Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

May 9, 2012

Members Present: Chair, Ms. LaTonya Porter, Ms. Janet Allen, Dr. Lucy Culpepper, Dr. Kelli Littlejohn, Mr. Ben Main, Dr. Melinda Rowe, Dr. Chivers Woodruff and Dr. James Yates

Members Absent: Dr. Julia Boothe and Dr. Gerard Ferris

Patient Care Networks of Alabama (PCNA) Staff Present: Dr. Cara Leos and Dr. Amanda Sparkman

Presenter: Dr. Tina Hisel

Presenters Present via Teleconference: Dr. Laureen Biczak

1. OPENING REMARKS

Ms. Porter called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:00 a.m.

2. APPROVAL OF MINUTES

Ms. Porter asked if there were any corrections to the minutes from the February 8, 2012 P&T Committee Meeting.

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

3. PHARMACY PROGRAM UPDATE

Dr. Littlejohn oriented the manufacturers in attendance to the Alabama Medicaid Agency's website (www.medicaid.alabama.gov). She reminded manufacturers that they are responsible for notifying Medicaid of their current contact information using the Pharmaceutical Manufacturer Contact Information form. She also briefly reviewed the policy and procedures for meeting with pharmaceutical manufacturers.

The Agency released a Request for Proposals (RFP) to expand the Patient Care Networks of Alabama (PCNA) into Mobile and Washington Counties.

Governor Bentley has appointed Stephanie Azar as Acting Commissioner of the Alabama Medicaid Agency effective May 1, 2012. Dr. Williamson continues to work closely with Governor's office, the legislature, and the Medicaid Agency on the budget.

Dr. Littlejohn oriented the Committee members to the Provider Alerts that are available on the Agency's website.

Dr. Littlejohn asked the Committee members if they were in favor of receiving the clinical review packet electronically rather than a hard copy. Mr. Main recommended that the clinical review packet be sent electronically and that Committee members could print a hard copy if that was their preference. Dr. Woodruff agreed with Mr. Main's suggestion. Ms. Porter asked the Committee members to vote on the recommendation that the clinical review packets will be sent electronically for future P&T Committee Meetings. Dr. Woodruff made a motion to approve the recommendation and Mr. Main seconded the motion. The recommendation was unanimously approved.

Dr. Littlejohn noted that there was also a recommendation to change the quarterly P&T Committee Meetings to semi-annually in an effort to reduce costs. She stated that it will require a Legislative change, which will be evaluated during the next session. Web conferences are not allowed due to the Sunshine Law.

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 five manufacturer verbal presentations at the meeting.

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

The pharmacotherapy class reviews began at 9:15 a.m. There were a total of 18 re-reviews; the classes were previously reviewed in November 2009. There was one new drug class review.

Allylamines: American Hospital Formulary Service (AHFS) 081404
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that terbinafine is the only allylamine that is currently available. It is approved for the treatment of onychomycosis and tinea capitis and only the tablet formulation is available generically. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed.

Therefore, all brand allylamines within the class reviewed are comparable to each other and to the generics and OTC 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Azoles: AHFS 081408
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that the azoles that are included in this review are listed in Table 1. These agents are approved to treat a variety of fungal infections, which are listed in Table 4. All of the products are available in a generic formulation, with the exception of posaconazole. 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.

Therefore, all brand azoles within the class reviewed are comparable to each other and to the generics and OTC 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Echinocandins: AHFS 081416
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that the echinocandins that are included in this review are listed in Table 1. These agents are approved for the treatment of *Candida* infections. Caspofungin is also approved for the treatment of invasive aspergillosis, as well as empirical therapy for presumed fungal infections in febrile, neutropenic patients. The echinocandins are only available in an injectable formulation and there are no generic products available. 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 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 generics and OTC 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Polyenes: AHFS 081428
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that the polyenes that are included in this review are listed in Table 1. These agents are approved for the treatment of a variety of infections, which are listed in Table 4. Conventional amphotericin B (deoxycholate) is associated with a high incidence of infusion-related adverse events and nephrotoxicity and the lipid formulations were developed to minimize toxicity. Nystatin and conventional amphotericin B are both 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 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 generics and OTC 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.

Dr. Woodruff noted that there were no topical formulations of nystatin included in the class review. He asked if this was because it was in a different class review. Dr. Hisel stated that the topical antifungals were previously reviewed with the skin and mucous membrane agents and were not included in this review.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Pyrimidines: AHFS 081432
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that flucytosine is the only pyrimidine that is currently available and it 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. Flucytosine 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 pyrimidines within the class reviewed are comparable to each other and to the generics and OTC 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Antifungals, Miscellaneous: AHFS 081492
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that griseofulvin is the only miscellaneous antifungal agent that is currently available and it is approved for the treatment of dermatophyte infections. Griseofulvin microsize suspension is the only product that 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 antifungals within the class reviewed are comparable to each other and to the generics and OTC 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Antituberculosis Agents: AHFS 081604
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that the antituberculosis agents that are included in this review are listed in Table 1. Ethambutol, isoniazid, pyrazinamide, rifampin, and rifampin/isoniazid are available in a generic formulation. 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. However, for the treatment of latent tuberculosis, the CDC now considers the combination of isoniazid and rifapentine as an equal alternative to monotherapy with isoniazid in patients ≥12 years of age. The preferred regimen for children 2–11 years of age is daily isoniazid.

Dr. Woodruff asked if the combination of isoniazid and rifapentine was included in the packet. Dr. Hisel stated that the two agents are only available in separate formulations. Ms Allen asked if combination of isoniazid and rifapentine was administered for 9 months. Dr. Hisel stated that it is administered for 12 weeks as directly observed therapy. Dr. Woodruff asked if the combination of isoniazid and rifapentine was administered daily. Dr. Biczak stated that the combination is administered on a weekly basis.

Therefore, all brand antituberculosis agents within the class reviewed are comparable to each other and to the generics and OTC products 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Antimycobacterials, Miscellaneous: AHFS 081692
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that dapsone is the only miscellaneous antimycobacterials 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.

Therefore, all brand miscellaneous antimycobacterials within the class reviewed are comparable to each other and to the generics and OTC products 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Adamantanes: AHFS 081804
Manufacturer comments on behalf of these products:
None

Dr. Hisel 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 and OTC products 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.

Mr. Main asked if the class reviews were moving so quickly because they were re-reviews. Dr. Hisel confirmed that all of the classes were previously reviewed in November 2009 and that she was highlighting the new information.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Interferons: AHFS 081820
Manufacturer comments on behalf of these products:
Pegasys® - Genentech
PegIntron® - Merck

Dr. Hisel commented that the interferons that are included in this review are listed in Table 1. 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. None of the interferons are available in a generic formulation.

Guidelines recommend the use of peginterferon alfa as one of several initial treatment options for patients with chronic hepatitis B. Interferon alfa-2a and peginterferon alfa-2a were shown to be equally effective following 48 weeks of treatment.

For the treatment of chronic hepatitis C, guidelines recommend the use of peginterferon alfa in combination with ribavirin. They do not give preference to one pegylated product over another. The peginterferon alfa products have both been shown to be more effective than standard interferon alfa products for the treatment of chronic hepatitis C. Studies directly comparing the peginterferon alfa products have demonstrated mixed results. The largest trial was conducted by McHutchison et al. and included over 3,000 patients with chronic hepatitis C genotype 1 infection. The investigators demonstrated similar sustained virologic response rates, relapse rates and adverse events with peginterferon alfa-2a and peginterferon alfa-2b.

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 and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Peginterferon alfa-2a (Pegasys®) and peginterferon alfa-2b (Pegintron®) offer significant clinical advantages in general use over the other brands, generics and OTC 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Neuraminidase Inhibitors: AHFS 081828
Manufacturer comments on behalf of these products:
None

Dr. Hisel commented that the neuraminidase inhibitors that are included in this review are listed in Table 1. These agents are approved for the treatment and prophylaxis of influenza A and influenza B virus infections. There are no generic products available. Guidelines recommend the use of

either oseltamivir or zanamivir for the treatment and prophylaxis of all influenza subtypes and do not give preference to one agent over another. 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, oseltamivir (Tamiflu®) and zanamivir (Relenza®) offer significant clinical advantages in general use over the other brands, generics and OTC products (if applicable).

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

Dr. Yates commented that it's important to start treatment early when prescribing the neuraminidase inhibitors.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Nucleosides and Nucleotides: AHFS 081832
Manufacturer comments on behalf of these products:
Baraclude® - Bristol-Meyers Squibb

Dr. Hisel commented that the nucleosides and nucleotides that are included in this review are listed in Table 1. These agents are approved for the treatment of infections caused by herpes simplex virus, varicella-zoster virus and cytomegalovirus, as well as for the treatment of chronic hepatitis B, chronic hepatitis C, and respiratory syncytial virus. Acyclovir, famciclovir, ganciclovir, ribavirin, and valacyclovir 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.

Adefovir, entecavir and telbivudine are approved for the treatment of chronic hepatitis B. Other FDA-approved agents include interferon alfa, peginterferon alfa, lamivudine and tenofovir. Although any of the agents can be used, guidelines recommend peginterferon alfa, tenofovir or entecavir for the initial treatment of patients with HBeAg-positive and HBeAg-negative chronic hepatitis B. Several clinical trials have demonstrated greater efficacy with entecavir and telbivudine than lamivudine. Serum HBV DNA levels were also reduced to a greater extent with telbivudine (24 weeks) and entecavir (12 weeks) compared to adefovir. In one study, telbivudine and entecavir decreased HBV-DNA levels to a similar extent after 24 weeks of therapy. However, telbivudine is associated with a high rate of resistance; therefore, telbivudine monotherapy has a limited role in the treatment of hepatitis B. Among the approved therapies for chronic hepatitis B, lamivudine is associated with the highest rate of resistance, and entecavir and tenofovir are associated with the lowest rates of resistance in drug-naïve patients. Judicious use of these agents is the most effective way to reduce the development of resistance. Patients with minimal disease and those who are unlikely to achieve a sustained response should not be treated with the nucleoside/nucleotide analogues, especially if they are <30 years of age.

Therefore, all brand nucleosides and nucleotides within the class reviewed are comparable to each other and to the generics and OTC 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

HCV Protease Inhibitors: AHFS 081840
Manufacturer comments on behalf of these products:
Incivek® - Vertex Pharmaceuticals
Victrelis® - Merck

Dr. Hisel commented that the HCV protease inhibitors that are included in this review are listed in Table 1. This is a new AHFS subclass, which has not been reviewed previously by this Committee. There are currently no generic products available.

Boceprevir and telaprevir are direct-acting antiviral agents, which are approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have previously been treated with interferon-based treatment. Boceprevir and telaprevir must not be used as monotherapy due to the development of resistance. Boceprevir in combination with peginterferon alfa and ribavirin has not been studied in patients documented to be historical null responders during prior therapy with peginterferon alfa and ribavirin.

Current treatment guidelines that incorporate the use of the HCV protease inhibitors are summarized in Table 2. According to the 2011 AASLD guidelines, the optimal treatment for chronic HCV genotype 1 infection is boceprevir or telaprevir in combination with peginterferon alfa and ribavirin. Triple therapy leads to further improvements in sustained virological response rates in treatment-naïve, as well as treatment-experienced patients compared to dual therapy with peginterferon alfa and ribavirin alone. The guidelines do not give preference to one HCV protease inhibitor over another.

Dr. Hisel asked Committee members to refer to Table 2 and Table 7 for specific recommendations on dosage, duration of treatment, and criteria for discontinuation of therapy in treatment-naïve patients. Retreatment with boceprevir or telaprevir is recommended for patients who had virological relapse or were partial responders after prior treatment with interferon alfa or peginterferon alfa and/or ribavirin. Retreatment with telaprevir may be considered for prior null responders to interferon alfa or peginterferon alfa and/or ribavirin. Response-guided therapy with boceprevir or telaprevir can be considered for relapsers, may be considered for partial responders, but is not recommended for null responders. Patients who fail to have a virological response, experience virological breakthrough, or relapse with one HCV protease inhibitor should not be retreated with the other HCV protease inhibitor.

Clinical studies evaluating the safety and efficacy of the HCV protease inhibitors are summarized in Table 8. Boceprevir and telaprevir improved sustained virologic response rates by ≥10% when added to peginterferon alfa and ribavirin therapy. The improved responses were maintained in difficult-to-treat groups, including patients who failed previous therapy, genotype 1 patients, and African-American patients. The HCV protease inhibitors may also offer a method to reduce the overall length of therapy in early virologic responders. Whether one agent has clinical advantages over the other still remains to be determined.

There is insufficient evidence to support that one brand HCV protease inhibitor is safer or more efficacious than another. The optimal treatment for chronic HCV genotype 1 infection is boceprevir or telaprevir in combination with peginterferon alfa and ribavirin. The HCV protease inhibitors must not be used as monotherapy due to the development of resistance. Since there are very specific criteria that must be met when initiating therapy, these agents should be managed through the medical justification portion of the prior authorization process.

Therefore, boceprevir (Victrelis®) and telaprevir (Incivek®) offer significant clinical advantages in general use over the other brands, generics and OTC products in the same class (if applicable), but are comparable to each other.

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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Antivirals, Miscellaneous: AHFS 081892
Manufacturer comments on behalf of these products:
None

Dr. Hisel 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 and OTC products 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Amebicides: AHFS 083004
Manufacturer comments on behalf of these products:
None

Dr. Hisel 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.

Therefore, all brand amebicides within the class reviewed are comparable to each other and to the generics and OTC products 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Antimalarials: AHFS 083008
Manufacturer comments on behalf of these products:
None

Dr. Hisel 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, and primaquine 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 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 and OTC products in the class (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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Antiprotozoals, Miscellaneous: AHFS 083092
Manufacturer comments on behalf of these products:
None

Dr. Hisel 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. Metronidazole is the only product that 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.

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 and OTC products 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Urinary Anti-infectives: AHFS 083600
Manufacturer comments on behalf of these products:
None

Dr. Hisel 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.

Therefore, all brand urinary anti-infectives within the class reviewed are comparable to each other and to the generics and OTC products 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.

There were no further discussions on the agents in this class. Ms. Porter asked the P&T Committee Members to mark their ballots.

Dr. Littlejohnn and Ms. Thomas thanked Goold Health Systems for their service as the pharmacy clinical support contractor.

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 Meetings are scheduled for 9:00 a.m. on August 8, 2012 and November 14, 2012 at the Medicaid Building in the Commissioner's Board Room.

9. ADJOURN

There being no further business, Dr. Woodruff moved to adjourn and Ms. Allen seconded. The meeting was adjourned at 10:16 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
May 9, 2012

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

Melinda D. Romey, MD ☒ 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

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

Melinda D. Romey, MD ☒ 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

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

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

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

Stephanie C. ☒ 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

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

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

Stephanie C. ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

E. 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

Melinda D. 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

F. 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

Melinda D. 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

G. **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

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

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

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

H. **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

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

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

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

I. **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

Melinda A. Ramsey ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

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

J. **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

Melinda A. Ramsey ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

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

K. 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

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

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

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

L. 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

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

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

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

M. 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

Melinda A. Rowsey ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

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

N. 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

Melinda A. Rowsey ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

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

O. 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

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

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

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

P. 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

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

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

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

Q. 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

Melinda H. Ramsey ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

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

R. 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

Melinda H. Ramsey ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

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

Respectfully submitted,

Tina Hisel

May 9, 2012

Tina Hisel, Pharm.D., BCPS