

## **Minutes of Meeting**

### **Alabama Medicaid Agency Pharmacy and Therapeutics Committee**

**November 12, 2014**

**Members Present:** Dr. Lee Carter, Dr. Frances Cohenour (Vice-chair), Dr. David Harwood (Chair), Dr. Kelli Littlejohn Newman, Dr. Pilar Murphy, Dr. Melinda Rowe, and Dr. Robert Smith

**Members Absent:** Ms. Janet Allen, Dr. Julia Boothe, and Dr. Elizabeth Jacobson

**Patient Care Networks of Alabama (PCNA) Staff Present:** Dr. Tammy Dubuc, Dr. Kristian Testerman

**Presenters:** Dr. Rachel Bastien and Ms. Amy Levy

**Presenters Present via teleconference:** Dr. Pavel Lavitas

#### **1. OPENING REMARKS**

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

#### **2. APPROVAL OF MINUTES**

Chairperson Harwood asked if there were any corrections to the August 13, 2014 P&T Committee Meeting's minutes.

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

#### **3. PHARMACY PROGRAM UPDATE**

Dr. Littlejohn Newman noted that a PDL update occurred on Oct 1. The PDL and ALERTS were sent to members and posted on the website.

Dr. Littlejohn Newman noted that effective October 1<sup>st</sup>, the Alabama Medicaid Agency reversed the payment reductions to certain providers implemented during 2013. Also in October, the Agency announced twelve applications submitted for RCO probationary certification. A list of applicants is posted on the Agency website. Dr. Littlejohn Newman noted that the Agency and HP will host another upcoming "ICD-10 General Overview" teleconference on January 22, 2015, at

10:00 a.m. The teleconference will provide an overview of changes being implemented by Alabama Medicaid for ICD-10. The sessions will include a segment where the HP ICD-10 team will be available to answer questions. Registration for both sessions is now open and available on the Alabama Medicaid website.

#### **4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES**

There were no 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 9:11 a.m. There were a total of 18 drug class re-reviews. The Allylamines, Azoles, Echinocandins, Polyenes, Pyrimidines, Miscellaneous Antifungals, Antituberculosis Agents, Miscellaneous Antimycobacterials, Adamantanes, Interferons, Neuraminidase Inhibitors, Nucleosides and Nucleotides, HCV Antivirals, Miscellaneous Antivirals, Amebicides, Antimalarials, Miscellaneous Antiprotozoals, and Urinary Anti-infectives were all last reviewed in May 2012.

Before beginning the re-reviews, Dr. Bastien asked all those present if there were conflicts with presenting the classes out of AHFS order so the drugs treating particular disease states would be presented sequentially. Dr. Littlejohn Newman asked if this would interrupt travel plans or inconvenience those present; hearing no objection, the order was adjusted.

##### **Allylamines: American Hospital Formulary Service (AHFS) 081404**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the allylamines that are included in this review are listed in Table 1. The topical antifungals were previously reviewed with the skin and mucous membrane agents (AHFS 840408) and are not included in this review. Terbinafine (tablet formulation) is available in a generic formulation. This class was last reviewed in May 2012. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

Therefore, all brand allylamines 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 allylamine 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Azoles: AHFS 081408**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the azoles that are included in this review are listed in Table 1. This review encompasses all systemic dosage forms and strengths. The topical antifungals were previously reviewed with the skin and mucous membrane agents and are not included in this review. All of the products are available in a generic formulation, with the exception of posaconazole. This class was last reviewed in May 2012. These agents are approved to treat a variety of fungal infections, which are listed in Table 4. There are many guidelines that define the appropriate place in therapy for the azoles. The agent that is recommended is dependent upon the infectious organism being treated and the location of the infection. 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 azole 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 azoles 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 azole 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Echinocandins: AHFS 081416**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the echinocandins that are included in this review are listed in Table 1. This review encompasses all systemic dosage forms and strengths. There are no generic products available. This class was last reviewed in May 2012.

There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand echinocandin is safer or more efficacious than another. Since these agents are not indicated as first-line therapy for the management of common infectious diseases that would be seen in general use and due to concerns for the

development of resistance, these agents should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand echinocandins 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 echinocandin 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Polyenes: AHFS 081428**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the polyenes included in this review are listed in Table 1. This review encompasses all systemic dosage forms and strengths. The topical antifungals were previously reviewed with the skin and mucous membrane agents and are not included in this review. Conventional Amphotericin B and nystatin are available in a generic formulation. This class was last reviewed in May 2012.

There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

According to the prescribing information, the use of amphotericin B (all formulations) should be reserved for the treatment of patients with progressive and potentially life-threatening fungal infections. There is insufficient evidence to support that one brand polyene is more efficacious than another. Since amphotericin B is not indicated as first-line therapy for the management of common infectious diseases that would be seen in general use, formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand polyenes 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 polyene 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Pyrimidines: AHFS 081432**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the pyrimidines that are included in this review are listed in Table 1. This review encompasses all systemic dosage forms and strengths. The topical antifungals were previously reviewed with the skin and mucous membrane agents and are not included in this review. Flucytosine is available in a generic formulation. This class was last reviewed in May 2012.

Flucytosine is approved for the treatment of serious infections caused by susceptible strains of *Candida* and/or *Cryptococcus*. It should be used in combination with amphotericin B because of the emergence of resistance.

There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

All brand pyrimidines 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 pyrimidine 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Antifungals, Miscellaneous: AHFS 081492**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that griseofulvin is the only miscellaneous antifungal agent that is currently available. This review encompasses all systemic dosage forms and strengths. All products are available in a generic formulation. This class was last reviewed in May 2012.

There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

Therefore, all brand miscellaneous antifungals 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 miscellaneous antifungal 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Antituberculosis Agents: AHFS 081604**

Manufacturer comments on behalf of these products:

None

Ms. Levy commented that the antituberculosis agents that are included in this review are listed in Table 1. Cycloserine, ethambutol, isoniazid, pyrazinamide, rifabutin, rifampin, and rifampin/isoniazid are available in a generic formulation. This class was last reviewed in May 2012. Recommendations regarding the use of these agents for the treatment of tuberculosis are listed in Tables 3 through 6. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed. Several guidelines included in these tables have been updated since the last class review and do not consist of significant changes concerning the utilization of the antituberculosis agents. The CDC has suggested that Bedaquiline may be added on a case by case basis when other effective treatment regimens cannot otherwise be provided to the following groups: children, individuals with HIV, pregnant woman, persons with extrapulmonary multi drug resistant tuberculosis, and patients with comorbid conditions on concomitant medications.

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

No brand antituberculosis 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Antimycobacterials, Miscellaneous: AHFS 081692**

Manufacturer comments on behalf of these products:

None

Ms. Levy commented that dapson is the only miscellaneous antimycobacterial that is currently available. It is approved for the treatment of leprosy and dermatitis herpetiformis and 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 in May of 2012.

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

No brand miscellaneous antimycobacterial 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Adamantanes: AHFS 081804**

Manufacturer comments on behalf of these products:

None

Ms. Levy commented that the adamantanes that are included in this review are listed in Table 1. These agents are approved for the treatment and prophylaxis of influenza A virus infections. Amantadine and rimantadine are available in a generic formulation. Guidelines recommend the use of oseltamivir or zanamivir for the treatment and prophylaxis of all influenza subtypes. Due to the emergence of resistance, the adamantanes are not effective. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed.

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

No brand adamantane 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Neuraminidase Inhibitors: AHFS 081828**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the neuraminidase inhibitors that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. There are no generic products available. This class was last reviewed in May 2012. The neuraminidase inhibitors are approved for the treatment and prophylaxis of influenza A and influenza B virus infections.

There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

Therefore, oseltamivir (Tamiflu®) and zanamivir (Relenza®) offer significant clinical advantages in general use over the other brands and to the generic products in the class (if applicable).

Oseltamivir (Tamiflu®) and zanamivir (Relenza®) are recommended for preferred status contingent upon statewide influenza epidemiology status as reported by the Centers for Disease Control and Prevention.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**HCV Antivirals: AHFS 081840**

Manufacturer comments on behalf of these products:

None

Dr. Lavitas commented that the HCV antivirals were last reviewed in May 2012. Four agents included in this review are listed in Table 1. This review includes all dosage forms and strengths. There are no generic products in this class. In 2013, two new agents, simeprevir, an HCV protease inhibitor, and sofosbuvir, an NS5B polymerase inhibitor, were FDA-approved and were included in this review. They join boceprevir and telaprevir, two protease inhibitors, which were already available on the market. Of note, telaprevir was discontinued in the United States in October 2014. Chronic Hepatitis C infection is the most common blood born infection in the United States. As many as 7 viral genotypes have been identified, of which genotype 1 is the most common. The goal of treatment is to eradicate the virus and prevent liver related complications and death.

Treatment guidelines are summarized in Table 2 for your reference. Several treatment guidelines have been updated since the last review. Treatment guidelines prefer sofosbuvir-based therapies for most patients with chronic hepatitis C infection. Treatment guidelines generally recommend delaying therapy for most patients with documented early fibrosis stage (F0-F2) given anticipated availability of highly effective, well tolerated, interferon-free regimens in the near future. The guidelines from AASLD/IDSA prioritize patients for treatment based on risk of developing severe complications.

In the treatment of genotype 1 infection, the recommended options include:

- Sofosbuvir with peginterferon and ribavirin triple therapy for 12 weeks
- Patients not eligible for peginterferon, may be candidates for either
  - o Sofosbuvir and ribavirin for 24 weeks
  - o Sofosbuvir and simeprevir for 12 weeks
- One of these three options may be preferred depending on prior treatment history and the stage of liver disease
- Telaprevir and boceprevir-containing regimens are considered inferior to sofosbuvir-containing regimens and are generally not recommended.

In the treatment of HCV genotype 2 and 3 infections, treatment guidelines prefer sofosbuvir and ribavirin for 12 or 24 weeks, respectively. In the treatment of HCV genotype 4, 5, 6 guidelines prefer sofosbuvir with peginterferon and ribavirin triple therapy for 12 weeks based on limited clinical trial data.

Turning to page 897, Table 3 summarizes FDA-approved indications. HCV protease inhibitors (boceprevir, simeprevir, and telaprevir) are all FDA-approved for the treatment of HCV genotype 1 infection in adults in combination with peginterferon and ribavirin. Combination therapy with sofosbuvir is FDA-approved for genotype 1, 2, 3, and 4 as well as in HCV/HIV-coinfection and in patients with hepatocellular carcinoma awaiting a liver transplant.

Turning to page 898, drug Interactions are summarized in Table 5 for your reference. There are many drug-interactions associated with protease inhibitors. Sofosbuvir, on the other hand, does not have as many drug interactions. Turning to page 903, adverse reactions are summarized in Table 6 for your reference. A new black box warning has been added to telaprevir prescribing information to highlight the risk of fatal and nonfatal serious skin reactions.

Turning to page 905, dosing and administration for sofosbuvir and simeprevir have been added to Table 8. Simeprevir is given once-daily in combination with peginterferon and ribavirin. Sofosbuvir is given once daily in combination with either peginterferon and ribavirin or ribavirin alone depending on the HCV genotype, and eligibility for peginterferon.

Turning to page 905, several new trials have been summarized in Table 9. The efficacy of simeprevir in combination with peginterferon and ribavirin in subjects with genotype 1 infection was evaluated in four clinical studies, including two Phase III trials in treatment-naïve subjects (QUEST 1 and QUEST 2) and two trials in treatment-experienced subjects who failed prior therapy with peginterferon and ribavirin (PROMISE and ASPIRE). Sustained virologic response (SVR) was achieved by 80% of treatment-naïve subjects and ranged between 53% and 79% in treatment-experienced subjects. Efficacy was reduced by about 30% in subjects with genotype 1a infection and Q80K polymorphism at baseline. The efficacy of sofosbuvir was based on the results of five Phase III trials (N=1,724) in treatment-naïve HCV mono-infected subjects with genotypes 1 to 6 (NEUTRINO, FISSION, POSITRON, FUSION, VALENCE) and one Phase III trial (N=223) HCV/HIV-1 (PHOTON-1) co-infected subjects with genotype 1, 2, or 3. When added to peginterferon and ribavirin for 12 weeks, SVR was 89% in treatment-naïve subjects with genotype 1; 96% in treatment-naïve subjects with genotype 4. When added to ribavirin for 12 weeks in subjects with genotype 2 infection, SVR was 95% in treatment-naïve and 82% in treatment-experienced subjects. When added to ribavirin for 24 weeks in subjects with genotype 3 infection, SVR was 93% in treatment-naïve and 77% in treatment-experienced subjects. An open-label clinical trial evaluated sofosbuvir plus ribavirin in subjects with genotypes 1 to 6 HCV and HCC prior to undergoing liver transplantation. Subjects were treated for 24 to 48 weeks or until the time of liver transplantation. The post-transplant virologic response rate was 64% in the 36 evaluable subjects who have reached the 12 week post-transplant time point.

Combination therapy of sofosbuvir and simeprevir with or without ribavirin has been evaluated in the Phase 2 COSMOS study (N=167 with genotype 1 infection). SVR12 rates were >90% regardless of the presence or absence of advanced liver disease or prior treatment history with peginterferon and ribavirin. There was little to no benefit from adding ribavirin in these difficult to treat groups of hepatitis C subjects and 12 week treatment provided similar clinical benefit to 24 week treatment.

Turning to page 937, in conclusion, of the agents included in this review, sofosbuvir used only in combination therapy offers significant clinical advantages over the other branded products in the same class. The drugs in this AHFS class are used in a specific patient population. Because these agents have narrow indications with limited usage, and very specific criteria must be met prior to initiating therapy, these agents should be managed through the medical justification portion of the prior authorization process.

No brand HCV antiviral 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. Littlejohn Newman discussed current Medicaid policy, and asked the committee to notify Medicaid of any further information of interest that becomes available pertaining to the HCV Antivirals.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Interferons: AHFS 081820**

Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the interferons that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. None of the interferons are available in a generic formulation. This class was last reviewed in May 2012.

Current treatment guidelines that incorporate the use of interferons are summarized in Table 2. The FDA-approved indications vary among the products; however, the interferons are primarily used for the treatment of chronic hepatitis B and chronic hepatitis C. As outlined in the HCV Antiviral review, for the treatment of chronic hepatitis C genotype 1, guidelines now recommend the use of peginterferon alfa in combination with sofosbuvir and ribavirin for 12 weeks. However, interferon-free regimens are becoming more prevalent, as they avoid the toxicity associated with interferon use. Guidelines do not give preference to one pegylated product over another.

Interferon alfa-2b and interferon alfa-n3 are approved for the treatment of condylomata acuminata. However, the interferons are considered a second-line treatment option by the CDC and there are no published clinical trials which directly compare these agents. Interferon alfa-2b is also approved for the treatment of selected patients with AIDS-related Kaposi's sarcoma, hairy cell leukemia, follicular Non-Hodgkin's lymphoma, and as an adjuvant to surgical treatment in patients with malignant melanoma. Due to the limited usage anticipated for most of these indications, the interferon alfa products should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand interferon alfa products within the class reviewed are comparable to each other and to the generics in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Peginterferon alfa-2a (Pegasys<sup>®</sup>) and peginterferon alfa-2b (PegIntron<sup>®</sup>) offer significant clinical advantages in general use over the other brand and generic products in the same class (if applicable) but are comparable to each other.

No brand interferon alfa 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.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand peginterferon alfa product is selected as a preferred agent.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

### **Nucleosides and Nucleotides: AHFS 081832**

#### Manufacturer comments on behalf of these products:

None

Dr. Bastien commented that the nucleosides and nucleotides that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. The majority of products in this review are available in a generic formulation. This class was last reviewed in May 2012.

Treatment guidelines and clinical studies have been updated since the last review. Notable changes include the discontinuation of the ganciclovir intraocular implant and revision of Hepatitis C guidelines. Turning to page 756, the Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents, Treatment of Cytomegalovirus disease has been updated. The ganciclovir implant, a surgically-implanted reservoir of ganciclovir, which lasts approximately six months, is very effective but it no longer is being manufactured. In its absence, some clinicians will use intravitreal injections of ganciclovir or foscarnet in conjunction with oral valganciclovir, at least initially, to provide immediate high intraocular levels of drug and presumably faster control of the retinitis. There are many effective treatments for cytomegalovirus retinitis, and no one regimen has been proven in a clinical trial to have greater efficacy in terms of protecting vision. Thus, clinical judgment must be used when choosing a regimen.

As outlined in the HCV Antiviral review, for the treatment of chronic hepatitis C genotype 1, guidelines now recommend the use of peginterferon alfa in combination with sofosbuvir and ribavirin for 12 weeks. All-oral sofosbuvir plus simeprevir with or without ribavirin is recommended as an off-label regimen in patients who are either peginterferon alfa ineligible, prior null or partial responders to peginterferon alfa and ribavirin dual therapy, or liver transplant recipients.

Therefore, all brand nucleosides and nucleotides 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 nucleoside or nucleotide 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

### **Antivirals, Miscellaneous: AHFS 081892**

#### Manufacturer comments on behalf of these products:

None

Ms. Levy commented that foscarnet is the only miscellaneous antiviral that is currently available. It is approved for the treatment of cytomegalovirus retinitis in patients with the acquired immunodeficiency syndrome. It is also approved for the treatment of acyclovir-resistant mucocutaneous herpes simplex virus infections in immunocompromised patients. Foscarnet 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 miscellaneous antivirals within the class reviewed are comparable to each other and to the generics in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand miscellaneous antiviral 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Amebicides: AHFS 083004**

Manufacturer comments on behalf of these products:

None

Ms. Levy commented that paromomycin is the only amebicide that is currently available. It is approved for the treatment of amebiasis, as well as an adjunctive agent for the treatment of hepatic coma, and 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 in May 2012.

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

No brand amebicide 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Antimalarials: AHFS 083008**

Manufacturer comments on behalf of these products:

None

Ms. Levy commented that the antimalarials that are included in this review are listed in Table 1. These agents are approved for the prevention and treatment of malaria. Atovaquone/proguanil, chloroquine, hydroxychloroquine, mefloquine, primaquine and quinine 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 in May 2012.

There is insufficient evidence to support that one brand antimalarial is more efficacious than another within its given indication. Since the antimalarials are not used for the management of common infectious diseases that would be seen in general use, formulations without a generic

alternative should be managed through the medical justification portion of the prior authorization process.

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

No brand antimalarial 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Antiprotozoals, Miscellaneous: AHFS 083092**

Manufacturer comments on behalf of these products:

None

Ms. Levy commented that the miscellaneous antiprotozoals that are included in this review are listed in Table 1. These agents are approved to treat a variety of infectious diseases, which are listed in Table 4. Atovaquone, metronidazole, and tinidazole 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 in May 2012.

There is insufficient evidence to support that one brand miscellaneous antiprotozoal agent is safer or more efficacious than another within its given indication. These agents may be considered first-line therapy in special circumstances. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

No brand miscellaneous antiprotozoal 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

**Urinary Anti-infectives: AHFS 083600**

Manufacturer comments on behalf of these products:

None

Ms. Levy commented that the urinary anti-infectives that are included in this review are listed in Table 1. These agents are approved for the prophylaxis and treatment of urinary tract infections, as well as for the relief of local symptoms associated with infections or caused by diagnostic procedures. Trimethoprim solution is also approved for the treatment of otitis media. The majority

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 in May of 2012.

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

No brand urinary anti-infective 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.

Chairperson Harwood asked the P&T Committee members to mark their ballots.

## **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 February 11, 2015 at the Medicaid Building in the Commissioner's Board Room.

## **9. ADJOURN**

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

Appendix

**RESULTS OF THE BALLOTING**  
**Alabama Medicaid Agency**  
**Pharmacy and Therapeutics Committee**  
**November 12, 2014**

- A. **Recommendation:** No brand allylamine 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. K. Rowe, MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Skell*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A*  Approve  Approve as amended  Disapprove  No action  
Commissioner

- B. **Recommendation:** No brand azole 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. K. Rowe, MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Skell*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A*  Approve  Approve as amended  Disapprove  No action  
Commissioner

C. **Recommendation:** No brand echinocandin 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 Heel  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie A.  Approve  Approve as amended  Disapprove  No action  
Commissioner

D. **Recommendation:** No brand polyene 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 Heel  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie A.  Approve  Approve as amended  Disapprove  No action  
Commissioner

**Recommendation:** No brand pyrimidine 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. K. Kowalski, MD  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

Kathy Hill  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie A. Fox  Approve  Approve as amended  Disapprove  No action  
Commissioner

**E. Recommendation:** No brand miscellaneous antifungal 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. K. Kowalski, MD  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

Kathy Hill  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie A. Fox  Approve  Approve as amended  Disapprove  No action  
Commissioner

**F. Recommendation:** No brand antituberculosis 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

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

*Kathy Steel*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A. A.*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**G. Recommendation:** No brand miscellaneous antimycobacterial 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. K. Rowe, MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Steel*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A. A.*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**H. Recommendation:** No brand adamantane 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. Skone, MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Hill*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A.*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**I. Recommendation:** No brand interferon 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.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand peginterferon alfa product is selected as a preferred agent.

**Amendment:** None

**Vote:** Unanimous to approve as recommended

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

*Kathy Hill*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A.*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**J. Recommendation:** Oseltamivir (Tamiflu®) and zanamivir (Relenza®) are recommended for preferred status contingent upon statewide influenza epidemiology status as reported by the CDC.

**Amendment:** None

**Vote:** Unanimous to approve as recommended

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

Jacky Steel  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie A.  Approve  Approve as amended  Disapprove  No action  
Commissioner

**K. Recommendation:** No brand nucleoside or nucleotide 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. Spore, MD  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

Jacky Steel  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie A.  Approve  Approve as amended  Disapprove  No action  
Commissioner

**L. Recommendation:** No brand HCV protease inhibitor 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

*Stephanie A. [Signature]*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**M. Recommendation:** No brand miscellaneous antiviral 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

*Stephanie A. [Signature]*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**N. Recommendation:** No brand amebicide 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. K. Rowe, MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Steel*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A. [Signature]*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**O. Recommendation:** No brand antimalarial 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. K. Rowe, MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Steel*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A. [Signature]*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**P. Recommendation:** No brand miscellaneous antiprotozoal 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. Rowley MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Hill*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A. Hill*  Approve  Approve as amended  Disapprove  No action  
Commissioner

**Q. Recommendation:** No brand urinary anti-infective 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. Rowley MD*  Approve  Approve as amended  Disapprove  No action  
Assistant Medical Director

*Kathy Hill*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A. Hill*  Approve  Approve as amended  Disapprove  No action  
Commissioner

Respectfully submitted,



November 19, 2014

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Rachel Bastien, Pharm.D.

Date



November 19, 2014

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Amy Levy, R.Ph., MHP

Date