL/28 days</td>
</tr>
<tr>
<td>Stelara®</td>
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<tr>
<td>6 mL/365 days</td>
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Discussion:

- Dr. Pittman stated the only change in the quantity limits was for the Enbrel 50mg dosage. The current quantity limit is set for 8 doses/month to allow for loading dose in selected diagnoses. She explained the review of claims data demonstrated patients were receiving the 50mg loading doses and were indefinitely remaining on higher dose therapy past the recommended time frame. Physicians will need to request the loading dose if necessary.
  - Dr. Shea asked if physicians would have to request an additional prior authorization for the quantity limit override.
    - Dr. Pittman stated all requests will still require initial prior authorization, she explained a question will be added to the current internal criteria to address the need for a loading dose and the required QL’s can be addressed on the same initial call.
    - Dr. Pittman stated additionally a PA fax form will be created for this category to facilitate the requests.
Dr. Corley asked if there was a mechanism to automate the loading dose as part of the prior authorization.

- Dr. Pittman stated from a system perspective the best way to handle the request was to have the call center enter a separate shorter term PA for the loading dose time period.

- Ms. Govette motioned to accept quantity limits
- Motion seconded and carried.

- Dr. Dowell asked about grandfathering for this category for product listing changes.

  - Dr. Pittman stated at this time there is no change to the current product listing.
  - Dr. Woods stated if changes were to be made for this category’s product listings the individuals on agents moved to non-preferred would be indefinitely grandfathered via a 60 day system look back. She expressed understanding of the concerns related to antibody development and potential for agents’ effects to lessen over time. She stated understanding of the implications of disrupting therapy in this category.

- Dr. Dowell asked if this type of patient would be included in the exemptions from the changes and reductions in of office visits, lab/x-ray and inpatient services.

  - Dr. Woods stated it was not known at this time whether this category of patients would be included in the exemption list.

Anti-Infectives

Pegylated Interferons

⇒ Hepatitis B

Peginterferon alfa-2a is the only pegylated interferon FDA-approved for the treatment of hepatitis B. In the treatment of chronic hepatitis B in adults, the AASLD guidelines give preference to pegylated interferons, adefovir and entecavir. Additionally, the CDC recommends use of any agent that is FDA approved for treatment of hepatitis B. Therefore it is recommended that peginterferon alfa-2a be available for the treatment of hepatitis B.

Hepatitis C

Pegylated interferons are considered part of first line therapy in the treatment of hepatitis C. The AASLD and the CDC guidelines, as well as the American Gastroenterological Association (AGA), recommend a pegylated interferon in combination with ribavirin as the primary treatment for hepatitis C. The clinical guidelines do not differentiate between the two available pegylated interferons, and the available head to head comparisons do not show significant differences between pegylated interferons with regards to sustained viral load reduction, early virologic response, undetectable hepatitis C virus at 12 weeks, or adverse events. Therefore, the pegylated interferons can be considered therapeutic alternatives to one another. The AGA and the AASLD recommend specific treatment durations based on genotypes and response by viral load. Therefore it is recommended that at least one pegylated interferon be available for use, with quantity limits to ensure appropriate duration of therapy.

Discussion:

- Dr. Blevins stated the categories of hepatitis drugs have greatly improved over the past several years. He stated the agents are effective and he stated
- Dr. Blevins motioned to accept the recommendation.
- Dr. Woods shared Dr. Capparelli’s comments: Dr. Capparelli stated the long term trials of these agents demonstrated the agents are relatively similar in use. He stated he felt both agents were comparable and agreed with the proposed recommendation. He stated if PegIntron® is chosen, clinical criteria for hepatitis B use for Pegasys® should be included.
- Motion seconded and carried.

Proposed Quantity Limits:

<table>
<thead>
<tr>
<th>Quantity Limits</th>
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<tbody>
<tr>
<td>Pegasys® (peginterferon alfa-2a)</td>
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<tr>
<td>Pegasys Convenience Pack®</td>
</tr>
<tr>
<td>Peg-Intron® (peginterferon alfa-2b)</td>
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<tr>
<td>Peg-Intron Redipen®</td>
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</table>

*Duration of therapy greater than 48 weeks will require a PA

Discussion:
- Dr. Blevins motioned to accept proposed quantity limits and duration of therapy.
- Motion seconded and carried.

**Non-Pegylated Interferons**

Interferon alfa agents are primarily used in antiviral and antineoplastic conditions. In the treatment of Hepatitis B and C, the AASLD, the CDC, and the AGA consistently place interferon alfa agents as alternative treatment regimens with the pegylated interferons as first line therapy options. Specifically, for the treatment of Hepatitis C, available clinical trials have demonstrated comparable efficacy between interferon alfa-2b and interferon alfacon-1, therefore the agents can be considered treatment alternatives. However, there is some data to support the use of interferon alfacon-1 in patients who exhibit a non-response or relapse following therapy with pegylated interferon. Additionally, interferon alfa-2b is included in antineoplastic treatment regimens for malignant melanoma, hairy cell leukemia, follicular non-Hodgkin’s lymphoma, and Kaposi’s sarcoma. Therefore, it is recommended that at least interferon alfa-2b be available for use due to its indications for hepatitis B, hepatitis C, and various cancers. Interferon alfacon-1 should be available for individuals who have experienced a treatment failure on pegylated interferon.

Discussion
- Dr. Blevins stated the interferon agents are generally second and third line choices for therapy but the agents should be available.
- Dr. Blevins motioned to accept recommendation.
- Motion seconded and carried.
Proposed Clinical Criteria:

<table>
<thead>
<tr>
<th>Clinical Criteria for Infergen®</th>
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<tbody>
<tr>
<td>Infergen® (interferon alfacon-1) will be approved for individuals with a diagnosis of chronic hepatitis C who have failed to response to an adequate trial of pegylated interferon or interferon alfa-2b.</td>
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</tbody>
</table>

Discussion:
- Lyn Govette motioned to accept the proposed clinical criteria.
- Motion seconded and carried.

**Hepatitis C Antivirals**

- Ribavirin is considered part of first line therapy for the treatment of hepatitis C. Combination therapy with a pegylated interferon plus ribavirin has demonstrated an increase in sustained virologic response in patients with hepatitis C. The American Association for the Study of Liver Diseases (AASLD), the Centers for Disease Control (CDC) and the American Gastroenterological Association (AGA) guidelines all recommend combination therapy with pegylated interferon and ribavirin as primary treatment for hepatitis C. No guidelines recommend one ribavirin formulation over another; therefore, they can be considered therapeutic alternatives. It is recommended that at least one ribavirin formulation indicated for use in combination with peginterferon alfa-2a and one ribavirin formulation indicated for use with interferon alfa-2b and peginterferon alfa-2b be available for use.

Discussion:
- Dr. Blevins motioned to accept recommendation.
- Motion seconded and carried.

Proposed Clinical Criteria:

<table>
<thead>
<tr>
<th>Clinical Criteria for Rebetol®</th>
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<tbody>
<tr>
<td>Rebetol® solution will be approved for any recipients who are 6 years of age or younger, or who are unable to swallow tablets/capsules.</td>
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</table>

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

**Oral Quinolones**

- Quinolones are highly effective in the treatment of infections due to aerobic gram-positive, gram-negative, and selected atypical bacteria; however, they have limited usefulness against most anaerobic bacteria. Specifically, the third generation respiratory quinolones have increased activity against gram-positive and atypical pathogens found in majority of respiratory infections. The respiratory quinolones are also highly effective against resistant strains of common respiratory pathogens such as *Streptococcus pneumoniae*, and *Haemophilus influenzae*. All quinolones share class-specific adverse reactions, which include gastrointestinal effects, phototoxicity, potential prolongation of the QTc interval and black box warning regarding potential tendon rupture. Head to head clinical trials between quinolones have shown the agents to be comparable to each other in terms of efficacy. The quinolones are included as first line treatment and as primary treatment alternatives in current clinical guidelines for gastrointestinal, genitourinary, dermatological and respiratory
Discussion

- Dr. Blevins stated he utilizes the oral quinolones on a daily basis for respiratory infections. He stated there should be awareness that the sensitivity to the agents can vary throughout the State. Dr. Blevins motioned to accept the recommendation.
- Dr. Woods shared Dr. Capparelli’s comments: Dr. Capparelli remarked on the interesting utilization in the category (80% usage of generic ciprofloxacin, 15% Avelox, and 2% Levaquin). He stated the utilization points to physician sensitivity to cost issues as well as the power of formulary placement. He stated agreement with the recommendation and applauded the continued inclusion of the clinical criteria for the non-formulary agents in setting of hospital follow up.
- Dr. Corley asked about the supply issues with the ciprofloxacin tablets.
  - Dr. Pittman stated typically the call center will notify the SXC Nashville team of supply issues and they will offer another agent or provide a one time override on the brand name until the supply/shortage is resolved.
  - Dr. Woods stated if the shortage or supply became severe enough the State would consider allowing brand to pay or another agent if necessary.
- Dr. Corley stated his experience with obtaining prior authorization for non-formulary agents after hospitalization has improved greatly. He stated he has not experienced problems recently with the process.
- Motion seconded and carried.

Proposed Clinical Criteria:

- Clinical Criteria for Factive®, Levaquin®, & Noroxin®
  - Individuals started on Factive®, Levaquin or Noroxin 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. Blevins motioned to accept proposed clinical criteria.
- Dr. Corley asked if the criteria were separate from the general non-preferred criteria.
  - Dr. Pittman stated the criteria was separate for individuals post hospital discharge.
- Motion seconded and carried.

Proposed Quantity Limits:

- Quantity Limits
  - Cipro XR® 1 tablet/day
  - Ciprofloxacin XR/ER 1 tablet/day
  - Proquin XR® 1 tablet/day

Discussion

- Dr. Shea motioned to accept the proposed quantity limits
- Motion seconded and carried.
Dermatologics

Topical Anti-psoriatic agents
⇒ For the treatment of psoriasis, topical therapy is the mainstay of treatment for localized disease. Current guidelines from the AAD recommend topical corticosteroids as the cornerstone of treatment; however, Vitamin D analogs are effective treatment options. Current guidelines do not differentiate between the available agents in this class, and head-to-head trials of calcitriol versus calcipotriene demonstrate similar efficacy. Therefore, it is recommended at least one topical anti-psoriatic agent should be available for use. It is also recommended all agents in this class should be subject to step therapy to reserve their use for second line therapy behind the topical steroids.

Discussion:
• Ms. Govette motioned to accept the recommendation
• Dr. Corley noted not all the formulations for Dovonex® were accounted for in the utilization data – utilization data for Dovonex® ointment had been omitted.
  o Dr. Pittman stated she would investigate as to why the ointment was not included.
• Motion seconded and carried.

<table>
<thead>
<tr>
<th>Step Therapy for Topical Anti-psoriatics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will be approved if recipient has had failure of, intolerance to, or contraindication to at least one topical steroid.</td>
</tr>
</tbody>
</table>

Discussion:
• Dr. Shea motioned to accept the recommendation.
• Motion seconded and carried.

Antibiotic Agents for Acne and Rosacea
⇒ Topical antibiotic agents are highly effective for the treatment of acne vulgaris and are a mainstay of treatment. Clinical trials consistently demonstrate equal efficacy when comparing single agent monotherapy regimens. Single agent topical antibiotics can be considered therapeutic alternatives. Clinical trials show combination agents have increased efficacy when compared to single agents; however, there is no data demonstrating increased efficacy of combination agents compared to their respective single agents taken concomitantly. Current clinical guidelines from the AAD recommend an antimicrobial agent and a topical retinoid as the preferred first line treatment regimens for the majority of acne vulgaris, and the guidelines do not give preference to one agent over another. Additionally, topical antibiotics are an effective pharmacological treatment for rosacea. For the topical antibiotic agents indicated for rosacea, limited clinical trials have demonstrated efficacy in reducing symptoms and lesions. Available guidelines from the AARS recommend topical azelaic acid, metronidazole, and sulfacetamide sodium/sulfur as primary treatment options and do not give preference to one agent over another Therefore, it is recommended that at least two topical antibiotic agents indicated for acne be available for use, which should include components of one combination product. Additionally, at least two topical antibiotic agents indicated for rosacea should be available for use.
Discussion

- Ms. Govette asked if the kits were more expensive than the individual agents.
  - Dr. Robin Ramsey stated the kits were significantly more expensive and generally contained a non-prescription product along with the prescription agent.
- Dr. Blevins motioned to accept the recommendation.
- Motion seconded and carried.

### Proposed Clinical Criteria

#### Clinical Criteria for Dermatological Kits

| Approval will be granted upon documentation of ALL of the following: |
| -- Trial and failure of three preferred agents |
| -- Trial and failure of the individual components of the kit |

Discussion:

- Dr. Corley read Dr. Capparelli’s comments: Dr. Capparelli stated he agreed with the recommendation; however he expressed confusion as to why, if the individual components of the kit were failed, the combination would be expected give a different result.
  - Dr. Woods stated the there was not an expectation that the kit would perform better than its individual agents. She stated there was not a mechanism to allow the State not to cover the kits and due to their significantly greater cost, the criteria was created to discourage use. It would be rare for an individual to meet the criteria.

### Proposed Quantity Limits

#### Quantity Limits Metronidazole

| Metronidazole products (cream, gel, lotion) 60g/RX |

Discussion:

- Dr. Pittman stated SXC was aware metronidazole is available in other package sizes, but review of claims data demonstrated several mis-billing scenarios.
- Dr. Blevins motioned to accept quantity limits
- Motion seconded and approved.

### Topical Antifungals

Topical antifungal agents are used to treat a variety of skin and related infections. Topical antifungals are indicated to treat cutaneous candidiasis, onychomycosis, seborrheic dermatitis and linea infections. Topical antifungal agents have a side effect profile limited primarily to the local application site and have no indentified systemic drug interactions. Head to head clinical trials have demonstrated comparable efficacy between the antifungal agents, and these agents can be considered therapeutic alternatives. Current clinical guidelines recommend use of topical antifungal agents for the management of non-invasive superficial fungal infections, selected onychomycotic infections, and for linea infections; the clinical guidelines do not give preference to one agent over another. Therefore it is recommended that at least three topical antifungal agents be available for use.

Discussion
Ms. Govette reviewed Dr. Capparelli’s comments: He stated the recommendation should reflect the need for a steroid/antifungal combination.
  - Dr. Ramsey explained the combination antifungal products were reviewed as a separate category. This recommendation is for single agent topical antifungal agents only.
  - Dr. Ramsey stated the combination antifungal agent recommendation stated to have “at least one topical combination antifungal agent available”

Dr. Blevins motioned to accept recommendation
Motion seconded and carried.

**Anti-Seborrheic Agents**

Seborrheic dermatitis is a common dermatological disease characterized by erythema, scaling skin and pruritus. The anti-seborrheic agents, selenium sulfide and sulfacetamide sodium, are treatment options for seborrheic dermatitis. The agents’ adverse effects are mild and limited to local effects. There are no head to head clinical trial comparisons to other available agents. There are no specific published clinical guidelines directly addressing treatment of seborrheic dermatitis; however these agents are recognized as a treatment options in patients with mild disease. Therefore it is recommended that at least one anti-seborrheic agent be available for use.

**Discussion**

- Dr. Blevins stated the agents are useful and should be available.
- Dr. Blevins motioned to accept recommendation
- Dr. Woods read Dr. Capparelli’s comments: He stated agreement with recommendation but thinks it would be wise to add “one lotion and one shampoo be available for use” to the recommendation and move the plain selenium sulfide shampoo to the preferred side.
- Dr. Woods stated in other categories with agents for the scalp there are a variety of formulations utilized (gel, lotions, solutions, creams as well as shampoos). Dr. Woods suggested adding phrase to the recommendation stating “one formulation for use on the scalp is available”.
- Dr. Blevins stated he felt the recommendation allowed for formulations for the scalp.
- Dr. Corley asked why only one agent was available. He suggested having both agents available since they were both available generically.
  - Dr. Woods asked if there was a difference clinically between the agents or a reason why a physician would choose one agent over another.
    - Dr. Corley stated there was not enough clinical data available to determine which agent was superior.
  - Dr. Woods stated she would like for the recommendation to allow the State freedom to move products if the cost were to change significantly.
- Ms. Govette motioned to accept the recommendation and include a phrase to address at least one formulation for the scalp be available.
- Motion seconded and carried.
**Topical Antipruritics**

The conditions of atopic dermatitis and lichen simplex chronicus can frequently cause chronic pruritis and itching. A topical antipruritic is one therapy used to control these dermatological conditions and topical doxepin is currently the only agent available. Adverse effects of topical doxepin therapy are primarily limited to local skin effects as well as some potential systemic sedation. An increased risk of systemic effects occurs when treatment is extended past eight days. There are no head to head clinical trials comparing the two doxepin products and limited clinical trials evaluating efficacy. According to current clinical guidelines from the AAD and a joint task force led by the ACAAI, topical doxepin is considered a second line therapy to topical corticosteroids for the treatment of atopic dermatitis. Treatment regimens for lichen simplex chronicus also recommend first line therapy with topical corticosteroids. Therefore, it is recommended that topical doxepin be reserved for patients who have failed first line therapy and be subject to clinical criteria.

Discussion:
- Dr. Blevins motioned to accept recommendation
- Motion seconded and carried.

**Proposed Clinical Criteria:**

<table>
<thead>
<tr>
<th>Clinical Criteria for Topical Antipruritics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval will be granted for individuals meeting the following criteria:</td>
</tr>
<tr>
<td>1. Recipient must have moderate pruritis due to various forms of eczematous dermatitis, including atopic dermatitis and lichen simplex chronicus</td>
</tr>
<tr>
<td>2. Recipient must have intolerance, contraindication to or inadequate response to BOTH of the following:</td>
</tr>
<tr>
<td>a. Topical corticosteroid</td>
</tr>
<tr>
<td>b. Oral antihistamine (First or second generation) OR a topical antihistamine agent (i.e. topical diphenhydramine)</td>
</tr>
</tbody>
</table>

**Note:**

- **5% Doxepin** cream may be used in combination with a topical or oral corticosteroid in order to relieve pruritis in order and to reduce length of corticosteroid course of therapy
- **5% Doxepin** cream should not be used for longer than eight days. Longer usage has been shown to result in higher systemic effects

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

**Quantity Limits**

<table>
<thead>
<tr>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxepin 5%  45g per 90 days</td>
</tr>
</tbody>
</table>

**Discussion:**
- Motion made to accept proposed quantity limits
- Motion seconded and carried.

**GUEST SPEAKER ON ATYPICAL & TYPICAL ANTI PSYCHOTIC AGENTS**

Dr. Jerri Fitzpatrick introduced Dr. William Bobo. Dr. Bobo is an Assistant Professor of Psychiatry at Vanderbilt University Medical Center.
Dr. Bobo stated his presentation will outline the primary clinical questions given to him by Dr. Woods.

- Factors to consider when selecting an atypical antipsychotic for a treatment naïve patient
  - Need to address whether antipsychotic is needed at all
  - Need to assess level of agitation and need for sedation plus antipsychotic effect
  - Need to assess other general medical comorbidities
  - Need to assess other concomitant medications, assess for drug interactions
  - Need to assess patient’s proneness to extrapyramidal side effects (EPS)
  - Need to assess ability of patient to handle dosing schedule, need for simplicity of regimen
  - Need to assess potential need for long acting antipsychotic medication (LAI), may impact choice of oral agent
  - Need to assess patient preference

- Role of agents with high risk of causing metabolic effects
  - When agents are considered for therapy, need to assess whether patient can handle the required screening and monitoring requirements associated with medication.
  - Patient is able to participate in other healthy activities to reduce overall medical risks.
  - Selected patients do not respond to lower risk medications or cannot tolerate medication.
  - Patients with treatment resistant schizophrenia or schizo-affective disorder have generally failed two other antipsychotics, should be considered for clozapine.
  - Patient needs a sedating medication. All of the agents with sedation effect carry increased risk of metabolic side effects
  - Patient needs a LAI however they cannot tolerate high potency neuroleptic medications.
  - Some of lower risk medications do not have indication for certain diagnoses or do not have as much clinical information.

- Role of newer agents
  - Paliperidone long acting injectable: every 4 week regimen
  - Risperidone long acting injectable: every 2 week regimen
  - Oral paliperidone: same receptor binding profile as risperidone
  - Iloperidone; similar mechanism of action to other existing agents
  - Asenapine: recently approved, mechanism of action is also similar to other existing agents.

- Role of utilizing dosing regimens above recommended dosing, what factors are considered
  - Considerations for increased dosing regimens should only be considered in settings where suboptimal response is clearly established & following factors have been addressed:
    - Switching agents: there would be minimum to no change in symptoms between agents, increase in dosage could result in increased side effects
Augmentation: use of second medication (non-antipsychotic medication), this practice is common and can be appropriate in certain scenarios.

Combination of two or more antipsychotics: concept is used but not adequately studied at this time; mechanisms are generally similar so risk of side effects is higher.

Optimization: maximizing dosing to achieve an adequate response.

- Some of the existing dosing regimens may be underestimated, clinical experience should guide the practitioner
- If dose exceeds approved dosing:
  - All other options are reviewed
  - Patient consent
  - Adequate monitoring will be performed
  - Patient is aware the dose is off label

Role of typical antipsychotics versus atypical antipsychotics

- Acute short acting injectable is needed for a dangerous situation
- Typical antipsychotics are available LAI
- Affordability
- Established tolerability is achieved
- Current good response and tolerability-no reason to change

When would practitioner not want to use a typical antipsychotic

- Treatment resistant schizophrenia-should use clozapine
  - High negative symptoms
  - High suicide risk-should use clozapine
  - Tardive dyskenesia
  - Secondary parkinsonism symptoms
  - EPS or history neuromalignant syndrome
  - Active catatonia or history of catatonia
  - Laryngeal dystonia
  - Treatment naive patient

When would practitioner choose typical antipsychotic over atypical antipsychotic agent

- Affordability
- Intravenous route is needed
- Patient responds to typical versus atypical
- Patient preference
- Patient needs LAI (& risperidone is not an option)
- Metabolic effects are a concern and patient does not respond to lower risk agent
- Failed trial of 2 atypical antipsychotics.
- Typical agents have more data in pregnancy

Overall Current Challenges

- Ongoing unmet patient needs
  - Specifically schizophrenia and bipolar disorder.
- Patient’s response are very individualized

General recommendations

- Clinicians need the broadest reasonable array of choices
- Use of clozapine and LAI in appropriate patients should be encouraged.
- Policies must allow for treatment regimens that are not traditional
Question/Comments regarding Dr. Bobo’s presentation:

- Dr. Woods asked if clozapine is generally reserved for schizophrenic patients with treatment resistance, or is it ever considered first line for schizophrenic patient with a high risk for suicide.
  
  Dr. Bobo stated in treatment resistant schizophrenic patients and in patients at high risk for suicide clozapine is always a treatment option. He stated he considers this medication for schizophrenic patient at high risk for suicide whether they have demonstrated treatment resistance or not.

- Dr. Corley stated currently TennCare requires trial and failure of an oral regimen in order to obtain authorization for a long acting injectable antipsychotic. He asked Dr. Bobo if that was an appropriate order of therapy.
  
  Dr. Bobo stated agreement that requiring patients to fail an oral regimen was an appropriate step therapy for long acting injectable antipsychotics.

- Dr. Corley asked Dr. Bobo if there were certain antipsychotic agents he prefers to use over other agents.
  
  Dr. Bobo stated he has had broad experience with most all of the antipsychotic agents. He stated his choice of antipsychotic agents was directly dependent on the patient’s situation and presentation.

- Dr. Corley asked if there was ever a situation where a practitioner would use all of the agents.
  
  Dr. Bobo stated there are some treatment naïve patients who present with first break symptoms who potentially could use any of the available agents.

- Dr. Fitzpatrick asked about patients who are hospitalized and then discharged home. She stated patients are generally discharged on an atypical antipsychotic medication that they have been stabilized on during hospitalization. She asked if it was appropriate to switch them to another agent after discharge.
  
  Dr. Bobo stated the patient should always remain on the medication they were stabilized on during their acute hospitalization.

- Dr. Fitzpatrick asked Dr. Bobo if he had a preference or could explain advantages/disadvantages as to why a practitioner would use a long acting injectable antipsychotic that is dosed every two weeks versus every four weeks.
  
  Dr. Bobo stated his preference would be every four weeks due to pragmatic reasons: less intervals of visits, less responsibility to remember appointments or arrange transportation.

CNS agents

Atypical Antipsychotics

The atypical antipsychotics are approved for the treatment of bipolar disorder and/or schizophrenia and are often a preferred treatment over the first generation antipsychotics since they are thought to have a more favorable outcome in the treatment of the negative symptoms of schizophrenia. Additionally, these agents are more selective in targeting the intended mesolimbic D2 pathway compared to typical antipsychotics, which results in a lower risk of EPS and tardive dyskinesia. The use of these agents is recognized by national and international guidelines as a mainstay in therapy. In general, guidelines recommend the use of atypical antipsychotics over the first generation antipsychotics. All agents in this class are FDA-approved for the
All agents in this class have been associated with numerous clinically significant adverse events and increased morbidity and mortality in select patient populations. Although most atypicals are associated with some degree of weight gain, olanzapine, clozapine, quetiapine, and risperidone appear to pose the greatest risk. Clinical evidence clearly identifies a direct relationship between diabetes and atypical antipsychotic use. Other common adverse events associated with the atypicals are hyperprolactinemia (with highest risk seen in risperidone, paliperidone, olanzapine, and iloperidone), QT prolongation (with highest risk seen in ziprasidone and iloperidone), extrapyramidal symptoms (with highest risk seen in risperidone, paliperidone, and olanzapine), and sedation (with highest risk seen in quetiapine, clozapine, olanzapine, and asenapine). In order to best meet patient and prescriber needs, several agents representing a variety of side effect profiles should be available for use. It is recommended that at least four atypical antipsychotic agents be available, one of which should be clozapine due to its unique indication for treatment resistant schizophrenia, one of which should have data for use in children, and one of which should have a low to moderate risk of hyperglycemia. Additionally, in order to guard against inappropriate and/or off-label use and to minimize the potential for adverse events, it is recommended that all agents in this class be subject to clinical criteria.

Discussion

- Dr. Fitzpatrick stated she understood the difficult balance of economic/financial burden and the burden of medical care and related costs. She stated as a practitioner treating adults and children with mental health disorders the care she provides is very individual. The medical care provided is not comparable to other conditions like diabetes or cardiovascular care. She stated practitioners have no ability to predict a patient's response or to predict how long the patient will respond to a particular agent. She stated the requirements for prior authorizations and the restrictions to certain numbers of drugs being preferred takes away from the practitioner being able to best care for their patient. She stated mental health diseases can be devastating to patient’s lives and their families. Dr. Fitzpatrick stated in this category she felt an open formulary would be appropriate. She stated not all psychotropic medications should fall under that open access but atypical antipsychotics are a category of medications that should be easily accessible.

- Dr. Fitzpatrick stated she is concerned that the recommendation states “at least four agents be available”. She stated the terminology is very restrictive. She stated the phrasing of having “one agent” for different indications as well as low risk of various side effects is also restrictive and the “one agent” may not be effective.

- Dr. Fitzpatrick stated the quantity limit restrictions are also very concerning and restrictive. She stated many of her patients present on multiple antipsychotic medications; she stated clinically it is better to maximize a
Dr. Pittman stated the atypical antipsychotic class is one where the member is only required to try and fail one preferred agent to receive a non-preferred agent. Additionally, auto look backs are in place.

Dr. Woods stated the internal criteria do address continuation of non-preferred agents post hospital discharge. She stated if the patient is only hospitalized for a day or so the call center may question length of therapy.

- Dr. Fitzpatrick stated the hospitalization process is difficult itself due to the constraints of patients only being certified to be hospitalized for a certain length of time. She stated many times patients are discharge before they are truly stabilized on a medication.

- Ms. Govette stated generally her patients who are hospitalized are only able to stay for a maximum of three days. Ms. Govette stated she had never had problems with continuation of non-preferred therapy post hospital discharge.

Dr. Fitzpatrick stated the care of these types of patients is not as easy as simply making a choice and trying it. She stated the response is extremely individualized and the side effects can be very significant.

Dr. Woods asked if there are any of the non-preferred agents that should be available for a treatment naïve patient.

- Dr. Fitzpatrick stated in treatment naïve patients there are good options on the preferred side.

- Dr. Pittman noted an experienced patient would most likely have already tried a preferred agent and should be able to easily obtain a non-preferred agent.

Dr. Fitzpatrick stated she has experienced difficulty with the process of the pharmacies submitting ICD-9 codes to override the PA process.

- Dr. Pittman stated TennCare/SXC has received similar complaints that the pharmacies do not understand how to submit the ICD-9 codes correctly.

- Dr. Pittman stated SXC’s provider educators have developed a fax form that the physician’s office can send to the pharmacy if they are having difficulty submitting the ICD-9 information and additionally, the pharmacy can contact their provider educator directly for assistance.

Dr. Fitzpatrick stated she would like to obtain a fax form and discuss the process further with a provider educator. She stated that would be very helpful in her practice.

- Dr. Woods stated TennCare also generally sends notices twice a year to pharmacies reminding them of the process of submitting ICD-9 codes and a list of approvable ICD-9 codes.

- Dr. Woods stated the call center also has list of ICD-9 codes and they will ask the caller if they have the ICD-9 code and if they do they will expedite the PA through.

Ms. Govette asked about the phrase in the recommendation of having “at least four atypical antipsychotics be available”
Dr. Pittman stated the phrase meant at the least the preferred list would have four unique agents.

Dr. Wood stated that the worst case scenario would be to have four unique agents, and to get to a non-preferred agent the member would need to try and fail one preferred agent.

Ms. Govette asked when a member was already on a non-preferred agent would a look back allow them to continue their therapy.

Dr. Pittman stated there are 60 day auto-lookbacks coded for all the non-preferred agents.

Dr. Woods stated it is the State’s intent to indefinitely grandfather members who are on non-preferred agents.

Dr. Fitzpatrick restated the restriction to four agents is very concerning.

Dr. Blevins stated agreement that these types of patients are very unique and complex. He stated he felt there needed to still be some preferred and non-preferred agents though. He stated the current listing did address adequate preferred and non-preferred agents.

Dr. Blevins motioned to accept the recommendation.

Dr. Fitzpatrick stated she did not think a number should be included in the recommendation.

Dr. Woods stated the recommendation could just include a directive that there be a variety of agents that address the side effects concerns. She stated the recommendation should allow for a practitioner to have reasonable options for a treatment naïve patient.

Dr. Fitzpatrick stated Dr. Bobo mentioned other side effects that are considered critical to address that are not specifically mentioned in the recommendation.

Dr. Pittman suggested the phrase “at least four atypical antipsychotics” be removed and could be replaced with specific phrasing to for the unique side effects profiles that should be addressed.

Dr. Pittman asked Dr. Fitzpatrick what other specific side effects should be addressed.

Dr. Fitzpatrick recommended adding at least one agent with low to moderate risk of QTc prolongation and risk of EPS along with the existing agents that are already addressed in the recommendation.

Dr. Corley asked if that could be the updated motion.

Dr. Fitzpatrick stated she motioned to accept recommendation as modified.

Motion seconded and carried.

Proposed Clinical Criteria

<table>
<thead>
<tr>
<th>Clinical Criteria for All Atypical Antipsychotics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For a diagnosis of bipolar:</strong></td>
</tr>
<tr>
<td>• Diagnosis must be documented in their medical record</td>
</tr>
<tr>
<td>• For a severe manic episode, one of the preferred atypical agents will be approved.</td>
</tr>
<tr>
<td>• For partial or non-response after a 4-week trial of a preferred atypical at the highest recommended or tolerated dose:</td>
</tr>
<tr>
<td>• Patients not on a mood stabilizer (lithium, divalproex, lamotrigine, oxcarbazepine, or</td>
</tr>
</tbody>
</table>
carbamazepine) will be required to try addition of a mood stabilizer before an alternative
preferred atypical or a non-preferred atypical will be approved.

Patients currently receiving a mood stabilizer will be approved for an alternative preferred
atypical or a non-preferred atypical.

For a diagnosis of schizophrenia or schizoaffective disorder:
• Diagnosis must be documented in their medical record.
• For the first episode or for patients with a history of response of positive symptoms to an
  antipsychotic drug, one of the preferred agents should be tried. If the patient is schizoaffective
  and currently in an excited state, a mood stabilizer may be used. If the patient is depressed at
  the end of four weeks, an antidepressant may be used.
• If psychosis persists after a trial of 4 weeks at an appropriate dose of a preferred atypical
  antipsychotic, then an alternative preferred atypical or a non-preferred atypical may be tried
  as monotherapy. If schizoaffective, a mood stabilizer may be used.

For a diagnosis of schizoaffective disorder, delusional disorder, psychotic depression,
tourettes/severe tic disorder, psychotic disorder NOS, agitation of dementia, psychosis secondary
to a medical condition, agitation or aggression in mental retardation or autism, aggression/impulse
control disorder, brief psychotic disorder, substance-induced psychotic disorder, severe refractory
depression, severe refractory OCD, or severe refractory PTSD:
• For partial or non-response following a 4-week trial of an appropriate dose of a preferred atypical,
an alternative preferred atypical or non-preferred atypical will be approved.

Preferred Atypical Antipsychotics will be approved for the following diagnoses:

- Aggression: disorder, in autism, in mental retardation
- Agitation: in autism, in mental retardation, of dementia
- Bipolar and manic disorders
- Bipolar depression, bipolar maintenance, bipolar mania-acute, bipolar mixed states
- Brief psychotic disorder
- Delusional disorder
- Depression with psychotic symptoms
- Drug-induced psychotic disorder with hallucinations
- Impulse control disorders, including Oppositional Defiant Disorder and Intermittent
  Explosive Disorder
- Organic psychotic condition
- Psychosis secondary to a medical condition, psychotic depression, psychotic disorders
- Schizoaffective disorder, schizoid/schizotypal personality disorder, schizophrenia,
  schizophrenic disorders
- Substance-induced psychotic disorder, Substance-induced withdrawal psychotic disorder
- Severe refractory obsessive compulsive disorder
- Severe refractory post-traumatic stress disorder
- Tourettes/Severe tic disorder

For a diagnosis of major depressive disorder (MDD):
• Atypical antipsychotics will be approved as adjunctive treatment for MDD only.
• Recipients must have undergone an adequate trial of at least one agent in three of the following
classes of antidepressants (unless contraindicated or intolerant to):
  – Selective serotonin reuptake inhibitors (SSRIs)
  – Serotonin-norepinephrine reuptake inhibitors (SNRIs)
  – New generation antidepressants (including bupropion, mirtazepine, etc.)
  – Tricyclic antidepressants (TCAs)

For patients without one of the above diagnoses:
• An atypical may be approved if the physician can provide documented clinical evidence
  supporting the use of the requested medication for the requested indication.

NOTE: Approval of non-preferred atypical antipsychotics will require trial and failure of ONE
preferred agent.
Discussion:
- Dr. Pittman stated the criteria have been updated to match the current internal criteria.
- Dr. Pittman stated the ICD-9 codes are listed that address all FDA approved and common off label uses.
- Dr. Fitzpatrick stated there are a few diagnoses not listed that might be commonly used, she mentioned mood disorder NOS and schizophreniform.
  - Dr. Pittman stated the diagnoses are listed in the ICD-9 code list.
- Ms. Govette stated the autism diagnosis is not included on the ICD-9 listing.
  - Dr. Woods and Dr. Pittman stated they thought the FDA-approval for this diagnosis was not available when the list was first created.
- Dr. Fitzpatrick stated between the two lists she felt most everything was covered however she stated she felt the two listing should match.
  - Dr. Pittman stated the ICD-9 listing is what is actually coded. She stated they would make sure both lists are matching.
  - Dr. Pittman stated the only diagnosis intentionally left off the ICD-9 listing was major depression because the diagnosis had additional criteria beyond just the diagnosis.
- Motion made to accept the clinical criteria provided the ICD-9 list is updated to match the list of approvable diagnoses.
- Motion seconded and carried.
- Dr. Woods stated the listings were done alphabetically, she asked the committee’s preference of alphabetically versus listed by more common usage.
  - Dr. Fitzpatrick stated she prefer listing by more common usage.

Proposed Clinical Criteria:

<table>
<thead>
<tr>
<th>Clinical Criteria for Risperdal Consta/Invega Sustenna</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Risperdal Consta® will only be authorized if the recipient has documented non-compliance with PO atypicals OR non-response due to noncompliance.</td>
</tr>
<tr>
<td>o Invega Sustenna® will only be authorized if the recipient has documented non-compliance with PO atypicals OR non-response due to noncompliance, AND failure of, or intolerance or contraindication to Risperdal Consta®</td>
</tr>
</tbody>
</table>

Discussion:
- Dr. Fitzpatrick asked why Invega Sustenna® is required to step through Risperdal Consta®.
  - Dr. Woods stated the products are similar in their clinical efficacy and both are utilized in the setting of non-compliance. Dr. Woods recognized that the dosing schedule is more convenient for Invega Sustenna® due to it’s once a month schedule.
  - Dr. Woods stated Invega Sustenna® requires an initial loading dose followed by maintenance therapy whereas as Risperdal Consta® requires a period of overlap with oral therapy and then maintenance therapy. Dr. Woods stated taking into account both of those factors, cost models were developed to evaluate the products. She stated the cost of the loading dose period for Invega Sustenna® is significantly more costly than the overlap period for the Risperdal Consta®. The maintenance dosing costs were similar for both
• Dr. Fitzpatrick asked how failure of an oral regimen is defined.
  ▪ Dr. Woods stated the definition is left up to the provider.
• Dr. Fitzpatrick stated the number of patients that are non-compliant with oral therapy is not a significant number of patients. She stated the cost of non-compliance with any therapy should also be factored in, example of cost of hospitalization.
• Ms. Govette stated she had more experience with Risperdal Consta® and in her experience her 2 week patients did succeed with compliance. She stated her patients experienced a social part of the process as well. She stated they had a few patients who did change to Invega Sustenna® because Risperdal Consta® no longer provided symptom control.
• Ms. Govette stated her patients who are non-compliant with visits are generally non-compliant with any visit and does not matter whether it is every 2 weeks or every 4 weeks. She stated her patients on Invega Sustenna® who are non-compliant with visits have to be re-loaded with the initial dose if the interval has been too long.
• Dr. Fitzpatrick asked how any of the visits would be counted towards TennCare’s office visit limitations.
  ▪ Dr. Woods stated she was not sure at this time but this type of patient or this type of visit may be considered for exemption from these limitations.
  ▪ **Dr. Woods stated she would bring these concerns to the group working on the decisions related to exempted groups/laboratory services.**
• Ms. Govette stated there should also be a statement included in the criteria that the patient must have tried and failed the respective oral agent prior to receiving approval for the injection. She stated the patient should not be given the injectable without ensuring there are not significant reactions to the ingredient.
• Ms. Govette motioned the clinical criteria for injectables be accepted with the modification to add the failure of the respective oral agent.
• Dr. Fitzpatrick commented that several providers have expressed their opinion that the last sentence of the criteria related to the step through Risperdal Consta® be removed from the criteria. She stated in her experience she has had better results with compliance from patients receiving injections every 4 weeks rather than every 2 weeks.
• Motion seconded and carried (with 1 opposed).
Proposed Quantity Limits:

<table>
<thead>
<tr>
<th>Quantity Limits</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Abilify®/Ability Discmelt®</td>
<td>1/day</td>
</tr>
<tr>
<td>Fanapt®</td>
<td>2/day</td>
</tr>
</tbody>
</table>
| FazaClo ODT®                                         | 12.5 mg: 2/day  
25 mg: 2/day  
50 mg: 2/day  
100 mg: 9/day |
| Geodon®                                              | 2/day |
| Invega Sustenna®                                     | 1 syringe/month/strength |
| Risperidone®/Risperdal                              | Consta: 2 vials/month  
tabs: 2/day  
ODT: 2/day |
| Saphris®                                             | 5 mg: 1/day  
10 mg: 2/day |
| Seroquel®                                            | 4/day |
| Seroquel XR®                                         | 2/day |
| Zyprexa®                                             | 1/day |
| Zyprexa Zydis®                                       | 1/day |

Discussion

- Ms. Govette stated the Saphris 5 mg should be changed to 2 tablets. She stated if the patient cannot tolerate 10mg daily it is recommended they try 5mg twice daily.
  - Dr. Pittman noted the QL will be updated to reflect this change.
- Dr. Corley asked if the injections’ quantity limits could be updated to reflect the fact that some months the patient will need more injections based on weeks of the month.
  - Dr. Pittman stated this can also be updated to per syringe per 28 days.
  - Dr. Woods stated the injections are also on the titration override list.
- Dr. Fitzpatrick asked about unique pediatric dosing and how to navigate the quantity limit restrictions.
  - Dr. Corley stated the pediatric needs for additional scripts would not be affected because of their exemption from script limits.
  - Dr. Pittman stated the titration list would exempt additional scripts needed from counting towards adult script limits.
  - Dr. Pittman also stated in the call center criteria there is a question addressing need for two different tablets to make up a unique dose.
- Dr. Blevins motioned to accept quantity limits with proposed changes to Saphris and the injectable agents.
- Motion seconded and carried.

Typical Antipsychotics

With the exception of pimozide, all of the first generation (or typical) antipsychotics are indicated for use in the treatment of schizophrenia. Pimozide is indicated only for the suppression of motor and phonic tics in patients with Tourette’s disorder. FGAs can be classified according to their affinity for the D₂ receptor. Low potency antipsychotics, such as chlorpromazine and thioridazine, are more sedating and associated with a higher incidence of anticholinergic side effects. The medium potency antipsychotics (loxapine, molindone, and perphenazine) possess a
Discussion

- Dr. Fitzpatrick stated these agents are not used as commonly and she feels this recommendation adequately addresses this category.
- Dr. Corley asked if the recommendation should specifically mention pimozide because of its unique indication for Tourette’s syndrome.
  - Dr. Pittman stated agreement the recommendation should specify the agent.
- Motion to accept the recommendation with the addition of pimozide to be available because of its unique indication.
- Motion seconded and carried.

REVIEW OF NOVEMBER PAC MEETING DECISIONS

SXC reviewed TennCare’s decisions from the November 11th 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 13, PAC: Approved the step therapy provided that the first bullet point is reworded to reflect similar wording as the Arthrotec criteria. Additionally, use of clopidogrel should be considered a risk factor for GI bleed. PAC asked that the use of ASA and traditional NSAIDs be further investigated and brought back to PAC at the next meeting for possible addition of ASA users to the Celebrex criteria. TennCare: Accepted PAC’s recommendation. Additionally, NSAID gastropathy will be added as a risk factor for GI bleed. (Note: This is currently in the criteria, but was accidentally omitted in the criteria above.)

TennCare looked into the use of ASA with traditional NSAIDS versus the use of ASA with Celebrex®. Please refer to hand-out for summary of comparative data regarding gastrointestinal and cardiovascular risks (and complete list of references).

- Regarding the gastrointestinal risks, NSAIDs have been associated with a higher risk of GI ulcers than celecoxib; however, no significant differences in GI risk exist between celecoxib and an NSAID in combination with a PPI.
- Regarding the cardiovascular risks, Celebrex® has not been shown to have a significant impact on the antiplatelet effect of aspirin, whereas the NSAIDs ibuprofen, naproxen, and indomethacin have been shown to interfere with aspirin’s antiplatelet effect. However, the NSAIDs diclofenac and sulindac have not demonstrated any significant effect on the anti-platelet effect of ASA. In addition, the impact of NSAIDs such as ibuprofen on the antiplatelet effect of ASA can be overcome by dosing the NSAID a few hours after the ASA dose.
For these reasons, TennCare will not add concomitant use of ASA to the Celebrex criteria at this time.

Page 22, PAC: Approved the recommendation provided that it be modified to read “at least 2 unique single agent short acting opioids be available for use, one of which is oxycodone and at least 2 unique combinations of short acting opioids be available for use, including one hydrocodone and one oxycodone product. In addition, liquid formulations of codeine, hydrocodone and morphine should be available for use.

TennCare: Disagreed with the PAC’s recommendation that oxycodone, hydrocodone/APAP, and oxycodone/APAP must all be available. No significant clinical differences in efficacy or safety have been established between the short-acting narcotics. All exhibit similar analgesic effects. Therefore, TennCare accepts the recommendation as proposed by SXC, requiring that at least two unique single-agent short-acting narcotics and at least two unique combination products be available. However, TennCare did agree with PAC that it would be useful to have a liquid formulation available for at least one single-agent short-acting narcotic and at least one combination product.

Discussion:

- Dr. Corley stated concern if the recommendation was left as it proposed, the agents available could be meperidine and propoxyphene or codeine.
- Dr. Woods stated the recommendation separates propoxyphene as an inferior agent.
- Dr. Corley stated he recalled the committee discussed propoxyphene
  - Dr. Woods stated the discussion was around moving propoxyphene to non-preferred and the decision was made to leave the agent as preferred but she felt it was clear the agent had lesser analgesic effect when compared to the other agents in the class.
- Dr. Woods stated the it was the State’s position that the agents in the class, with the exception of propoxyphene, all have similar analgesic effects and the request to have specific hydrocodone and oxycodone products in the recommendation was based more on market share than clinical effects.
- Dr. Corley stated his concern with the current listing, excluding propoxyphene, is that it will become too restrictive.

Page 49, PAC: Approved the recommendation provided that it is changed to read “at least tretinoin and tazarotene be available for use”. TennCare: Head-to-head trials of tretinoin and adapalene have been conducted and found no significant differences between the agents in regards to efficacy. Additionally, clinical guidelines do not distinguish between the agents in the category for the treatment of acne vulgaris. Given that PAC did not provide clinical rationale as to why tretinoin must be available, TennCare did not accept PAC’s recommendation. TennCare accepted the recommendation as presented by SXC.

Discussion

- Dr. Woods read Dr. Capparelli comments: Following further research by TennCare about the age indications, a sentence in the clinical criteria restricting use under age 10 would be appropriate. Dr. Capparelli said that he resented the comment in the general recommendations that stated, "Given that PAC did not provide clinical rationale as to why tretinoin should be available..." Dr. Capparelli stated PAC is a group of clinicians trying to
Dr. Woods stated there was no argument made during the PAC discussion regarding better efficacy or safety of the products. She stated the committee was in agreement the two products were similar in those regards. However, she stated the recommendation to have tretinoin available stemmed from a discussion around which product had a larger market share.

Dr. Woods stated that Dr. Capparelli had expressed it would be acceptable if the packet wording was changed to state the “given that the bulk of the argument was based around market share of tretinoin and we have demonstrated ability to shift market share, TennCare did not feel this was a compelling argument.” He felt this would better capture the committee’s discussion.

Dr. Woods stated the packet can be updated to reflect the proposed wording changes. Dr. Woods stated it was never TennCare’s intent to disrespect the PAC committee. She emphasized that TennCare greatly values and respects the PAC’s clinical input in all areas. She stated for classes like this category where the products are similar, there needs to be specific data to demonstrate clinical superiority to support the need to have specific products in the recommendation. She stated she confirmed with Dr. Capparelli the previous discussion was more focused around market share.

**SPEAKERS FOR PUBLIC TESTIMONY**

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An announcement: Next PAC meeting will be Tuesday, May 11, 2010 at the Cool Springs Marriott.

Meeting Adjourned.