

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

February 21, 2018

Members Present: Dr. Lee Carter (Vice-Chairperson), Dr. Elizabeth Dawson, Dr. Kimberly Graham, Dr. Frances Heinze (Chairperson), Dr. Amber Hutchison, Dr. Kelli Littlejohn Newman, Dr. Melinda Rowe, Dr. Robert Smith

Members Absent: Dr. Ramakanth Vemuluri

Health Home/Probationary RCO Pharmacists Present via Teleconference: Amy Donaldson, Joshua Lee, Lacy Miller, Lydia Rather, and Lauren Ward

Presenters: Dr. Rachel Bacon

Presenters Present via teleconference: None

1. OPENING REMARKS

Chairperson Heinze called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:04 a.m.

2. APPROVAL OF MINUTES

Chairperson Heinze asked if there were any corrections to the minutes from the November 8, 2017 P&T Committee Meeting.

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

3. PHARMACY PROGRAM UPDATE

Dr. Littlejohn Newman stated that the legislative session is currently ongoing and the Medicaid budget has been presented. The DUR Board has been working to address the opioid crisis.

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 2 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 9:15 a.m. There were a total of 7 drug class re-reviews. The inhaled antimuscarinics, respiratory β -adrenergic agonists, leukotriene modifiers, inhaled mast-cell stabilizers, respiratory agents-corticosteroids, respiratory smooth muscle relaxants, and intranasal corticosteroids were last reviewed in November 2015.

Inhaled Antimuscarinics: American Hospital Formulary Service (AHFS) 120808

Manufacturer comments on behalf of these products:

Seebri Neohaler[®] – Sunovion

Dr. Bacon commented that the inhaled antimuscarinics included in this review are listed in Table 1 on page 7. 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. In September 2015, Spiriva Respimat[®] was FDA-approved for the long-term, once-daily, prescription maintenance treatment of asthma in people age 12 years and older. In February 2017, the indication was expanded to include children six years and older. Tiotropium has a longer duration of action than ipratropium, which distinguishes tiotropium and ipratropium as long- and short-acting antimuscarinics, respectively. Aclidinium and umeclidinium are both newer long-acting inhaled antimuscarinics, similar to tiotropium. Ipratropium inhalation solution is the only product that is available in a generic formulation. In October 2015, Seebri Neohaler[®] (glycopyrrolate) became the most recently approved long-acting inhaled antimuscarinic, and it is dosed twice-daily.

Since gaining the indication for the treatment of asthma in 2015, tiotropium been added to the Global Initiative for Asthma and British Thoracic Society/Scottish Intercollegiate Guidelines Network guidelines as step four or five add-on therapy for patients with a history of exacerbations. In three clinical trials, Spiriva Respimat[®] was found to have a greater improvement in the primary endpoint of peak FEV₁ response compared to placebo.

Approval of the Seebri Neohaler[®] (glycopyrrolate) was based on results from the GEM trials. The primary efficacy endpoint from the two placebo-controlled trials, GEM1 and GEM2, was the change from baseline in FEV₁ AUC_{0 to 12 h} at week 12 compared with placebo. In both trials, the glycopyrrolate group demonstrated a larger increase in mean change from baseline in FEV₁ AUC_{0 to 12 h} compared to placebo (P<0.001). In addition, several secondary endpoints were evaluated that showed improvements in COPD symptoms based on the St. George's Respiratory Questionnaire as well as quality of life and medication use in patients with moderate to severe airflow limitation.

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, glycopyrrolate, 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 Heinze asked the P&T Committee members to mark their ballots.

Respiratory Beta-Adrenergic Agonists: AHFS 121208

Manufacturer comments on behalf of these products:

Utibron Neohaler[®] – Sunovion

Dr. Bacon commented that the respiratory β_2 -agonists included in this review are listed in Table 1 on page 84. The respiratory beta-adrenergic agonists (β_2 -agonists) are approved for the treatment of asthma, chronic obstructive pulmonary disease (COPD), and exercise-induced bronchospasm. They stimulate β_2 -receptors and relax airway smooth muscle, which leads to bronchodilation. Since the last review, new combination products indicated for the treatment of patients with COPD became available, including glycopyrrolate-formoterol (Bevespi[®]), indacaterol-glycopyrrolate (Utibron Neohaler[®]), and tiotropium-olodaterol (Stiolto Respimat[®]). Glycopyrrolate and tiotropium are both anticholinergic agents. Each of these three combination products were evaluated in comparison to their individual components and placebo and demonstrated improved FEV₁ outcomes with the combination product after 12 or 24 weeks.

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. All of the long-acting beta-2 adrenergic agonists carry a boxed warning for an increased risk of asthma-related death. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from long-acting beta-2 adrenergic 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 Heinze 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 205. Montelukast and zafirlukast are classified as leukotriene receptor antagonists, whereas zileuton is classified as a 5-lipoxygenase inhibitor. All agents 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.

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 Heinze 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 262, cromolyn sodium inhalation solution is the only inhaled mast-cell stabilizer that is currently available in this class, and it is available in a generic formulation. 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 Heinze asked the P&T Committee members to mark their ballots.

Respiratory Agents-Corticosteroids: AHFS 481008

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the respiratory corticosteroids included in this review are listed in Table 1 on page 282. Budesonide inhalation solution and one formulation of the fluticasone propionate-salmeterol dry powder inhaler are the only products that are currently available in a generic formulation. The combination product fluticasone propionate and salmeterol (Airduo Respiclick[®]) and its authorized generic were both approved in 2017 for the treatment of asthma in patients ≥ 12 years of age. Airduo Respiclick[®] contains the same active ingredients as Advair Diskus[®] and Advair HFA[®], however the products differ in dosage strength, formulation, and approved indication.^{12,13,18} Advair Diskus[®] is approved for the treatment of asthma in patients four years of age and older, while Advair HFA[®] and Airduo Respiclick[®] are approved in patients 12 years and older. A new formulation of fluticasone, ArmonAir RespiClick[®], has also been approved since the last review. It is a multi-dose dry powder inhaler indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years and older.

Although included in the clinical packet, the FDA recently removed the boxed warning on drug labels for combination inhaled corticosteroid/long-acting beta agonist medications. This is based on data from four large clinical safety trials which found “no increase in serious asthma-related side effects with ICS/LABA vs ICS alone.” 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.

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.

Dr. Dawson asked about the removal of QVAR from the market and alternative agents that are available to be used with a spacer for pediatric patients. This issue will be addressed with the April update of the PDL.

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

Respiratory Smooth Muscle Relaxants: AHFS 861600

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the respiratory smooth muscle relaxants included in this review are listed in Table 1 on page 482. They are approved for the treatment of asthma, chronic bronchitis, and emphysema. All of the products are available in a generic formulation. 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.

The P&T members had a brief discussion on the low utilization of agents in this class.

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

Intranasal Corticosteroids: AHFS 520808

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the intranasal corticosteroids included in this review are listed in Table 1 on page 531. Budesonide, flunisolide, fluticasone propionate, and mometasone are available in a generic formulation. 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 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 Heinze asked the P&T Committee members to mark their ballots.

Upon conclusion of the class presentations, the Health Home pharmacists thanked the group for addressing the QVAR discontinuation issue. Pharmacists on the committee reiterated to the physicians that they are welcome to use their local dispensing pharmacists for new inhaler instructions and demonstrations. The Health Home pharmacist Amy Donaldson also said that they are able to send someone to patient homes for medication instruction if it is requested. Dr. Dawson asked where this information is available, and Dr. Newman replied that she will ensure there is a listing on the Medicaid website.

6. 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.

7. NEW BUSINESS

There was no new business.

8. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for May 9, 2018 at the Medicaid Building in the Commissioner's Board Room.

9. ADJOURN

There being no further business, Dr. Carter moved to adjourn and Dr. Smith seconded. The meeting adjourned at 9:58 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
February 21, 2018

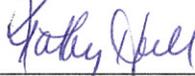
- A. **Recommendation:** No brand short-acting inhaled antimuscarinic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

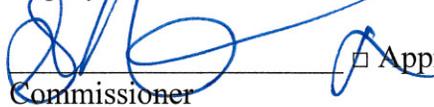
At least one long-acting inhaled antimuscarinic is recommended for preferred status. Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand long-acting antimuscarinic is selected as a preferred agent.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 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

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 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

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

[Signature] 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

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

[Signature] 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

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Gathey Dell Approve Approve as amended Disapprove No action
Deputy Commissioner

[Signature] 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

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Gathey Dell Approve Approve as amended Disapprove No action
Deputy Commissioner

[Signature] 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

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Robby Bell Approve Approve as amended Disapprove No action
Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action
Commissioner

Respectfully submitted,

Rachel Bacon

Rachel Bacon, PharmD

March 2, 2018

Date