Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

August 2, 2023

Members Present: Dr. Lee Carter (Chairperson), Dr. Peter Hughes, Dr. Kelli Littlejohn Newman, Dr. Tiffany Lyght (Vice-Chairperson), Dr. Melinda Rowe

Members Absent: Dr. Frances Heinze, Dr. Albert Holloway, and Dr. George Sutton

Presenters: Dr. Rachel Bacon and Dr. Thomas Pomfret

1. OPENING REMARKS

Chairperson Carter called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 1:57 p.m.

2. APPROVAL OF MINUTES

Chairperson Carter asked if there were any corrections to the May 3, 2023 P&T Committee Meeting's minutes.

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

3. PHARMACY PROGRAM UPDATE

Dr. Newman stated that there are several ALERTs in your packets and on the website. Dr. Kimberly Graham was introduced as the new clinical pharmacist through the Kepro contract and just started last week.

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 were explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were two manufacturer verbal presentations at the meeting.

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

The pharmacotherapy class reviews began at approximately 2:01 p.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, Miscellaneous Antivirals, Amebicides, Antimalarials, Miscellaneous Antiprotozoals, and Urinary Anti-infectives were all last reviewed in August 2021.

HCV Antivirals: American Hospital Formulary Service (AHFS) 081840
Manufacturer comments on behalf of these products:
Gilead – Epclusa®
Gilead - Harvoni®

Dr. Bacon commented that the HCV antivirals that are included in this review are listed in Table 1 on page 812. There have been no major changes in the prescribing information or clinical studies since this class was last reviewed.

In general, the guideline recommendations are in line with FDA-approved indications, and the HCV antivirals in various combinations, with or without ribavirin, are the preferred treatment regimens. Treatment regimens are recommended based on HCV genotype, previous treatment experience, presence of cirrhosis, and certain special populations. Overall, data from clinical trials support the FDA-approved indications and dosing recommendations for these agents. The trials demonstrate that treatment with HCV antiviral agents result in a significant improvement in SVR when compared to historical response rates or placebo.

There is insufficient evidence to support that one HCV antiviral is safer or more efficacious than another. 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 existing medical justification portion of the prior authorization process.

Therefore, all brand HCV antivirals 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 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.

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

Allylamines: AHFS 081404
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that terbinafine is the only allylamine included in this review. Terbinafine is available in a generic formulation. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

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

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

Dr. Bacon commented that the azoles that are included in this review are listed in Table 1 on page 35. All of the products are available in a generic formulation, with the exception of isavuconazonium and oteseconazole.

Vivjoa® (oteseconazole) was approved in 2022 and is indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. Females who are not of reproductive potential are defined as: persons who are biological females who are postmenopausal or have another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy). There are two recommended oteseconazole dosage regimens: an oteseconazole-only regimen and a fluconazole/oteseconazole regimen. Additionally, posaconazole and voriconazole have gained approved for pediatric use for certain indications.

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

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

Dr. Bacon commented that the echinocandins that are included in this review are listed in Table 1 on page 175. Caspofungin and micafungin are available in a generic formulation. 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, formulations without a generic alternative 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 Carter asked the P&T Committee members to mark their ballots.

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

Dr. Bacon commented that the polyenes included in this review are listed in Table 1 on page 245. Amphotericin B (conventional and liposome) and nystatin are available in a generic formulation.

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

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

Dr. Bacon commented that the flucytosine is the only pyrimidine included in this review which begins on page 342. Flucytosine is available in a generic formulation. 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.

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

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

Dr. Bacon commented that the miscellaneous antifungals are listed in Table 1 on page 377. Griseofulvin is available in generic formulations. Ibrexafungerp (Brexafemme®) is approved for the treatment of vulvovaginal candidiasis and reduction in the incidence of recurrent vulvovaginal candidiasis in adult and post-menarchal pediatric females. Ibrexafungerp inhibits glucan synthase, an enzyme necessary to produce fungal cell walls. Ibrexafungerp has concentration-dependent fungicidal activity against *Candida* species, including most *Candida* species resistant to treatment with fluconazole. Ibrexafungerp has a boxed warning stating that it is contraindicated in pregnancy because it may cause fetal harm based on findings from animal reproductive studies. The consensus guidelines have not been updated to reflect this agent's approval. Fluconazole is the guideline recommended first line agent for both acute and recurring treatment of vulvovaginal candidiasis.

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

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

Dr. Pomfret commented that the antituberculosis agents that are included in this review are listed in Table 1 on page 412. Most of the agents 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. The standard treatment of tuberculosis is a six month course of four antibiotics. Treatment for drug-resistant tuberculosis is longer and more complex. Recent treatment options for latent tuberculosis have shortened the duration of treatment to only one or three months, as compared to six or more months in the past. The newer World Health Organization eTB Guidelines state that people aged 12 years or older with drug-susceptible pulmonary TB may receive a four-month regimen of isoniazid, rifapentine, moxifloxacin and pyrazinamide. These guidelines also state that latent tuberculosis infection may be treated with six or nine months of daily isoniazid, or a three-month regimen of weekly rifapentine plus isoniazid, or a three-month regimen of daily isoniazid plus rifampicin. A one-month regimen of daily rifapentine plus isoniazid or four months of daily rifampicin alone may also be offered as alternatives.

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

Therefore, all brand 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 Carter asked the P&T Committee members to mark their ballots.

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

Dr. Pomfret commented that dapsone 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 prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

All brand miscellaneous antimycobacterials within the class reviewed are comparable to each other and to the generics and in the class 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 Carter asked the P&T Committee members to mark their ballots.

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

Dr. Pomfret commented that the adamantanes that are included in this review are listed in Table 1 on page 508. 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, zanamivir, peramivir, or baloxavir for the treatment 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 or clinical studies since this class was last reviewed.

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

Interferons: AHFS 081820
Manufacturer comments on behalf of these products:
None

Dr. Pomfret commented that the interferons that are included in this review are listed in Table 1 on page 552. None of the interferons are available in a generic formulation. The Food and Drug

Administration (FDA)-approved indications vary among the products; however, the interferons are primarily used for the treatment of chronic hepatitis B.

Guidelines recommend the use of peginterferon alfa as one of several initial treatment options for patients with chronic hepatitis B. For the treatment of chronic hepatitis C genotype 1, guidelines recommend the use of all oral regimens.

Interferon alfa-2b is approved for the treatment of condylomata acuminata. However, the interferons are considered an alternative treatment option by the CDC. 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 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.

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.

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

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

Dr. Pomfret commented that the neuraminidase inhibitors that are included in this review are listed in Table 1 on page 605. Oseltamivir capsules are available in a generic formulation. The neuraminidase inhibitors are approved for the treatment and prophylaxis of influenza A and influenza B virus infections.

The 2022 Centers for Disease Control and Prevention (CDC): Influenza Antiviral Medications recommendations state that for outpatients with acute uncomplicated influenza, oral oseltamivir, inhaled zanamivir, intravenous peramivir, or oral baloxavir may be used for treatment.

Therefore, oseltamivir (Tamiflu®) and zanamivir (Relenza®), along with baloxavir (Xofluza®), offer significant clinical advantages in general use over the other brands in the class (if applicable). Because peramivir (Rapivab®) is indicated only for the treatment of acute uncomplicated influenza and is generally reserved for those patients who cannot tolerate an inhaled or oral agent, it should be managed through the medical justification portion of the prior authorization process.

Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products (brand or generic) of oseltamivir (Tamiflu®) and zanamivir (Relenza®), along with baloxavir (Xofluza®), and designate one or more preferred products contingent upon statewide influenza epidemiology status as reported by the Centers for Disease Control and Prevention.

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

Nucleosides and Nucleotides: AHFS 081832
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that the nucleosides and nucleotides that are included in this review are listed in Table 1 on page 669. The majority of products in this review are available in a generic formulation. The nucleosides and nucleotides are approved for the treatment of infections caused by herpes simplex virus (HSV), varicella-zoster virus (VZV) and cytomegalovirus (CMV), as well as for the treatment of chronic hepatitis B, chronic hepatitis C, and respiratory syncytial virus, and COVID-19.

Molnupiravir has been added since the last review. Molnupiravir has not been approved, but has been authorized for emergency use by the FDA under Emergency Use Authorization (EUA). Molnupiravir is an investigational medicine used to treat adults with a current diagnosis of mild-to-moderate COVID-19 who are at risk for progression to severe COVID-19 including hospitalization or death, and for whom other COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. Remdesivir is approved for the treatment of COVID-19 in adult and pediatric patients (28 days of age and older weighing at least 3 kg) who require hospitalization or nonhospitalized patients with mild to moderate COVID-19 at high risk for progression to severe COVID-19, including hospitalization or death. Remdesivir is given as a once-daily infusion (for three to 10 days depending on the indication) and may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system. According to the National Institutes of Health Coronavirus Disease COVID-2019 Treatment Guidelines, for the therapeutic management of non-hospitalized adults with COVID-19 who are at high risk of progressing to severe COVID-19, preferred therapies listed in order of preference include ritonavir-boosted nirmatrelvir (Paxlovid®) and remdesivir. Alternative therapy for use when the preferred therapies are not available, feasible to use, or clinically appropriate include molnupiravir. The Infectious Diseases Society of America guidelines also recommend these three agents in line with their approved or authorized uses.

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

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

Dr. Bacon commented that the miscellaneous antivirals included in this review are listed in Table 1 on page 902. Foscarnet is available in a generic formulation. Baloxavir (Xofluza®) is indicated for the treatment of acute uncomplicated influenza in otherwise healthy patients five years of age and older or 12 years of age and older at high risk of influenza-related complications who have been symptomatic for no more than 48 hours, and for post-exposure prophylaxis of influenza in patients five years of age and older following contact with an individual who has influenza.

Maribavir (Livtencity®) is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients 12 years of age and older and weighing at least 35 kg with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet. Maribavir is the first drug approved for use in this specific population.

Paxlovid® received emergency use authorization from the FDA for the treatment of adults and pediatric patients 12 years of age and older and weighing at least 40 kg with a current diagnosis of mild-to-moderate coronavirus disease 2019 (COVID-19) and who are high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid® received FDA approval in May 2023 for the treatment of mild-to-moderate COVID-19 in *adults* who are at high risk for progression to severe COVID-19, including hospitalization or death. It is not approved for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19. Paxlovid® should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset, and the full five-day treatment course should be completed even if hospitalization due to severe COVID-19 occurs. Consensus guidelines from the Infectious Diseases Society of America and National Institutes of Health in 2023 recommend Paxlovid® as a treatment for ambulatory or non-hospitalized patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease.

The 2022 Centers for Disease Control and Prevention (CDC): Influenza Antiviral Medications recommendations state that for outpatients with acute uncomplicated influenza, oral oseltamivir, inhaled zanamivir, intravenous peramivir, or oral baloxavir may be used for treatment. Therefore, baloxavir (Xofluza®), along with oseltamivir (Tamiflu®) and zanamivir (Relenza®), offer significant clinical advantages in general use over the other brands in the class (if applicable).

The remaining brand miscellaneous antivirals 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.

Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products (brand or generic) of baloxavir (Xofluza®), along with oseltamivir (Tamiflu®) and zanamivir (Relenza®), and designate one or more preferred products contingent upon statewide influenza epidemiology status as reported by the Centers for Disease Control and Prevention.

None of the remaining brand miscellaneous antivirals are 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 Carter asked the P&T Committee members to mark their ballots.

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

Dr. Bacon 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.

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

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

Dr. Bacon commented that the antimalarials that are included in this review are listed in Table 1 on page 962. These agents are approved for the prevention and treatment of malaria. Most of the agents are available in a generic formulation. In 2023, the Centers for Disease Control (CDC) updated guidelines for the treatment of malaria based on drugs currently available in the United States. In the United States, most cases of malaria occur among individuals who traveled to endemic regions without receiving appropriate prophylactic therapy. Treatment for malaria should not be initiated until the diagnosis has been confirmed by laboratory investigations. Once the diagnosis of malaria has been confirmed, appropriate antimalarial treatment must be initiated immediately. Treatment decisions are based upon the infecting *Plasmodium* species, the clinical status of the patient, and the drug susceptibility of the infecting parasites as determined by the geographic area where the infection was acquired.

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

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

Dr. Bacon commented that the miscellaneous antiprotozoals that are included in this review are listed in Table 1 on page 1035. Many agents are available in a generic formulation. Secnidazole has gained approval for the treatment of trichomoniasis. 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 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 Carter asked the P&T Committee members to mark their ballots.

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

Dr. Bacon commented that the urinary anti-infectives that are included in this review are listed in Table 1 on page 1126. 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.

There is insufficient evidence to support that one brand urinary anti-infective 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 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 Carter 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 November 8th at the Medicaid Building in the Commissioner's Board Room.

9. ADJOURN

There being no further business, Dr. Carter moved to adjourn and Dr. Hughes seconded. The meeting adjourned at 2:32 p.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
August 2, 2023

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

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

☑ 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. McRowe, MD — ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

☑ 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. McRowe, MD — ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

Stephanie A — ☑ 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

M S Rowe, MD — ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

Stephanie A — ☐ 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

M S Rowe, MD — ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

Stephanie A — ☐ 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

Assistant Medical Director	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

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

Assistant Medical Director	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☒ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

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

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

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

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

J. **Recommendation:** 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.

Amendment: None

Vote: Unanimous to approve as recommended

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

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

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

K. **Recommendation:** Oseltamivir (Tamiflu®) and zanamivir (Relenza®), along with baloxavir (Xofluza®), offer significant clinical advantages in general use over the other brands in the class (if applicable). Because peramivir (Rapivab®) is indicated only for the treatment of acute uncomplicated influenza and is generally reserved for those patients who cannot tolerate an inhaled or oral agent, it should be managed through the medical justification portion of the prior authorization process.

Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products (brand or generic) of oseltamivir (Tamiflu®) and zanamivir (Relenza®), along with baloxavir (Xofluza®), and designate one or more preferred products contingent upon statewide influenza epidemiology status as reported by the Centers for Disease Control and Prevention.

Amendment: None

Vote: Unanimous to approve as recommended

McRowe, MD — ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

Stephanie A — ☒ 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

McRowe, MD — ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

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

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

M. **Recommendation:** 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.

Amendment: None

Vote: Unanimous to approve as recommended

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

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

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

N. **Recommendation:** Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products (brand or generic) of baloxavir (Xofluza®), along with oseltamivir (Tamiflu®) and zanamivir (Relenza®), and designate one or more preferred products contingent upon statewide influenza epidemiology status as reported by the Centers for Disease Control and Prevention.

None of the remaining brand miscellaneous antivirals are 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

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

Stephanie A ☒ 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

M. McRae, MD	☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action	Assistant Medical Director
	☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action	Deputy Commissioner
Stephanie A.	☒ 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

M. McRae, MD	☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action	Assistant Medical Director
	☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action	Deputy Commissioner
Stephanie A.	☒ 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

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

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

Stephanie A — ☐ 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

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

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

Stephanie A — ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

Respectfully submitted,

Rachel Bacon

08/03/2023

Rachel Bacon, PharmD, MPH — Date