INTRODUCTIONS
The meeting was called to order by Chairman Alan Corley. Dr. Corley stated that committee members are volunteers, appointed according to public act (TCA 71-5-2401) establishing the Pharmacy Advisory Committee (PAC). Dr. Corley asked the members of the Committee to introduce themselves.

PAC MINUTES
The February 12, 2013 PAC meeting minutes which included requested corrections were reviewed.
- Dr. Ernest Jones motioned to approve the minutes as presented with corrections.
- Motion seconded by Dr. Edward Capparelli.
- Motion carried.

TENNCARE UPDATE
Dr. Vaughn Frigon gave this quarter’s TennCare update. Dr. Frigon thanked the committee for their time and service on the TennCare Pharmacy Advisory Committee and expressed appreciation for their input regarding the pharmacy program as this type of participation is vital to the continued success of the program.

- Pharmacy Program Team: Dr. Bryan Leibowitz, our Pharmacy Director left in April to take another position. Dr. Leibowitz left on very good terms with the state and the Bureau of TennCare wishes him well on his new endeavors. Moving forward, the Bureau of TennCare feels confident we have a strong team in place to continue our efforts.
- Pharmacy Benefit Vendor: We are currently transitioning to the new pharmacy benefit manager vendor which will occur on June 1, 2013. A lot of work is being placed on the vendor transition to ensure the change is a smooth and seamless event. As it stands now, we do not anticipate any major issues to occur and expect a successful transition over to Magellan without major disruption.
- Health Care Reform: As you may all be aware of now, Governor Haslam has decided not to expand the TennCare Medicaid population. Currently, TennCare is having ongoing discussions with the federal government and CMS regarding how to handle those who would have qualified under the expansion program. TennCare is exploring premium support opportunities and other options available that may assist this population of patients under the TennCare Program. Dr. Frigon stated he will keep the committee updated regarding any new changes.
- Payment Reform Opportunities: Dr. Frigon commented that the way we deliver healthcare in this country will be very different 3 years from today. The idea is to move away from the volume based, fee for service model to a model that is driven by value and high quality of care. TennCare is very involved with
working with our provider and patients to develop a system that will move us forward toward a value based model. Over the next 6 months, more information will become available regarding this move to an exciting new standard of healthcare.

- **Dental Benefit Manager Vendor**: TennCare just completed the RFP process to obtain a vendor to handle the dental benefits for our TennCare population. As a result, TennCare will be moving to a new dental benefit manager, Dental Quest on October 1, 2013. Dr. Frigon stated that he has been in his position for approximately 3 months and has already been involved with 2 major vendor transitions, so by the end of the year he should be well versed on vendor transitions.

- **Dual-Eligible Population**: TennCare currently has a subpopulation of 120,000 members who are eligible for both Medicare and Medicaid benefits. This subpopulation of patients is our most vulnerable group of patients. So, TennCare is currently working with our Medicare Advantage Plan and Managed Care Organizations (MCOs) to set up programs that will provide better coordination of care in an effort to provide higher quality of care specifically to this group of patients. This is an interesting project that will significantly impact this subpopulation and improve the quality of care they will receive in a cost-effective manner.

- **Pharmacy Advisory Committee (PAC)**: A few changes have occurred since the last meeting. Dr. Jeri Fitzpatrick and Dr. Stanley Dowell have left our committee. TennCare is currently in the process of replacing their positions. Dr. Jeri Fitzpatrick served as our Vice-Chairman for the committee. Governor Haslam has appointed Dr. Edward Capparelli as our new Vice-Chairman for the committee. Dr. Frigon thanked Dr. Capparelli for taking on the extra responsibility and looks forward to working with him in the future.

  Dr. Frigon expressed to the committee that they should feel very confident about the operations of the TennCare Program. Dr. Frigon challenged the committee to serve as ambassadors for the program as their role on the committee gives them unique insight into the daily operation of the program. Dr. Frigon stated that this year alone, 12 states have visited to obtain insight on the TennCare Program, which is a huge indicator that we are doing something positive and others want to know how to create a program similar to TennCare. Dr. Frigon invited the committee, to reach out to him if they would like to visit and learn more about the Bureau of TennCare.

  - Dr. Capparelli asked if the PAC Drug Agendas following transition to Magellan will be available in a timely manner to allow appropriate preparation for the meetings. Dr. Frigon stated that we will make every effort to get this information out in a timely manner going forward and thanked Dr. Capparelli for his suggestion.

  - Dr. Johns asked if the 2014 PAC Agenda Dates could also be available as well. Dr. Polson stated that they will work on finalizing those dates and will provide those dates as soon as possible.

**AE SUBCOMMITTEE**

Dr. Leslie Pittman reported to the PAC committee there was 1 new drug addition to an existing category on the Auto-Exemption (AE) List for 1Q2013. This 1 addition includes Pomalyst®, an oncology agent.
DRUG CLASS REVIEWS

The drug class review section of the meeting consisted of a Catamaran 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 Catamaran’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 Catamaran, please refer to the May 16, 2013 PAC review packet at: https://tnm.providerportal.sxc.com/rxclaim/TNM/PAC%20packet%20051613.pdf

Ophthalmic Agents

Ophthalmic Alpha-2 Agonists

- Brimonidine and apraclonidine are ophthalmic alpha agonists indicated for the management of elevated IOP from glaucoma, ocular hypertension and after surgical treatments. The American Academy of Ophthalmology, American Optometric Association and National Institute for Clinical Excellence recommend ophthalmic prostaglandin analogues and ophthalmic beta blockers as first-line medication agents in patients with elevated IOP. Combination or monotherapy with agents from another class is recommended in patients that experience intolerable side effects or do not achieve goal IOP reductions with first-line agents. Ophthalmic alpha agonists are considered second-line therapy agents and current guidelines do not differentiate between the agents within the class. Additionally, head to head comparisons demonstrate ophthalmic alpha agonists are comparable in efficacy. Therefore it is recommended that at least one ophthalmic alpha agonist be available for use.

Discussion:

- Dr. Capparelli stated that he understands there is no differentiation between the agents based on the presentation. However, utilization shows only 6 claims were processed for apraclonidine whereas over 90% of the claims are for brimonidine. Dr. Capparelli stated that based on the utilization data there seems to be a difference. Therefore recommended at least brimonidine be available for use.
  - Dr. Lovett verified if Dr. Capparelli wanted the recommendation to include only brimonidine. Additionally, Dr. Jones asked for clarification on the recommendation. Dr. Capparelli clarified that in order to ensure brimonidine is available he wanted this agent to be included as the 1 agent that would be available.

- Dr. Capparelli motioned to modify the recommendation to read “…recommend that at least brimonidine be available for use”
- Motion seconded and carried.

Ophthalmic Prostaglandin Agonists
The ophthalmic prostaglandin analogues are approved by the Food and Drug Administration (FDA) to reduce IOP in patients with open-angle glaucoma or ocular hypertension. Clinical guidelines by the American Academy of Ophthalmology, American Optometric Association and the National Institute for Clinical Excellence support the use of ophthalmic β adrenergic antagonists or ophthalmic prostaglandin analogues as initial medical therapy to lower IOP and reduce the risk of progression to visual field loss or optic disc changes in patients with elevated IOP. Guidelines do not recommend one ophthalmic prostaglandin analogue over another and differences in IOP-lowering ability among the agents within the class are small and clinical significance has not been established. Therefore it is recommended that at least 2 ophthalmic prostaglandin analogues are available for use.

Discussion:
- Dr. Corley reminded the committee that an updated drug listing for this category was placed on their table.
- Dr. Capparelli stated the recommendation needs to include the word “distinct” between the number “2” and word “ophthalmic” to ensure the listing does not include both the brand and generic version of an agent as the preferred agents.
- Dr. Johns inquired as to whether there was any concern of off label use to increase lash growth.
  - Dr. Lovett stated there is currently no concern with off label use as the utilization did not show an increase in claims. Dr. Pittman stated that when this indication first came out, utilization was reviewed at that time and an increase was not seen at that time.
- Lyn Govette asked what is required to obtain the non-preferred, preservative free agent if a patient required this agent.
  - Dr. Lovett stated that the general non-preferred criteria will allow use of the agent if the provider indicates the patient has an allergy to the preservative contained in the preferred agent.
- Dr. Capparelli made a motion to include the word “distinct” between the number “2” and word “ophthalmic” in the drug class recommendation.
- Dr. Jones seconded the motion.
- Motion carried.

### Quantity Limits

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>latanoprost/Xalatan®</td>
<td>1 bottle/RX</td>
</tr>
<tr>
<td>Lumigan®</td>
<td>5ml/RX</td>
</tr>
<tr>
<td>Rescula®</td>
<td>5ml/RX</td>
</tr>
<tr>
<td>Travatan Z®</td>
<td>5ml/RX</td>
</tr>
<tr>
<td>travoprost</td>
<td>5ml/RX</td>
</tr>
<tr>
<td>Zioptan®</td>
<td>60each/RX</td>
</tr>
</tbody>
</table>

Discussion:
- Dr. Corley stated that latanoprost comes in a 2.5ml bottle and many patients are unable to get the 2.5ml bottle to last a full month.
  - Dr. Lovett asked Dr. Corley if he was seeing this in practice.
  - However, Dr. Corley stated that he was seeing quite a number of patients who required 2 bottles per month as the 2.5ml bottle does not give them
a full month’s worth of drops. This may possibly be due to lost drops upon instillation.

- Dr. Jones inquired as to the number of drops contained in 1 ml. Dr. Corley stated the rule of thumbs is approximately 20 drops/ml, but this does not seem to be the case with this agent.
- Dr. Lovett and Pittman stated they could definitely discuss this concern.

- Dr. Jones motioned to approve the quantity limits with a request to review the quantity limit for latanoprost.
- Motion seconded and carried.

**Ophthalmic Steroids**

- The ophthalmic steroids are FDA-approved for the treatment of steroid-responsive inflammatory ocular conditions, with the exception of difluprednate and rimexolone. Difluprednate is approved for the treatment of post-operative inflammation and pain following ocular surgery. Rimexolone is approved for the treatment of post-operative inflammation as well as the treatment of chronic anterior uveitis. Prolonged use of ophthalmic steroids may result in ocular hypertension and/or glaucoma. Results from clinical trials demonstrate that loteprednol is less likely than prednisolone acetate to cause clinically significant increases in intraocular pressure when used long-term. Currently available clinical guidelines do not recommend one particular ophthalmic steroid over another in the treatment of most ocular conditions; however, the American Optometric Association does recommend the use of ophthalmic prednisolone acetate 1% to control inflammation associated with anterior uveitis. Therefore, it is recommended at least three ophthalmic steroids should be available for use, one of which should be prednisolone acetate. Additionally, due to the decreased relative risk of elevated intraocular pressure, loteprednol should be available for patients where a potential increase in intraocular pressure would place the patient at risk.

**Discussion:**

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

**Ophthalmic NSAIDs**

- Ophthalmic NSAIDs are most commonly used for the treatment of inflammation and pain secondary to ophthalmic surgery. Ophthalmic corticosteroids are widely considered first line therapy for the treatment of ophthalmic inflammatory conditions. However, due to adverse effects, certain patient populations should avoid the use of corticosteroids. Ophthalmic NSAIDs offer the anti-inflammatory benefits without the risks associated with ophthalmic corticosteroids in these patient populations. Guidelines from the AAO regarding the post-operative management of cataracts recommend ophthalmic NSAIDs as an alternative to or in combination with ophthalmic corticosteroids for the prevention and treatment of cystoid macular edema associated with cataract surgery. The AAO guidelines do not distinguish between the various NSAIDs. Based on all of this information, it appears that the ophthalmic NSAIDs produce similar anti-inflammatory and pain relieving effects and can thus be considered therapeutic alternatives to one another. In order to maintain
costs and ensure appropriate use, it is recommended that ophthalmic NSAIDs be reserved for patients for whom corticosteroid monotherapy is not appropriate.

Discussion:
- Dr. Johns expressed concern as to whether there is a need to reserve for patients unable to use ophthalmic steroids or these agents are not appropriate. Dr. Johns stated that from a cost standpoint the price appears similar to the ophthalmic steroids.
  - Dr. Pittman stated that the cost information provided does not reflect rebates that may be received on a particular agent, so the cost shown may be misleading.
  - Dr. Capparelli inquired as to whether rebates disappear when a drug becomes available generically. Dr. Pittman stated this is not always the case. Dr. Capparelli stated he understands across the board rebates are available, but supplemental rebates are not provided on generic agents. Dr. Pittman stated that CMS rebates are sometimes determined by how long the agent has been on the market. Many of the corticosteroids have been around longer than the NSAIDs.
  - Dr. Polson stated additionally, the Affordable HealthCare Act changed how certain drugs are rebated. Agents that fall in the group of drugs termed the five i’s- inhalation, instillation, implanted, infusion and injection are the exception to the standard federal rules of determining rebates. Therefore, rebates work a little different for the ophthalmic agents.
- Dr. Capparelli inquired about this drug class qualifying for the low utilization category.
  - Dr. Pittman stated the low utilization criteria requires less than 100 claims AND less than 100,000 per year in order to be classified as a low utilization category. Dr. Polson stated that with the new way of scheduling drug categories to review, this drug class will not be reviewed for several years.
  - Dr. Pittman reiterated that unless there are changes to the guidelines, this drug category should not be reviewed for some time with the new PAC scheduling rules.
- Dr. Johns motioned to accept the recommendation.
- Dr. Bush seconded the motion.
- Motion carried.
Will be approved if ANY of the following are true:

- Recipient has a contraindication, intolerance or adverse reaction to an ophthalmic steroid (i.e. prednisolone). Acceptable reasons for not using an ophthalmic steroid (not inclusive):
  - Potential increase in intraocular pressure (IOP) with ophthalmic steroids that would place the patient at risk (i.e. glaucoma, pre/post-cataract surgery)
  - Concerns that the steroid would impair wound healing
  - Concerns that the steroid may cause/induce infection due to immunosuppression.
  - Use of the agent is for pain pre/post-ocular surgery
  - Concomitant use of an ophthalmic steroid and an ophthalmic NSAID is needed to control inflammation

- Approval of non-preferred agents additionally requires trial and failure, contraindication or intolerance of 2 preferred agents

Discussion:

- Dr. Pittman stated that the last bullet point was added for clarification purposes, which is basically the general non-preferred criterion. This was added to prevent confusion when the same criteria are listed for preferred and non-preferred agents.
  - Lyn Govette asked is this was to prevent movement to non-preferred agents without trial of the preferred agents. Dr. Pittman stated that for preferred agents, patients have to meet the first part of the criteria. Patients that require non-preferred agents will have to meet both the first part of the criteria as well the last bullet point.
  - Dr. Capparelli stated that since the recommendation does not specifically state 2 distinct agents, it is quite possible that only 1 preferred agent would be available. So the last bullet point would need to be changed. It is more of a word-smart issue. Dr. Pittman stated the last bullet point is our standard non-preferred criterion that has always been in place. If there was only 1 preferred agent then it would require only trial/failure of 1 preferred agent. Discussion continued.
- Lyn Govette made a motion to accept the quantity limits.
- Dr. Capparelli seconded the motion
- Motion carried.

Gastrointestinal Agents

GLP-2 Analogs

- Teduglutide is FDA-approved for the treatment of adult patients with SBS who are dependent on parenteral support. Clinical trial data demonstrates that treatment with teduglutide provides increased absorption of fluids and nutrients and reduces patients’ dependency on parenteral support. However, further evidence is warranted regarding its long term safety. Current evidence indicates that most SBS patients are able to wean off TPN without pharmacologic assistance; however, teduglutide adds to the limited clinical treatment options available for patients with short bowel syndrome. Therefore, it is recommended teduglutide should be subject to prior authorization to ensure appropriate utilization.

Discussion:
• Dr. Jones inquired about the PA (prior authorization) duration. Dr. Pittman stated that typically are PAs are for 1 full year and this drug would receive a 1 year PA duration.

• Dr. Capparelli stated that what he remembers from 10-15 years ago. All of Pharma conducted multi-center studies, and then would pick out those studies that showed promise and presented certain pieces of data. Dr. Capparelli based on the presented information it appears this is information from specific studies and I was under the impression that the FDA only accepts pooled data. Dr. Capparelli inquired if any pooled data was available for this agent. Dr. Pittman stated she was unsure if this information was available, only data regarding the drug being evaluated in 2 randomized double-blind placebo controlled parallel group multi-center trials. Dr. Capparelli stated he questions the validity of the data if the information provided is cherry picked from certain trials. This makes it hard to make any interpretation as the data is lacking. Discussion continued.

• Dr. Corley asked if the drug was a subcutaneous and self-administered injection.
  o Dr. Pittman stated this was correct, the drug is both injected SQ and may be self-administered.

• Dr. Capparelli motioned to accept the recommendation as presented.
• Lyn Govette seconded the motion.
• Motion carried.

<table>
<thead>
<tr>
<th>Prior Authorization Criteria for Gattex®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will be approved for patients that meet ALL of the following criteria:</td>
</tr>
<tr>
<td>• Diagnosis of short bowel syndrome, AND</td>
</tr>
<tr>
<td>• Dependent on parenteral nutrition for at least 12 months (initial approval only), AND</td>
</tr>
<tr>
<td>• Receiving parenteral nutrition at least 3 times weekly (initial approval only)</td>
</tr>
</tbody>
</table>

Discussion:
• Dr. Jones stated the data given about the drug from clinical trials is why I inquired about the PA duration.
  o Dr. Pittman stated that the last 2 bullet points will be required only for initial approval. The renewal criteria will be slightly different to ensure patients that initially received approved the drug will continue to obtain the agent if needed.

• Dr. Bush asked for clarification regarding the statement about “50-70% of patients wean off of parenteral nutrition in 3 to 6 months”. Dr. Bush recommended that the initial renewal is set at 6 months to reassess.
  o Dr. Pittman stated that the patient would have to be on parenteral nutrition for at least 12 months before being considered a candidate for this drug. Discussion continued.

• Dr. Jones motioned to accept the criteria.
• Lyn Govette seconded the motion.
• Motion carried.

Respiratory Agents

Steroids, Orally Inhaled
➢ All of the inhaled corticosteroids (ICSs) are FDA approved for the maintenance treatment of asthma as prophylactic therapy. Beclomethasone and fluticasone
Propionate are also indicated for use in asthma patients who require systemic corticosteroid therapy when the addition of an ICS could reduce or eliminate the need for systemic corticosteroids. The 2012 GINA guidelines for Asthma state ICSs are currently the most effective anti-inflammatory medications for the treatment of persistent asthma for patients of all ages. Although ICSs may differ in potency and bioavailability, trial data does not indicate the clinical relevance of these differences and clinical guidelines do not give preference to one ICS over another. ICSs are also recommended by the Global Initiative for Chronic Lung Disease (GOLD) guidelines to treat COPD (chronic obstructive pulmonary disease) patients with an FEV1 <60% of the predicted value. Therefore, it is recommended that at least 2 ICS agents are available for use, with budesonide respules available for the pediatric population who are unable to use proper inhaler technique.

**Discussion:**
- Dr. Capparelli asked if an age point should be added to the recommendation to define pediatric population.
  - Dr. Pittman stated we have it listed in the criteria specifically for budesonide respules.
  - Dr. Capparelli asked if the recommendation should specifically state for children 6 and under. Dr. Lovett states the system will allow the agent to pay at point-of-sale for children 6 and under. Dr. Corley also made the point if we specifically list an age in the recommendation. This will further restrict the agent preventing perhaps an 8 year old that may require the respules due to improper technique via a prior authorization. Dr. Lovett also commented that we have a few CF (Cystic Fibrosis) patient that are much older, that receive the agent via prior authorization as a result of the medical condition and not being able to properly use an inhaler, so modifying the recommendation with an age may prevent these patients as well.

- Dr. Capparelli motioned to accept the recommendation as presented.
- Motion seconded and carried.

**Prior Authorization Criteria for Pulmicort Respules®/budesonide respules:**
- PA not required for enrollees ages 6 and under.

**Discussion:**
- Dr. Johns inquired about the criteria for patients 7 and older.
  - Dr. Pittman stated the criteria for 7 and older, is our standard non-preferred criteria, which is trial/failure of 2 preferred agents.
  - Dr. Capparelli stated that Dr. Johns is referring to whether or not the criteria should specifically be listed for patients 7 and older. Dr. Pittman stated that the assumption is patients over the age of 6 should be able to use an inhaler properly. Dr. Lovett stated that this criterion was added to ensure providers understood that for patients 6 and under, a request for a PA is not required.
- Lyn Govette motioned to accept the prior authorization criteria.
- Dr. Bush seconded the motion.
- Motion carried.
### Quantity Limits

<table>
<thead>
<tr>
<th>Product</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asmanex®</td>
<td>1 per 30 days</td>
</tr>
<tr>
<td>Alvesco®</td>
<td>2 per 30 days</td>
</tr>
<tr>
<td>Flovent HFA®</td>
<td>2 per 30 days</td>
</tr>
<tr>
<td>Flovent Diskus®</td>
<td>50mcg: 2 blisters/day  &lt;br&gt;100mcg: 4 blisters/day &lt;br&gt;250mcg: 8 blisters/day</td>
</tr>
<tr>
<td>Pulmicort Flexhaler®</td>
<td>2 per 30 days</td>
</tr>
<tr>
<td>Pulmicort Respules®</td>
<td>0.25mg/2ml &amp; 0.5mg/2ml: 2 vials/day &lt;br&gt;1mg/2ml: 1 vial/day</td>
</tr>
<tr>
<td>QVAR®</td>
<td>2 per 30 days</td>
</tr>
</tbody>
</table>

**Discussion:**
- Dr. Capparelli motioned to accept the quantity limits.
- Dr. Bush seconded the motion.
- Motion carried.

### Leukotriene Receptor Antagonists

- The leukotriene modifiers are Food and Drug Administration (FDA) approved for prophylaxis and chronic treatment of asthma. Montelukast is also FDA approved for the relief of symptoms of seasonal and perennial allergic rhinitis and for the prevention of exercise-induced bronchoconstriction. The GINA guidelines list leukotriene modifiers as a treatment alternative to low-dose inhaled corticosteroids (ICSs) in patients with mild persistent asthma. These agents are also considered as adjunctive therapy to reduce the dose of the ICS required by patients with moderate to severe asthma, and in patients not achieving adequate symptom control with an ICS as monotherapy or in combination with a long-acting β₂-agonist (LABA). The allergic rhinitis guidelines consider the leukotriene modifiers either alone or in combination with antihistamines useful. The guidelines for exercise induced bronchoconstriction state leukotriene receptor antagonists may be used daily or intermittently for prevention of exercise-induced bronchoconstriction without the development of beta-agonist tolerance. However these agents do not reverse airway obstruction. Currently, there are no head-to-head trials directly comparing the efficacy and safety of the leukotriene modifiers to each other. However, clinical data shows zafirlukast and zileuton have a higher risk of hepatotoxicity than montelukast. Therefore based on the safety risk profiles and clinical guidelines which view these agents as an alternative treatment option; it is recommended these agents are available for use subject to prior authorization.

**Discussion:**
- Dr. Capparelli stated that the recommendation does not specifically state 1 agent should be available or montelukast should be made available.
  - Dr. Corley commented that maybe “these agents” should be changed to read “leukotriene modifiers”.
  - Dr. Lovett asked for verification on what was being requested. So based, on what you are saying we want “these agents’ to change to ‘leukotriene modifiers’ and a statement regarding montelukast being used first due to the safety profile. Dr. Capparelli stated based on the presented information, it is clear that montelukast may be the safer agent and the
recommendation should state that montelukast should be tried first. Dr. Capparelli suggested removing the last 2 sentences and state: based on the clinical guidelines that view this agents as alternative options; it is recommended that the leukotriene receptor antagonists are available for use subject to prior authorization. In addition, clinical data show zafirlukast and zileuton have a higher risk of hepatotoxicity than montelukast, so montelukast should be tried/failed first prior to approval of zafirlukast and zileuton. Discussion continued.

- Dr. Johns stated that understanding the cost information provided may not be 100% accurate; there is approximately a 100-fold price difference, so it’s not likely that zafirlukast and zileuton agents will be placed as preferred.

- Dr. Capparelli made a motion to approve the recommendation with modification by moving the sentence beginning with “Currently, there are no head-to-head trials….hepatotoxicity than montelukast” to the very end. Then add “therefore, montelukast should be the first agent used in this class due to the relative lower risk of hepatotoxicity.” Also the words “these agents are available for use subject to prior authorization” in the sentence before should be changed to read “it is recommended leukotriene modifiers are available for use subject to prior authorization.”

- Lyn Govette seconded the motion.

- Motion carried.

<table>
<thead>
<tr>
<th>Prior Authorization Criteria for montelukast/Singulair® tabs &amp; chewables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Unrestricted for recipients 17 years and younger.</td>
</tr>
<tr>
<td>• Recipients &gt; 17 years old:</td>
</tr>
<tr>
<td>• Unrestricted for asthma documented with concomitant use of at least one other asthma medications</td>
</tr>
<tr>
<td>• For treatment of seasonal allergic rhinitis, patient must have failed trial of a non-sedating antihistamine.</td>
</tr>
</tbody>
</table>

Discussion:

- Dr. Bush asked what percentages of PAs are approved for asthma versus allergic rhinitis patients.
  - Dr. Lovett stated she did not have an exact number on hand. However, many of the PAs are approved based on the asthma diagnosis, as the system looks back in the system for an asthma related medication.
  - Dr. Bush stated that she was reviewing the cost of the medication and how it would relate to the cost of obtaining a PA. Dr. Pittman stated that the cost has decreased significantly since the generic became available. In fact, the cost has decreased enough to allow changes for the criteria requirement for patients with allergic rhinitis. Previously, the criteria required trial/failure of a non-sedating antihistamine and an intranasal steroid. The criterion was loosened to only require use of a non-sedating antihistamine. As the requirement for an intranasal steroid was more costly than allowing the montelukast for patients with a diagnosis of allergic rhinitis. Dr. Pittman stated approximately 75% or more are approved due to the look backs that are set-up in the system. Discussion continued.
- Dr. Capparelli asked if diagnosis codes must be submitted with the claim.
  - Dr. Pittman stated that currently, diagnosis codes are not required.
- Dr. Capparelli motioned to accept the clinical criteria as presented.
- Lyn Govette seconded the motion.
- Motion carried.

### Prior Authorization Criteria for montelukast granules:

<table>
<thead>
<tr>
<th>Category</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipients less than 3 years of age</td>
<td>No prior authorization required.</td>
</tr>
<tr>
<td>Recipients 3-17 years</td>
<td>Will be approved ONLY for patients who have clinically valid reason not to use chewable tablets.</td>
</tr>
<tr>
<td>Recipients &gt; 17 years old</td>
<td>Diagnosis of asthma documented with concomitant use of at least one other asthma medication.</td>
</tr>
<tr>
<td></td>
<td>For treatment of seasonal allergic rhinitis, patient must have failed trial of a non-sedating antihistamine.</td>
</tr>
<tr>
<td></td>
<td>Will be approved for patient meeting the above criteria ONLY for patients who have clinically valid reason not to use chewable tablets</td>
</tr>
</tbody>
</table>

**Discussion:**
- Dr. Corley inquired about use of chewable tablets listed in the criteria. Dr. Pittman stated that it is assumed if they are requesting granules, the patient is unable to swallow a tablet.
- Lyn Govette motioned to accept the criteria.
- Motion seconded and carried.

### Prior Authorization Criteria for Singulair® granules:

<table>
<thead>
<tr>
<th>Category</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipients 17 years and younger</td>
<td>Will be approved ONLY for patients who have clinically valid reason not to use chewable tablets.</td>
</tr>
<tr>
<td>Recipients &gt; 17 years old</td>
<td>Diagnosis of asthma documented with concomitant use of at least one other asthma medication.</td>
</tr>
<tr>
<td></td>
<td>For treatment of seasonal allergic rhinitis, patient must have failed trial of a non-sedating antihistamine.</td>
</tr>
<tr>
<td></td>
<td>Will be approved for patient meeting the above criteria ONLY for patients who have clinically valid reason not to use chewable tablets</td>
</tr>
</tbody>
</table>

**Discussion:**
- The committee asked for clarification on the 1st bullet point. Dr. Lovett stated that patients 3 and younger are allowed to receive montelukast granules without a PA. However, the brand name Singulair granules will require a PA for anyone less than 17 years of age; includes those patients that are less than 3 years of age.
- Dr. Capparelli motioned to accept the criteria.
- Lyn Govette seconded the motion.
- Motion carried.

### Quantity Limits

<table>
<thead>
<tr>
<th>Product</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>montelukast/ Singulair® tabs &amp; chewables</td>
<td>1 /day</td>
</tr>
<tr>
<td>montelukast/ Singulair® granules</td>
<td>1 /day</td>
</tr>
<tr>
<td>Medication</td>
<td>Dosage</td>
</tr>
<tr>
<td>--------------------</td>
<td>--------</td>
</tr>
<tr>
<td>zafirlukast/ Acolate®</td>
<td>2/day</td>
</tr>
<tr>
<td>Zyflo®</td>
<td>4/day</td>
</tr>
<tr>
<td>Zyflo CR®</td>
<td>2/day</td>
</tr>
</tbody>
</table>

**Discussion:**
- Lyn Govette motioned to accept the quantity limits presented.
- Dr. Capparelli seconded the motion.
- Motion carried.

**Beta-Agonists: Combo Products**

- Inhaled bronchodilators and corticosteroids are the mainstay of chronic obstructive pulmonary disease (COPD) and Asthma treatment. The beta2-agonist combination agents, fluticasone propionate/salmeterol, budesonide/formoterol, and mometasone/formoterol are all FDA approved for the treatment of asthma, with only budesonide/formoterol and fluticasone propionate/salmeterol being FDA-approved for the treatment of COPD. Consensus guidelines from both the Global Initiative for Chronic Obstructive Lung Disease and the National Institute for Health and Clinical Excellence recommend the use of combination ICS/LABA products as second-line, when a patient remains symptomatic and has repeated exacerbations while on an initial short- and long-acting bronchodilator. The current guidelines for the treatment of Asthma support the use of combination ICS/LABA products for long term control and prevention of symptoms in patients who do not achieve sufficient symptom control with an ICS (low to medium dose) as monotherapy, as LABA medications are the preferred add on therapy in these patients. Based on current guidelines that place beta2-agonist combination agents as second-line therapy, it is recommended that the combination LABA/ICS agents be reserved for asthma patients who require frequent use of an inhaled short-acting bronchodilator while maintained on an optimal dose of an inhaled steroid, and for COPD patients who have symptoms despite optimal doses of a LABA.

**Discussion:**
- Dr. Capparelli expressed concerned regarding the optimal doses of a LABA (long-acting beta-agonist) in COPD. The studies show there was no increase in risk when the LABA is used in combination with a steroid. My concern is offering my COPD patients, who are typically an older population of patients and give them a LABA by itself, thus increasing their chances of cardiovascular events for which a black box warning is currently listed for these agents.
  - Dr. Lovett stated that this warning is specifically for asthma patients and not COPD patients. Dr. Pittman further explained the studies were only done in Asthma patient and thus the risk is specifically in this group of patients.
  - Dr. Capparelli stated that he is not comfortable using a LABA in his COPD patients. Dr. Lovett stated the clinical guidelines for COPD patients recommend use of LABAs. Dr. Pittman stated the guidelines changed for asthmatic patients as a result of this this risk, but the guidelines were not changed for COPD patients based on this risk in Asthma patients.
- Dr. Jones motioned to accept the recommendation.
- Lyn Govette seconded the motion.
• Motion carried.

### Prior Authorization Criteria for Advair Diskus®, Advair HFA®, Dulera®, & Symbicort®

<table>
<thead>
<tr>
<th>Will be approved if ONE of the following is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• For the treatment of asthma or the treatment of other reversible airway disease(s) where optimal doses of</td>
</tr>
<tr>
<td>inhaled steroids are being used and breakthrough symptoms require frequent use of inhaled short-acting</td>
</tr>
<tr>
<td>bronchodilators.</td>
</tr>
<tr>
<td>• For the treatment of COPD where optimal doses of a long-acting beta agonist are being used and symptoms</td>
</tr>
<tr>
<td>are still uncontrolled.</td>
</tr>
</tbody>
</table>

Discussion:
• Lyn Govette motioned to accept the criteria.
• Dr. Johns seconded the motion.
• Motion carried.

### Quantity Limits

<table>
<thead>
<tr>
<th>Quantity Limits</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Advair Diskus®</td>
<td>2 blisters/day</td>
</tr>
<tr>
<td>Advair HFA®</td>
<td>1 inhaler/month 30 days</td>
</tr>
<tr>
<td>Dulera®</td>
<td>1 inhaler/month 30 days</td>
</tr>
<tr>
<td>Symbicort®</td>
<td>1 inhaler/month 30 days</td>
</tr>
</tbody>
</table>

Discussion:
• Dr. Bush inquired as to whether this is a hard limit of exactly 30 days.
  • Dr. Lovett stated the system allows the drug to pay at point-of-sale when 85% of the drug has been used.
• Dr. Jones made a motion to accept the quantity limits.
• Dr. Bush seconded the motion.
• Motion carried.

### Anti-cholinergics, Inhaled

- Aclidinium, ipratropium and tiotropium are Food and Drug Administration (FDA) approved for the maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. The combination agent, ipratropium/albuterol is indicated for treatment of bronchospasms associated with COPD in patients who require more than one bronchodilator. The guidelines state that regular use of long-acting β2-agonists or short- or long-acting anticholinergics improve health status and long-acting anticholinergics reduce the rate of COPD exacerbations and improve the effectiveness of pulmonary rehabilitation. Treatment with aclidinium has demonstrated statistically significant improvements in pulmonary function in patients with COPD compared to placebo. However, there are currently no head-to-head studies with other anticholinergics available. Tiotropium is the only inhaled anticholinergic that is FDA-approved for reducing exacerbations associated with COPD. Therefore it is recommended that at least 2 inhaled anticholinergics are available for use, which should include tiotropium.

Discussion:
• Dr. Capparelli stated in the previous discussion with the beta agonist products, it was decided to break these agents up into sub-categories. Dr. Capparelli asked why these were lumped together and not broken down by their duration of action.
Dr. Pittman stated that these agents have always been listed this way. Dr. Pittman stated that the previous classes were sub-divided due to rebate issues and in this class rebates were not an issue.

- Dr. Capparelli stated that if we are going to keep them all together in one class, then we should make it clear that 1 short-acting agent, 1 long-acting agent and 1 combination agent is available.
  - Dr. Lovett stated this could be done.
- Dr. Capparelli inquired as to whether Combivent® MDI is still available.
  - Dr. Pittman stated that currently it is still available. However, Dr. Lovett stated that July 2013 is the month given that the agent will no longer be commercially available. Dr. Corley stated that his wholesaler no longer has any of the Combivent® MDI available. Basically, it depends on when the particular wholesaler depletes their supply.
- Dr. Capparelli voiced concern about only a short-acting nebulized solution being preferred which also requires the use of a nebulizer. Dr. Pittman stated that when cost is reviewed for the nebulized solutions, the cost of the nebulizer is accounted for as well in the total cost.
- Dr. Jones asked the committee about side effects from the use of tiotropium. Dr. Jones stated that he has had several patients experience moniliasis of the mouth, which may mainly due to incorrect use of the drug. Dr. Capparelli stated that he sees more of this in his patients that use inhaled corticosteroids, but informs his patients that use orally inhaled agents to rinse the mouth out following administration.
- Dr. Corley suggested that the nebulized formulation should be available as well.
- Dr. Capparelli motioned to accept the recommendation with modification that the last sentence reads “Therefore it is recommended that at least 2 inhaled one short-acting, one long-acting and one-combination anticholinergic should be available for use, which should include tiotropium.” Also an additional sentence should be added to read: “Additionally, both nebulized and inhalation formulations should be available for use when available.”

- Dr. Jones seconded the motion.
- Motion carried.

### Quantity Limits

<table>
<thead>
<tr>
<th>Product</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>albuterol/ipratropium /DuoNeb®</td>
<td>18 mL/day</td>
</tr>
<tr>
<td>Atrovent® HFA</td>
<td>2 inhalers/month 30 days</td>
</tr>
<tr>
<td>Combivent®/Combivent Respimat®</td>
<td>2 inhalers/month 30 days</td>
</tr>
<tr>
<td>ipratropium solution</td>
<td>10 mL/day</td>
</tr>
<tr>
<td>Spiriva®</td>
<td>30 capsules/month 1 cap/day</td>
</tr>
<tr>
<td>Tudorza®</td>
<td>1 inhaler/ 30 days</td>
</tr>
</tbody>
</table>

Discussion:
- Dr. Jones asked if the quantity limit changes to 30 days will affect the refill schedule.
  - Dr. Lovett stated no this change will not change how often the patient can refill; it is mainly for making coding uniform.
- Dr. Capparelli voiced concern that the Combivent Respimat® device is marketed to last a full month and perhaps some education by providers regarding the difference in dosing between the Combivent® MDI and Combivent Respimat® will
prevent any confusion but in the meantime this may need to be monitored by the pharmacy benefit manager successor.

- Dr. Capparelli motioned to accept the quantity limits.
- Dr. Jones seconded the motion.
- Motion carried.

**Endocrine & Metabolic Agents**

**Anti-rheumatic: Kinase Inhibitors**

- Tofacitinib is the first FDA-approved oral JAK inhibitor, which is indicated for the treatment of patients with moderately to severely active RA who have had an inadequate response or intolerance to methotrexate. In clinical trials involving adult patients with moderately to severely active rheumatoid arthritis, treatment with tofacitinib resulted in improved clinical response and physical functioning compared to treatment with placebo. Tofacitinib carries a boxed warning highlighting the risks of serious infections and malignancy. Additionally, the agent was approved with a Risk Evaluation and Mitigation Strategy program to inform healthcare providers and patients about the serious risks associated with treatment. The ACR guidelines recommend traditional DMARDs as first-line treatment in rheumatoid arthritis patients. In patients with inadequate response to DMARDs, adding or switching to another traditional or biologic DMARD is appropriate. Therefore, due to the fact that tofacitinib is not considered first line therapy, as well as the risk of significant adverse events, it is recommended that tofacitinib should be subject to prior authorization.

**Discussion:**
- Dr. Capparelli stated he was appalled by the cost of tofacitinib. Dr. Capparelli stated that the only justification to explain the cost is that the manufacturer was trying to align the price with the injectable biologic products, which must be produce under stricter conditions. However, having an oral product is great, but the price of this agent is outrageous. I agree with the recommendation and feel this product should be subject to criteria. Dr. Phares concurred with Dr. Capparelli regarding the high cost of the drug, but stated he was familiar with the technical aspects of drug development and specifically getting an antibody in a pill formulation is very difficult. Dr. Phares stated the cost of the drug may be priced at this level, so the pharmaceutical company could recoup the research and development cost of making the drug. Discussion continued.
- Dr. Capparelli motioned to accept the recommendation.
- Dr. Phares seconded the motion.
- Motion carried.

**Prior Authorization Criteria for XelJanz®**

XelJanz will be approved, if ALL of the following have been met:

- Diagnosis of rheumatoid arthritis
- Patient must have tried and failed or been intolerant to at least methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease) AND one preferred immunomodulator.
- Patient is not currently taking biologic agents (i.e. adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab and abatacept), OR potent immunosuppresants (i.e. azathioprine, or cyclosporine)
Discussion:
- Dr. Phares asked for clarification regarding if a patient is unable to take injections or afraid of needles will be allowed as part of the criteria.
  - Dr. Pittman stated these types of requests will have to go through the appeals process due to the subjective nature of the request.
- Dr. Capparelli motioned to accept the criteria.
- Lyn Govette seconded the motion.
- Motion carried.

<table>
<thead>
<tr>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>XelJanz®</td>
</tr>
</tbody>
</table>

Discussion:
- Dr. Jones asked if the 5mg should be specified in the quantity limit, as I read that a 10mg may become available.
  - Dr. Pittman stated that currently only the 5mg dose is approved. However, if the 10mg dose is approved it will like be given as a twice a day drug and the same quantity limit will apply.
- Dr. Capparelli motioned to accept the quantity limits.
- Lyn Govette seconded the motion.
- Motion carried.

The committee was dismissed for lunch break.

Attendance after lunch: all committee members returned with the exception of Dr. Frigon.

Criteria and/or Quantity limits for Review

**Prior Authorization Criteria & Quantity Limits for Eliquis®**

<table>
<thead>
<tr>
<th>Prior Authorization Criteria for Eliquis®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliquis will be approved for recipients meeting the following criteria:</td>
</tr>
<tr>
<td>- Diagnosis of non-valvular atrial fibrillation, AND</td>
</tr>
<tr>
<td>- Failure of warfarin therapy due to inability to maintain therapeutic INR, OR</td>
</tr>
<tr>
<td>- Recipient does not have access to adequate monitoring services for warfarin therapy, OR</td>
</tr>
<tr>
<td>- Non-bleeding related contraindication to warfarin therapy</td>
</tr>
</tbody>
</table>

Discussion:
- Dr. Jones asked if p values were given for the studies performed.
  - Dr. Pittman stated that this information was provided in the mailed packet.
- Dr. Phares expressed his concern that these guidelines are the same for the other 2 agents and feel they should all be treated equally. These 3 anticoagulant medications are cost effective globally as they eliminate the need for INR monitoring and reduce hospitalizations. Dr. Phares recognized that the INR monitoring component does not come out of the Pharmacy department budget, but felt it still plays a role in overall cost. However, with the new healthcare
reform, providers will be reimbursed based on value of care and overall global savings. Dr. Phares stated that going forward, the use of these medications will reduce overall cost. The overall numbers are small, but the cost associated with treated those patients who are hospitalized are astronomical and we should see a decline in cost in this area.

- Dr. Bush commented that this cost does come out of her pharmacy budget; with apixaban being first new generation of anticoagulants to show improvement in mortality and lower bleeding rates compared to warfarin. Dr. Bush felt this agent has a place as first-line therapy in the treatment of non-valvular atrial fibrillation (AF) equivalent to warfarin.
  - Dr. Phares stated that the superiority status was combined. When the data was teased out, this rating was mostly related to a decrease in cranial hemorrhage, which is why it was superior to warfarin. Pradaxa® also received the same superior status and you can also make the same argument with Pradaxa®.
  - Dr. Polson stated that the primary endpoint was non-inferiority. Therefore, you could say that it is no worse than warfarin but it is not any better than warfarin, but there is a cost component to using these medications. We are trying to move to a global view of evaluating the cost drug agents. Dr. Phares agreed that Pradaxa was shown superior, the other 2 agents’ primary trial endpoints were non-inferiority and the secondary trial endpoints showed the agents as superior. However, by overall trial design, only 1 agent was found to be superior.

- Dr. Capparelli stated that this is an interesting drug category. In addition, this is the only category of drugs that we have never reviewed the whole category. We have only reviewed the individual drugs.
  - Dr. Pittman stated that we just reviewed the entire category in November.

- Dr. Bush stated that one other thing to consider in regards to criteria; on the managed care side, including states other than Tennessee relates to the cost of discharges. We were seeing a limited number of cases where patients were being discharged on apixaban who did not have non-valvular a-fibrillation and clearly do not meet prior authorization criteria, but are receiving the drug on an emergency 5 day fill request.
  - Dr. Pittman stated that is clearly off-label and there are warnings against this practice. Discussion continued.

- Dr. Capparelli motioned to accept the criteria.
- Lyn Govette seconded the motion.
- Motion carried.

<table>
<thead>
<tr>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliquis®</td>
</tr>
</tbody>
</table>

Discussion:
- Dr. Phares motioned to accept the quantity limits.
- Dr. Jones seconded the motion.
- Motion carried.
**Prior Authorization Criteria for Oseni**

Will be approved for recipients who meet the following criteria:

- Diagnosis of type 2 diabetes AND
  - Hemoglobin A1c ≥6.5, AND
    - Trial and failure of metformin AND either a GLP-1, DPP-4, TZD, SU, or glinide agent (unless, recipient has an adverse reaction, intolerance or contraindication to metformin)

**Discussion:**

- Dr. Pittman stated this is being brought to committee to review, as this is the first DPP-4/TZD combination product and there is not a standard criteria basis for a combination of this type.
- Dr. Capparelli asked if this criteria was the same for our GLP-1 and DPP-4 sole agents. Dr. Pittman stated that it is slightly different, includes metformin, DPP-4 or a TZD agent that must be tried/failed first prior to approval. This combination is a little different as it includes 2 second-line agents.
- In most combination agent has been failure of drugs by themselves. It appears this is easier to get than Januvia. Dr. Pittman stated that it will be similar to Januvia but not exactly the same criteria. The difference is Januvia is trial/failure of one 1st line agent. This combination requires trial and failure of two 1st line agents. Discussion continued.
- Dr. Capparelli motioned to accept the criteria.
- Lyn Govette seconded the motion.
- Motion carried.

<table>
<thead>
<tr>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kazano</strong></td>
</tr>
<tr>
<td><strong>Nesina</strong></td>
</tr>
<tr>
<td><strong>Oseni</strong></td>
</tr>
</tbody>
</table>

**Discussion:**

- Dr. Capparelli asked if Kazano and Nesina had already been reviewed.
  - Dr. Pittman stated they had not as they fail in a category that had already been reviewed. Therefore they defaulted to a non-preferred status and received the already approved criteria for that category. Discussion continued.
- Dr. Capparelli motioned to accept the quantity limits.
- Lyn Govette seconded the motion.
- Motion carried.

**Prior Authorization Criteria for Fulyzaq**

Fulyzaq will be approved for recipients meeting ALL of the following criteria:

- Patient has non-infectious diarrhea AND
- Diagnosis of HIV or AIDS AND
- Currently receiving anti-retroviral therapy

**Discussion:**
• Dr. Jones inquired about the cost of the agent.
  o Dr. Pittman stated we do not have cost available as we have not had anybody in the pharmacy program to use the agent.
  o Lyn Govette asked if the medication will be added to the Auto-Exemption list. Dr. Pittman stated that this agent is not really classified as an anti-retroviral but it is approved for use in HIV/AIDS patients. Dr. Polson stated we could add to the Auto-Exemption list. Dr. Capparelli asked if the committee needed to vote on this agent being added. The consensus from the committee was that only agents added to an already existing category could be added without a vote. So a vote will be required as this will be in a different category. Dr. Capparelli made a comment that he would rather see simvastatin added to the list before Fulyzaq®. Dr. Polson stated that the Pharmacy Program sees a small percentage of these patients as most of these patients are seen by the Ryan White Foundation.
  o Dr. Capparelli stated he wanted to add some additional parameters to the criteria. Based on the clinical trial data which states non-infectious diarrhea greater than or equal to 1 month; review of the proposed criteria does not provide a time frame.
  o Dr. Capparelli made a motion to add that the patient has non-infectious diarrhea of 1 month or greater to the criteria.
• Dr. Capparelli made a motion to add that the patient has non-infectious diarrhea of 1 month or greater to the criteria.
• Dr. Jones seconded the motion
• Motion carried.
• Dr. Corley also stated that the request to add Fulyzaq® to the Auto-Exemption list will be brought back for review at the August meeting.

Prior Authorization Criteria for Abilify Maintena®
Atypical Antipsychotics will be approved for the following:

- 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 OCD or PTSD
- Tourette’s/Severe tic disorder
- For a diagnosis of major depressive disorder (MDD):
  - Atypicals will be approved only as adjunctive treatment for MDD. 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):
    - SSRIs
    - SNRIs
    - TCAs
    - New generation antidepressants (including bupropion, mirtazapine, etc.)
  - For patients without one of the above diagnoses: May be approved if the physician can provide documented clinical evidence supporting the use of the requested medication for the requested indication.

AND

- Abilify Maintena™ will only be authorized if the recipient has documented non-compliance with PO atypicals (which must include aripiprazole) OR non-response due to noncompliance.

Discussion:

- Lyn Govette asked for clarification on the use of Abilify Maintena™ being used as an adjunct agent for Major Depressive Disorder.
  - Dr. Pittman stated that the pharmacy program has never restricted the use of Atypical Agents based on their labeled indications. Dr. Capparelli asked for clarification on the last bullet point.
  - Dr. Capparelli asked if the injectable medications fall under the medical or pharmacy benefit. Dr. Pittman stated that currently these agents are on the pharmacy covered injectable list and could be received under both the pharmacy and medical benefit. Dr. Capparelli expressed concern for patients who may come into the program already well maintained on the agent and there is no pathway for grandfathering these patients so they may continue the drug. Dr. Pittman stated that typically these patients are handled through the appeals process. Dr. Capparelli stated that we
should consider this concern for the Atypical Antipsychotic agents, specifically the injectable agents. Discussion continued.

- Dr. Capparelli motioned to accept the prior authorization criteria.
- Lyn Govette seconded the motion.
- Motion carried.
- **Dr. Capparelli made a motion to add a quantity limit (QL) of 1/28 days for Abilify Maintena™.**
  - Dr. Jones seconded the motion.
  - Motion carried.

Prior Authorization Criteria for Preferred ARB CCBs

<table>
<thead>
<tr>
<th>Will be approved for patients with a diagnosis of hypertension requiring combination therapy with an ARB and a calcium channel blocker who meet ONE of the following criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Diagnosis of diabetic nephropathy, heart failure, left ventricular hypertrophy, or renal insufficiency. ARB/CCBs will be reserved for those patients who have a contraindication to an ACEI (history of ACEI-induced angioedema, hypersensitivity to an ACEI, pregnancy) or are unable to tolerate an ACEI due to cough.</td>
</tr>
<tr>
<td>- History of ACEI-induced angioedema, hypersensitivity to an ACEI, or inability to tolerate ACEI due to cough. ARB-CCBs will be approved, without contraindication or intolerance to an ACEI, for patients with diabetes.</td>
</tr>
</tbody>
</table>

Discussion:

- Dr. Pittman stated that changes were made to the ARB (Angiotensin II Receptor Blockers) at the last meeting, so the criteria for ARB-CCBs is being brought to the committee today to align the criteria with the changes made to the ARB criteria.
- Dr. Capparelli commented that the ARB class will start to have more utilization as they become generic. Dr. Capparelli asked as these agents become generic, will they also be added to the Auto-Exemption list.
  - Dr. Pittman stated she will have to check on the generic ARB-CCB agents. Dr. Capparelli clarified that it can be just the ARB agents. Dr. Pittman stated the generic ARB agents were already placed on the list.
- Dr. Phares motioned to accept the prior authorization criteria.
- Motion seconded and carried.

Prior Authorization Criteria for Non-preferred ARB-CCBs

<table>
<thead>
<tr>
<th>Will be approved for patients with a diagnosis of hypertension requiring combination therapy with an ARB and a calcium channel blocker who meet ONE of the following criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Diagnosis of diabetic nephropathy, heart failure, left ventricular hypertrophy, or renal insufficiency. ARB/CCBs will be reserved for those patients who have a contraindication to an ACEI (history of ACEI-induced angioedema, hypersensitivity to an ACEI, pregnancy) or are unable to tolerate an ACEI due to cough AND are unable to take the products individually.</td>
</tr>
<tr>
<td>- History of ACEI-induced angioedema, hypersensitivity to an ACEI, or inability to tolerate ACEI due to cough. ARB-CCBs will be approved, without contraindication or intolerance to an ACEI, for patients with diabetes AND are unable to take the products individually.</td>
</tr>
</tbody>
</table>

Discussion:

- Dr. Jones asked how prior authorizations will be handled if the patient is unable to take an ARB or a CCB individually.
Dr. Pittman stated they would have to not be able to take the components individually to receive non-preferred ARB-CCBs.

Dr. Capparelli asked for clarification on not taking the components individually. Dr. Pittman stated that this was added to make the criteria the same across the board. Additionally, Dr. Pittman stated that without this added requirement obtaining a non-preferred ARB-CCB would only require trial/failure of the preferred ARB-CCB combination which contains different combinations, so it would not make sense to just have just the standard criteria in place.

- Dr. Capparelli motioned to accept the prior authorization criteria.
- Lyn Govette seconded the motion.
- Motion carried.

### Prior Authorization Criteria for TOBI Podhaler®

<table>
<thead>
<tr>
<th>TOBI Podhaler® will be approved for patients meeting ALL of the following criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diagnosis of cystic fibrosis, AND</td>
</tr>
<tr>
<td>• A clinically valid reason not to use TOBI® nebulizer solution</td>
</tr>
</tbody>
</table>

**Discussion:**

- Lyn Govette asked for clarification on what will be considered a clinically valid reason.
  
  - Dr. Pittman stated a patient may be allergic to an agent contained in the nebulizer solution or can’t use a nebulizer may serve as clinically valid reasons to request the Podhaler®.

- Dr. Jones motioned to accept the prior authorization criteria.
- Motion seconded and carried.

### Quantity Limits

| TOBI Podhaler® | 8/day |

**Discussion:**

- Dr. Capparelli asked for clarification on the last bullet point.
  
  - Dr. Pittman stated that the last bullet point listed in italics is new to the current criteria in place today.

- Lyn Govette motioned to accept the quantity limits.
- Dr. Capparelli seconded the motion.
- Motion carried.

### REVIEW OF FEBRUARY PAC MEETING DECISIONS

SXC reviewed TennCare’s decisions from the February 12, 2013 meeting. In the interest of time, decisions were presented only for those classes in which TennCare did not accept the Committee’s recommendations.

- Page 20 Ophthalmic Immunomodulators: This is also addressed on the handout title Change Summary of PAC Documents. PAC approved the prior authorization criteria as presented by Catamaran. Additionally, the committee asked TennCare to investigate if a quantity limit was needed for Restasis®. TennCare accepted PAC’s recommendation for both the prior authorization criteria as well as to implement a quantity limit of 2 mLs per day. However, in the grayed out packet this was listed as 2 ml per day, this should read 2 vials/day and the grayed
out packet has been updated to reflect this change. Additionally, this agent is actually coded as 2 vials/day in the system.

- Public testimony speakers were allowed 5 minutes to address the committee on their respective drug(s).
- Bristol-Myers Squibb representative asked the committee if there were any questions regarding their products and relinquished remaining time available.

Public Testimony Speakers

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Organization</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim Laubmeier</td>
<td>Otsuka America Pharmaceutical, Inc</td>
<td>Abilify Maintena®</td>
</tr>
<tr>
<td>Olga Pratt</td>
<td>Bristol-Myers Squibb</td>
<td>Eliquis®</td>
</tr>
<tr>
<td>Patricia Grossman</td>
<td>Boehringer Ingelheim</td>
<td>Spiriva® Combivent® Respimat®</td>
</tr>
<tr>
<td>Christy Cappelletti</td>
<td>AstraZeneca</td>
<td>Symbicort® Pulmicort Flexhaler®</td>
</tr>
</tbody>
</table>

Next Meeting will be August 13, 2013 at the Nashville Public Library
Meeting Adjourned