Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

November 4, 2015

Members Present: Dr. Frances Cohenour (Chair), Dr. David Harwood, Dr. Pilar Murphy, Dr. Kelli Littlejohn Newman, Dr. Melinda Rowe, and Dr. Robert Smith

Members Absent: Ms. Janet Allen, Dr. Lee Carter (Vice-chair), Dr. Elizabeth Jacobson

Patient Care Networks of Alabama (PCNA) Staff Present: Lisa Channell, Angela Lowe, Lacy Miller, Lydia Rather, Holley Rice, Machelle Stiles, Kristian Testerman, Lauren Ward

Presenters: Dr. Rachel Bacon and Ms. Amy Levy

Presenters Present via teleconference: None

1. OPENING REMARKS

Chairperson Cohenour called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:06 a.m.

2. APPROVAL OF MINUTES

Chairperson Cohenour asked if there were any corrections to the minutes from the August 19, 2015 P&T Committee Meeting.

There were no objections. Dr. Harwood made a motion to approve the minutes as presented and Dr. Smith seconded to approve the minutes. The minutes were unanimously approved.

3. PHARMACY PROGRAM UPDATE

Dr. Littlejohn Newman stated that there are several Agency-wide updates that are available in your packet, including the implementation of ICD-10 on October 1, 2015, ICD-10 upcoming Virtual Town Hall Meetings, claims for drug testing in physician offices, and PDL quarterly updates. She also reminded the committee that Agency review of RCO solvency and provider networks is underway. Also, the Agency is working to complete the most recent Cost of Dispensing Survey for submission of a State Plan Amendment (SPA) to CMS.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations was explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were a total of two manufacturer verbal presentations at the meeting.

5. PHARMACOTHERAPY CLASS RE-REVIEWS (Please refer to the website for full text reviews.)

The pharmacotherapy class reviews began at approximately 9:18 a.m. There were a total of 11 drug class re-reviews. The inhaled antimuscarinics, respiratory β-adrenergic agonists, leukotriene modifiers, inhaled mast-cell stabilizers, respiratory agents-corticosteroids, respiratory smooth muscle relaxants, intranasal corticosteroids, eye, ear, nose and throat preparations-antiallergic agents, eye, ear, nose and throat preparations-antibacterials, eye, ear, nose and throat preparations-vasoconstrictors, and androgens were last reviewed in August 2013. There were two new drug reviews: Afrezza® and Jardiance®.

Inhaled Antimuscarinics: American Hospital Formulary Service (AHFS) 120808
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that the inhaled antimuscarinics included in this review are listed in Table 1 on page 10. Since the last review umeclidinium was approved by the FDA. The inhaled antimuscarinics are approved for the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Tiotropium is also approved to reduce exacerbations in patients with COPD. Tiotropium has a longer duration of action than ipratropium and can be dosed once daily. Aclidinium was FDA-approved in July 2012. Similar to tiotropium, aclidinium is a long-acting inhaled antimuscarinic but requires twice daily dosing. In April 2014 umeclidinium was approved: It is also a long-acting agent approved for once-daily use. The Respimat formulation of Spiriva has also been approved since the last review. Ipratropium inhalation solution is the only product that is available in a generic formulation.

Although there have been updates to the existing treatment guidelines in Table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

Therefore, all brand short-acting inhaled antimuscarinics within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Aclidinium, tiotropium, and umeclidinium offer significant clinical advantages in general use over short-acting inhaled antimuscarinics.

No brand short-acting inhaled antimuscarinic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

At least one long-acting inhaled antimuscarinic is recommended for preferred status. Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand long-acting antimuscarinic is selected as a preferred agent.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Respiratory Beta-Adrenergic Agonists: AHFS 121208
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that the respiratory β_2-agonists included in this review are listed in Table 1 on page 70. Since the last review, olodaterol solution inhaler, fixed dose umeclidinium-vilanterol dry powder inhaler, and albuterol dry powder inhaler were approved by the FDA. Olodaterol (Striverdi Respimat®) and umeclidinium-vilanterol (Anoro Ellipta®) are approved for maintenance treatment of airflow obstruction in patients with COPD. Like previous albuterol formulations, the dry powder inhaler (ProAir Respiclick®) is indicated for treatment or prevention of bronchospasm in patients with reversible airway disease and prevention of exercise-induced bronchospasm. Albuterol (immediate-release tablets, inhalation solution, sustained-release tablets, and syrup), ipratropium-albuterol (inhalation solution), levalbuterol (inhalation solution), metaproterenol (syrup and tablets), and terbutaline (tablets) are available in a generic formulation.

Although there have been updates to the existing treatment guidelines in Table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

For the treatment of asthma, several comparative studies have demonstrated similar improvements in respiratory endpoints with the use of short-acting β2-agonists; however, a few studies have demonstrated greater efficacy with one agent over another. The long-acting β2-agonists have been shown to be more effective than the routine use of short-acting β2-agonists for the maintenance treatment of asthma. Long-acting β2-agonists should not be used as monotherapy since they do not affect airway inflammation. Guidelines do not give preference to one short- or long-acting β_2-agonist over another for the treatment of asthma.

For the treatment of COPD, regular treatment with long-acting bronchodilators is more effective than treatment with short-acting bronchodilators. Studies directly comparing the long-acting β2-agonists have demonstrated similar improvements in some, but not all, respiratory endpoints. Some studies suggest that formoterol may have a faster onset of action than salmeterol. Tiotropium may provide a greater clinical benefit than long-acting β2-agonists with regards to spirometric endpoints, dyspnea, exacerbations, quality of life, and health care resource utilization. Data are not available to determine whether the rate of death in patients with COPD is increased by long-acting β2-agonists.

Therefore, all brand short-acting respiratory beta-adrenergic agonists within the class reviewed are comparable to each other and to the generic products (if available) and offer no significant clinical advantage over other alternatives in general use. The brand long-acting respiratory beta-adrenergic agonists offer significant clinical advantages over the short-acting respiratory beta-adrenergic agonists and are comparable to each other and to the generic products (if available). However, for patients with asthma, the long-acting respiratory beta-adrenergic agonists are not recommended as first-line therapy. For patients with

COPD, the long-acting respiratory beta-adrenergic agonists do not offer significant clinical advantages over other long-acting inhaled bronchodilators (e.g., inhaled antimuscarinics). Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

No brand respiratory beta-adrenergic agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Leukotriene Modifiers: AHFS 481024
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that the leukotriene modifiers included in this review are listed in Table 1 on page 181. Montelukast and zafirlukast are classified as leukotriene receptor antagonists, whereas zileuton is classified as a 5-lipoxygenase inhibitor. Montelukast and zafirlukast are available in generic formulations.

Although there have been updates to the existing treatment guidelines in Table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There is insufficient evidence to support that one brand leukotriene modifier is more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand leukotriene modifiers within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand leukotriene modifier is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Inhaled Mast-Cell Stabilizers: AHFS 481032
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that turning to page 236, cromolyn sodium inhalation solution is the only inhaled mast-cell stabilizer that is currently available in this class. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

Therefore, all brand inhaled mast-cell stabilizers within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.
No brand inhaled mast-cell stabilizer is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Respiratory Agents-Corticosteroids: AHFS 481008
Manufacturer comments on behalf of these products:
None

Ms. Levy commented that the respiratory agents-corticosteroids that are included in this review are listed in Table 1 on page 255. Budesonide inhalation solution is the only product that is currently available in a generic formulation. This class was last reviewed in August 2013. Flunisolide was last reviewed in February 2015 as a new drug. Fluticasone furoate (Arnuity Ellipta®) was approved in 2014 for the maintenance treatment of asthma. Fluticasone furoate and fluticasone propionate are distinct drugs with differing pharmacokinetic and pharmacodynamic properties. Fluticasone furoate has enhanced affinity for the target receptors in both nasal and lung tissues and therefore is approved for use at a lower daily dose as compared with fluticasone propionate. A combination inhaler of fluticasone furoate and vilanterol (Breo Ellipta®) has also been FDA-approved since the last review. It is an additional treatment option for patients requiring inhaled corticosteroid and long-acting β-2 agonist (LABA) combination therapy and is available as a dry powder inhaler.

Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

Given the role of the single entity inhaled corticosteroids in the management of asthma, one or more brand products within the class reviewed offers significant clinical advantage in general use over the generic products (if applicable), but is comparable to all other brands in the same class. All brand fixed-dose combination inhaled corticosteroids within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. The fixed-dose combination inhaled corticosteroids should be available through the medical justification portion of the prior authorization process for patients who require the combination of an inhaled corticosteroid and LABA to control their respiratory symptoms.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one single entity brand respiratory agents-corticosteroids is selected as a preferred agent.

No brand fixed-dose combination respiratory agents-corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Respiratory Smooth Muscle Relaxants: AHFS 861600
Manufacturer comments on behalf of these products:
None

Ms. Levy commented that the respiratory smooth muscle relaxants that are included in this review are listed in Table 1 on page 444. They are approved for the treatment of asthma, chronic bronchitis, and emphysema. All of the products are available in a generic formulation, with the exception of dyphylline. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand respiratory smooth muscle relaxant is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand respiratory smooth muscle relaxants within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand respiratory smooth muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Intranasal Corticosteroids: AHFS 520808
Manufacturer comments on behalf of these products:
None

Ms. Levy commented that the intranasal corticosteroids that are included in this review are listed in Table 1 on page 494. Budesonide, flunisolide, fluticasone propionate, and triamcinolone are available in a generic formulation. This class was last reviewed in August 2013.

Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

Comparative clinical trials have demonstrated similar efficacy with the intranasal steroids for the majority of the endpoints assessed in patients with allergic rhinitis. The differences in potencies, systemic bioavailabilities, and onset of action did not translate to improved efficacy. However, there were subtle differences reported among the various agents in tolerability and patient preference. Guidelines do not give preference to one intranasal corticosteroid over another for the treatment of allergic rhinitis.

There is insufficient evidence to support that one brand intranasal corticosteroid is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand intranasal corticosteroids within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand intranasal corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Eye, Ear, Nose, and Throat Preparations: Antiallergic Agents: AHFS 520200
Manufacturer comments on behalf of these products:
None

Ms. Levy commented that The EENT antiallergic agents that are included in this review are listed in Table 1 on page 561. Azelastine, cromolyn, epinastine, and olopatadine are available in a generic formulation. This class was last reviewed in August 2013.

Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There are relatively few comparative studies that have been conducted with the EENT antiallergic agents in a 'real-life' setting. While some of these trials have demonstrated similar outcomes with regards to ocular symptoms, nasal symptoms, and patient preference, other studies have demonstrated greater efficacy with one agent over another. Many comparative studies have been performed using environmental challenge chambers. However, the antiallergic agents are typically administered as a single dose and the clinical outcomes are assessed after several minutes or hours.

There is insufficient evidence to support that one brand EENT antiallergic agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand EENT antiallergic agents within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand eye, ear, nose, and throat (EENT) antiallergic agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Eye, Ear, Nose, and Throat Preparations: Antibacterials: AHFS 520404
Manufacturer comments on behalf of these products:
None

Ms. Levy commented that the EENT antibacterials that are included in this review are listed in Table 1 on page 612. The topical antibacterials (AHFS 840404) and systemic antibacterials (AHFS 081200) were previously reviewed and are not included in this review. Many of the products are available in a generic formulation. This class was last reviewed in August 2013. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand EENT antibacterial is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand EENT antibacterials within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand eye, ear, nose, and throat (EENT) antibacterial is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Eye, Ear, Nose, and Throat Preparations: Vasoconstrictors: AHFS 523200
Manufacturer comments on behalf of these products:
None

Ms. Levy commented that the EENT vasoconstrictors that are included in this review are listed in Table 1 on page 710. Naphazoline and phenylephrine are available in a generic formulation. This class was last reviewed in August 2013.

Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

The scientific evidence regarding the efficacy of the EENT vasoconstrictors is extremely limited. There were no studies found in the medical literature that directly compared the safety and efficacy of the ophthalmic or nasal EENT vasoconstrictors.

There is insufficient evidence to support that one brand EENT vasoconstrictor is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand EENT vasoconstrictors within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand eye, ear, nose, and throat (EENT) vasoconstrictor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Androgens, AHFS 680800
Manufacturer comments on behalf of these products:
AndroGel® - AbbVie

Ms. Levy stated that the androgens included in this review are listed in Table 1 on page 726. Danazol, fluoxymesterone, methyltestosterone, oxandrolone, testosterone cypionate, and testosterone enanthate are available in a generic formulation. This class was last reviewed in August 2013.

Testosterone undecanoate (Aveed®) was FDA approved in March 2014 and is a longer-acting injectable formulation of testosterone. Maintenance treatment occurs every 10 weeks; however, patients need to be observed for at least 30 minutes after injection due to the risk of serious pulmonary oil microembolism reactions and anaphylaxis. Aveed® includes a boxed warning regarding this risk and is only available through a Risk Evaluation and Mitigation Strategy (REMS) program.

Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There is insufficient evidence to support that one brand androgen is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

No brand androgen is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Therefore, all brand androgens within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

There were no further discussions on the agents in this class. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

6. NEW DRUG REVIEWS (Please refer to the website for full text reviews.)

Afrezza®

Manufacturer comments on behalf of these products:

(Afrezza® - Sanofi was scheduled to present but could not attend the meeting. The one-page verbal presentation is available to the P&T members in their clinical packets.)

Dr. Bacon commented that inhaled human insulin (Afrezza®) is a new delivery format for insulin therapy used for the treatment of diabetes mellitus. Human insulin is derived from a biosynthetic process and is structurally identical to endogenous insulin. Regular insulin as used in Afrezza® is rapid-acting. The inhaled human insulin as used in Afrezza® is a dry powdered formulation known as Technosphere® insulin. It is administered in disposable, single-use cartridges, which allows for a more efficient inhalation device than what has been used in the past. Another inhaled formulation of regular insulin, Exubera®, was previously FDA-approved; however, this agent was removed from the market in 2007 due to low patient and provider acceptance.

Afrezza® is available in 4, 8, and 12 unit doses per cartridge. The dose must be individualized based on response or conversion from other formulations and should be administered at the beginning of the meal. For doses greater than 8 units, multiple cartridges will be needed. Afrezza® is intended for use in combination with long-acting insulin when used in patients with type 1 diabetes mellitus. In general, Afrezza® has an earlier peak and shorter duration of action when compared with other rapid-acting insulin products.

Significant drug interactions with the insulins are listed in Table 5 on page 789. Afrezza® has an additional drug interaction with bronchodilators and inhaled steroids when compared with other insulin products. Albuterol increased the area under the curve of insulin by 25% in patients with asthma. Effect of fluticasone on insulin exposures following Afrezza® administration has not been evaluated in patients with asthma; however, no significant change in insulin exposure was observed in a study in healthy volunteers. Frequent glucose monitoring and dose reduction may be necessary for Afrezza® if it is co-administered with albuterol.

Unlike the injectable products, inhaled human insulin has several respiratory adverse events which include cough (27%), throat pain/irritation (5%) and bronchitis (2.5%). Additionally, patients treated with inhaled regular insulin had a greater decrease in forced expiratory volume in one second (FEV_1) by 40 mL (95% CI, -80 to -1) compared to patients treated with other antidiabetic treatments in a clinical trial. The decline occurred during the first three months of therapy and persisted over two years. Afrezza® carries a boxed warning for the risk of acute bronchospasm in patients with chronic lung disease: Acute bronchospasm has been observed in patients with asthma and COPD using Afrezza®, and its use is contraindicated in patients with chronic lung disease such as asthma or COPD. Before initiating Afrezza®, a detailed medical history, physical examination, and spirometry (FEV_1) should be performed to identify potential lung disease in all patients. The use of Afrezza® is not recommended in patients who smoke or who have recently stopped smoking. Due to these adverse events and warnings, a Risk Evaluation and Mitigation Strategy is required by the FDA for the use of Afrezza®.

Diabetes mellitus guidelines state that insulin regimens should be tailored to the specific clinical circumstances in individual patients; however, the specific role of inhaled human insulin (Afrezza®) is not presently addressed in the guidelines.

At this time, there is insufficient data to conclude that inhaled human insulin (Afrezza®) is safer or more efficacious than other brand or generic products within this class, and that it offers a significant clinical advantage over other alternatives in general use.

No brand inhaled human insulin product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on this agent. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Jardiance®
Manufacturer comments on behalf of these products:
Jardiance® - Boehringer Ingelheim

Dr. Bacon commented that sodium-glucose cotransport 2 (SGLT2) inhibitors are a novel class of oral antidiabetic agents recently approved by the Food and Drug Association (FDA). The SGLT2 inhibitors were initially reviewed by Alabama Medicaid in February 2015. SGLT2 inhibitors improve glycemic control by producing glucosuria. This is accomplished by inhibiting SGLT2 and increasing urinary glucose excretion. The net effect is an increase excretion of glucose from the body and normalizing plasma glucose levels. SGLT2 inhibitors also have beneficial nonglycemic effects, including weight loss and small decreases in systolic and diastolic blood pressure as observed during clinical trials. Empagliflozin (Jardiance®) is a once daily tablet indicated an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

There are no significant drug interactions reported with empagliflozin. Coadministration of empagliflozin with diuretics may result in increased urine volume and frequency of voids, which can increase the risk of volume depletion. The primary side effects are increased urinary tract and genitourinary infections. An unexplained adverse effect is increased LDL cholesterol. Jardiance® should not be initiated in patients with an eGFR <45 mL/min/1.73 m^2.

According to current clinical guidelines for the management of type 2 diabetes, metformin remains the cornerstone to most antidiabetic treatment regimens. Additionally, patients with a high glycosylated hemoglobin (HbA1c) will most likely require combination or triple therapy in order to achieve glycemic goals. At this time, uniform recommendations on the best agent to be combined with metformin cannot be made; therefore, advantages and disadvantages of specific antidiabetic agents for each patient should be considered. The role of SGLT2 inhibitors as a class are addressed in treatment guidelines and are recommended as a potential first, second, or third-line treatment option to be added as an alternative to or in combination with metformin in patients not achieving glycemic goals. SGLT2 inhibitors are acceptable therapeutic alternatives that reduce glucose without weight gain or hypoglycemia.

Empagliflozin is available as an oral once-daily tablet and has demonstrated to be significantly more effective compared to placebo in reducing HbA1c. Limited trials have compared empagliflozin to other classes of oral antidiabetic agents: Studies thus far have demonstrated noninferiority to glimepiride.

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with empagliflozin or any other antidiabetic drug.

There is insufficient evidence to support that one brand empagliflozin product is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand empagliflozin product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on this agent. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

7. RESULTS OF VOTING ANNOUNCED

The results of voting for each of the therapeutic classes were announced; all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

8. NEW BUISNESS

The dates for the 2016 Alabama Medicaid P&T Meetings were provided and are as follows: February 10, 2016, May 11, 2016, August 10, 2016, and November 9, 2016.

9. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for February 10, 2016 at the Medicaid Building in the Commissioner's Board Room.

10. ADJOURN

There being no further business, Dr. Harwood moved to adjourn and Dr. Smith seconded. The meeting adjourned at 9:56 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
November 4, 2015

A. Recommendation: No brand short-acting inhaled antimuscarinic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

At least one long-acting inhaled antimuscarinic is recommended for preferred status. Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand long-acting antimuscarinic is selected as a preferred agent.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda L. Rouse MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

B. Recommendation: No brand respiratory beta-adrenergic agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda L. Rouse MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

C. **Recommendation:** No brand leukotriene modifier is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

D. **Recommendation:** No brand inhaled mast-cell stabilizer is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

E. **Recommendation:** Alabama Medicaid should work with manufacturers on cost proposals so that at least one single entity brand respiratory agents-corticosteroids is selected as a preferred agent.

No brand fixed-dose combination respiratory agents-corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda D. Rowe MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

F. **Recommendation:** No brand respiratory smooth muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda D. Rowe, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

G. **Recommendation:** No brand intranasal corticosteroid is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda G. Rowland ☒ Approve □ Approve as amended □ Disapprove □ No action
Assistant Medical Director

Kathy Hall ☒ Approve □ Approve as amended □ Disapprove □ No action
Deputy Commissioner

Stephanie ☒ Approve □ Approve as amended □ Disapprove □ No action
Commissioner

H. **Recommendation:** No brand eye, ear, nose, and throat (EENT) antiallergic agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda G. Rowland ☒ Approve □ Approve as amended □ Disapprove □ No action
Assistant Medical Director

Kathy Hall ☒ Approve □ Approve as amended □ Disapprove □ No action
Deputy Commissioner

Stephanie ☒ Approve □ Approve as amended □ Disapprove □ No action
Commissioner

I. **Recommendation:** No brand eye, ear, nose, and throat (EENT) antibacterial is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melissa D. Rowan, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

J. **Recommendation:** No brand eye, ear, nose, and throat (EENT) vasoconstrictor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melissa D. Rowan, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

K. **Recommendation:** No brand androgen is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rougeau ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kelley Neel ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

Stephanie Azar ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

L. **Recommendation:** No brand inhaled human insulin product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rougeau ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kelley Neel ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

Stephanie Azar ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

M. Recommendation: No brand empagliflozin product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe, MD ☒ Approve □ Approve as amended □ Disapprove □ No action
Assistant Medical Director

Kathy Neel □ Approve □ Approve as amended □ Disapprove □ No action
Deputy Commissioner

Stephanie ☒ Approve □ Approve as amended □ Disapprove □ No action
Commissioner

Respectfully submitted,

Rachel Bacon

November 11, 2015

Rachel Bacon, PharmD — Date

Amy Levy

November 11, 2015

Amy Levy, RPh, MHP — Date