

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

November 3, 2021

Members Present: Dr. Lee Carter, Dr. Frances Heinze, Dr. Albert Holloway, Dr. Peter Hughes, Dr. Tiffany Lyght, Dr. Charles Nevels, Dr. Kelli Littlejohn Newman, and Dr. Christopher Stanley

Members Absent: None

Presenters: Dr. Eliza Anderson, Dr. Rachel Bacon, and Dr. Thomas Pomfret

1. OPENING REMARKS

Chairperson Carter called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 1:05 p.m.

2. APPROVAL OF MINUTES

Chairperson Carter asked if there were any corrections to the minutes from the May 5, 2021 P&T Committee Meeting.

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

3. PHARMACY PROGRAM UPDATE

Dr. Newman stated that the federal COVID-19 state of emergency has been extended and the end date may continue to change. There have been updates to eyeglass and eye exam benefits for adults and the ambulance reimbursement rate increase has occurred. These updates are available on the website as ALERTs.

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 five 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 1:08 p.m. There were 18 drug class re-reviews from the canceled August meeting. 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 May 2019. There were additionally 19 drug class re-reviews. The first generation antihistamines; estrogens; alpha glucosidase inhibitors; amylinomimetics; biguanides; dipeptidyl peptidase-4 inhibitors; incretin mimetics; insulins; meglitinides; sodium-glucose cotransport 1 inhibitors; sodium-glucose cotransport 2 inhibitors; sulfonylureas; thiazolidinediones; antidiabetic agents, miscellaneous; prenatal vitamins; immunomodulatory agents used to treat multiple sclerosis; and antigout agents were all last reviewed in August 2019. The genitourinary smooth muscle relaxants: antimuscarinics and genitourinary smooth muscle relaxants: beta-3 agonists were last reviewed in November 2020.

Antiprotozoals, Miscellaneous: American Hospital Formulary Service (AHFS) 083092

Manufacturer comments on behalf of these products:

Solosec® - Lupin

Dr. Bacon commented that the miscellaneous antiprotozoals that are included in this review are listed in Table 1 on page 1005. The majority of the agents are available in a generic formulation.

Nifurtimox (Lampit®) has been approved since the last review. It is a nitrofurantoin antiprotozoal, indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American Trypanosomiasis), caused by *Trypanosoma cruzi*. This indication is approved under accelerated approval based on the number of treated patients who became immunoglobulin G (IgG) antibody negative or who showed an at least 20% decrease in optical density on two different IgG antibody tests against antigens of *T. cruzi*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Nitazoxanide has been added back into the review. The antiprotozoal activity of nitazoxanide is thought to be due to interference with the pyruvate:ferredoxin oxidoreductase enzyme-dependent electron transfer reaction, which is essential to anaerobic energy metabolism.

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.

Allylamines: AHFS 081404

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that terbinafine is the only allylamine included in this review. The topical antifungals were previously reviewed with the skin and mucous membrane agents (AHFS 840408) and are not included in this review. Terbinafine tablets 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.

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 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. 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 isavuconazonium.

A new formulation of itraconazole, Tolsura[®], has been approved since the last review. The bioavailability of Tolsura[®] 65 mg capsules is approximately double that of conventional 100 mg itraconazole capsules. Therefore, it is not interchangeable or substitutable with other itraconazole products. These agents are approved to treat a variety of fungal infections and 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 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 172. Caspofungin and micafungin are available in a generic formulation. Anidulafungin has gained approval for use in patients one month of age and older. Micafungin gained approval for the treatment of candidemia, acute disseminated candidiasis, candida peritonitis and abscesses *without* meningoencephalitis and/or ocular dissemination in pediatric patients *younger than 4 months of age*. There have been no other 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 242. 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.

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 339. 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. 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 griseofulvin is the only miscellaneous antifungal agent that is currently available. All products 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.

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

Antituberculosis Agents: AHFS 081604

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the antituberculosis agents that are included in this review are listed in Table 1 on page 399. Cycloserine, ethambutol, isoniazid, pretomanid, pyrazinamide, rifabutin, and rifampin 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. Pretomanid is a newly included agent, and it is indicated, as part of a combination regimen with bedaquiline and linezolid, for the treatment of adults with pulmonary extensively drug resistant, treatment-intolerant or nonresponsive multidrug-resistant tuberculosis.

Treatment of latent tuberculosis consists of three preferred and two alternative regimens. Rifamycin-based regimens, including three months of once-weekly isoniazid plus rifapentine, four months of daily rifampin, and three months of daily isoniazid plus rifampin are the preferred recommended regimens because of their effectiveness, safety, and high treatment completion rates. Regimens of six or nine months of daily isoniazid are alternative recommended regimens; although efficacious, they have higher toxicity risk and lower treatment completion rates, which decrease effectiveness. Isoniazid plus rifapentine for three months is recommended for adults and children aged >2 years, including HIV-positive persons as drug interactions allow. Rifampin for four months is recommended for HIV-negative adults and children of all ages. Isoniazid plus rifampin for three months is conditionally recommended for adults and children of all ages and for HIV-positive persons as drug interactions allow. Isoniazid for six months is recommended for HIV-negative adults, children of all ages, and conditionally for HIV-positive adults and children of all ages. Isoniazid for nine months is conditionally recommended for adults and children of all ages, both HIV-negative and HIV-positive.

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. Bacon 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. The World Health Organization guidelines were updated in 2018 to recommend a three-drug regimen of rifampicin, dapson, and clofazimine for all leprosy patients, with a duration of treatment of six months for paucibacillary leprosy and 12 months for multibacillary leprosy. Previously the recommendation for paucibacillary leprosy included only rifampicin and dapson.

Therefore, 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. Bacon commented that the adamantanes that are included in this review are listed in Table 1 on page 495. 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.

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 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 542. 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. Interferon alfa-2a and peginterferon alfa-2a were shown to be equally effective following 48 weeks of treatment.

The treatment for HCV infection has evolved substantially since the introduction of highly effective HCV protease inhibitor therapies in 2011. In general, combination regimens that include newer direct hepatitis C antivirals are preferred over older pegylated interferon-based regimens (including those containing older protease inhibitors) due to a higher SVR rate, improved side effects profile, and reduced pill burden. Current HCV treatment guideline recommendations do not recommend use of interferon products. Peginterferon and ribavirin, typically in combination with a direct-acting antiviral, remain in use for certain genotypes, particularly in resource-limited settings where newer interferon-free regimens are not accessible.

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 2020 Centers for Disease Control and Prevention (CDC): Influenza Antiviral Medications guidance 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. Pomfret commented that the nucleosides and nucleotides that are included in this review are listed in Table 1 on page 670. 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.

Additionally, remdesivir has been approved for the treatment of COVID-19 requiring hospitalization in patients ≥ 12 years old and ≥ 40 kg weight.

As outlined in the interferon review, for the treatment of chronic hepatitis C, treatment guidelines developed by the American Association for the Study of Liver Diseases and Infectious Diseases Society of America in general recommend combination regimens that include newer HCV antivirals over older peginterferon-based regimens due to a higher SVR rate, improved side effects profile, and reduced pill burden. Recommended regimens may include ribavirin to improve SVR rates in certain difficult-to-treat populations (e.g., based on HCV genotype, prior treatment history, presence of cirrhosis, or when used in certain special populations).

Remdesivir is the first FDA-approved agent for the treatment of coronavirus 2019 in patients ≥ 12 years of age, weighing ≥ 40 kg, and requiring hospitalization. It is recommended for use in hospitalized patients who require supplemental oxygen. However, it is not routinely recommended for patients who require mechanical ventilation due to the lack of data showing benefit at this advanced stage of the disease.

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

HCV Antivirals: AHFS 081840

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the HCV antivirals that are included in this review are listed in Table 1 on page 803. This review encompasses all dosage forms and strengths. Harvoni[®] and Epclusa[®] have an available authorized generic. Sofosbuvir is now available in a pellet pack which is approved for patients ≥ 3 years of age. Ledipasvir-sofosbuvir has also been approved for children as young as 3 years of age, and Sofosbuvir-velpatasvir has been approved for patients ≥ 6 years of age and weighing ≥ 17 kg.

Prior to the availability of HCV antivirals, combination of peginterferon and ribavirin has been the standard of care for the treatment of chronic hepatitis C. According to treatment guidelines developed by the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA), in general, combination regimens that include newer HCV antivirals are preferred over older peginterferon-based regimens due to a higher SVR rate, improved side effects profile, and reduced pill burden. However, recommended regimens may occasionally include ribavirin to improve SVR rates in certain difficult-to-treat populations (e.g.,

based on HCV genotype, prior treatment history, presence of cirrhosis, or when used in certain special populations). The guidelines also state that although regimens of sofosbuvir and ribavirin or pegylated interferon/ribavirin plus sofosbuvir are FDA-approved for particular genotypes, they are inferior to the current recommended regimens. The interferon-containing regimens are associated with higher rates of serious adverse events (e.g., anemia and rash), longer treatment duration in some cases, high pill burden, numerous drug-drug interactions, more frequent dosing, and higher intensity of monitoring for safety or treatment response.

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 with direct-acting agents or combinations, which may or may not also include ribavirin, 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. Direct-acting antivirals have not been directly compared in clinical trials.

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 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.

Antivirals, Miscellaneous: AHFS 081892

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the miscellaneous antivirals included in this review are listed in Table 1 on page 891. Foscarnet is available in a generic formulation. Baloxavir (Xofluza[®]) is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and has gained additional approval for post-exposure prophylaxis of influenza in patients 12 years of age and older following contact with an individual who has influenza.

The 2020 Centers for Disease Control and Prevention (CDC): Influenza Antiviral Medications guidance 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. Pomfret 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. Pomfret commented that the antimalarials that are included in this review are listed in Table 1 on page 936. These agents are approved for the prevention and treatment of malaria. Most of the

agents are available in a generic formulation. Tafenoquine (Krintafel®) has been approved since the last review. It is an 8-aminoquinoline antimalarial drug approved for the radical cure (prevention of relapse) of *P. vivax* malaria in patients ≥ 16 years of age who are receiving appropriate antimalarial therapy for acute *P. vivax* infection. Due to its prolonged excretion, tafenoquine can only be administered to nonpregnant individuals ≥ 16 years of age with G6PD (glucose-6-phosphatase dehydrogenase) activity $>70\%$ of normal activity whereas primaquine can be administered to nonpregnant individuals >6 months of age with G6PD activity $>30\%$ of normal activity.

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.

Urinary Anti-infectives: AHFS 083600

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the urinary anti-infectives that are included in this review are listed in Table 1 on page 1093. 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.

Incretin Mimetics: AHFS 682006

Manufacturer comments on behalf of these products:

Ozempic® - NovoNordisk

Rybelsus® - NovoNordisk

Dr. Anderson commented that the incretin mimetics included in this review are listed in Table 1 on page 480. All incretin mimetics are FDA approved for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Byetta® and Bydureon® contain the same active ingredient, exenatide. Bydureon® is a long-acting formulation of exenatide. There are no incretin mimetics available generically.

Since the last review, one new incretin mimetic has been approved. Rybelsus® (semaglutide) was approved in 2019. Rybelsus® contains the same active ingredient as Ozempic®, semaglutide. Rybelsus® is the first orally available GLP-1 agonist. Victoza® (liraglutide) and Ozempic® (semaglutide) are approved to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. Trulicity® (dulaglutide) is also approved to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. Bydureon® and Victoza® are approved for use in patients 10 years of age and older.

According to current clinical guidelines for the management of type 2 diabetes, metformin remains the cornerstone of most antidiabetic treatment regimens. At this time, uniform recommendations on the best agent to be combined with metformin cannot be made; therefore, advantages and disadvantages of specific antidiabetic agents for each patient should be considered. Updated guidelines recommend that independent of glycemic control, if established atherosclerotic cardiovascular disease (ASCVD) or high risk, chronic kidney disease stage 3, or heart failure with reduced ejection fraction (HFrEF), start long-acting GLP-1 receptor agonist or SGLT2 inhibitor with proven efficacy (current incretin mimetics with cardiovascular benefit include liraglutide, injectable semaglutide, exenatide extended-release). Specifically, for patients with type 2 diabetes and established atherosclerotic cardiovascular disease where major adverse cardiovascular events is the gravest threat, the level of evidence for major adverse cardiovascular events benefit is greatest for GLP-1 receptor agonists.

According to FDA-approved package labeling, due to the uncertain relevance of the rat thyroid C-cell tumor findings to humans, exenatide (Bydureon®), and semaglutide (Rybelsus®) are not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise. Liraglutide, dulaglutide, and semaglutide (Ozempic®) also have the warning for the risk of thyroid C-cell tumors, but may be used as first-line therapy in patients with compelling indications.

In 2019, Rybelsus® (semaglutide) was approved as an oral formulation based on the PIONEER 1 trial. It was a multicenter, randomized, double-blind, parallel-group, placebo-controlled trial investigating the effects of 3 mg, 7 mg, and 14 mg semaglutide compared to placebo, in patients with type 2 diabetes insufficiently controlled with diet and exercise with HbA1c 7.0 to 9.5% (n=703). The primary outcome was change in HbA1c from baseline. Monotherapy with 7 mg and 14 mg once daily for 26 weeks resulted in a statistically significant reduction in HbA1c compared with placebo (-1.2% and -1.4% vs -0.3%, respectively; P<0.001 for both comparisons). The secondary endpoints involving measures of glycemic control, weight loss, and lipid levels favored semaglutide over placebo. Both strengths were also associated with decreases in body weight (-2.3 kg and -3.7 kg vs -1.4 kg, respectively; P<0.001 for both comparisons).

There is insufficient evidence to support that one brand incretin mimetic is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process. The incretin mimetics that have demonstrated cardiovascular disease benefit (currently liraglutide, injectable semaglutide, and exenatide extended-release) should be available for treatment of patients with type 2 diabetes and cardiovascular disease.

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

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

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

Immunomodulatory Agents used to treat Multiple Sclerosis: AHFS 922000

Manufacturer comments on behalf of these products:

Ocrevus® - Genentech

Ponvory® - Janssen

Dr. Bacon commented that several immunomodulatory agents are Food and Drug Administration (FDA)-approved for the treatment of patients with multiple sclerosis (MS), including six agents that have been approved since the last review, as listed in Table 1 on page 1154.

Vumerity® (diroximel fumarate) is approved for the treatment relapsing forms of MS in adults. Diroximel fumarate was approved as a new dosage form of dimethyl fumarate (Tecfidera®) via the 505(b)(2) drug approval pathway. Diroximel fumarate, similar to dimethyl fumarate (Tecfidera®), is a fumaric acid ester prodrug that is metabolized to active monomethyl fumarate prior to systemic circulation. Monomethyl fumarate is thought to act by modulating cell-signaling pathways, but the exact mechanism of action in MS is unknown. FDA-approval of diroximel fumarate was established based on bioavailability studies in patients with RMS comparing dimethyl fumarate

and diroximel fumarate.³ Monomethyl fumarate (Bafiertam DR[®]) is also indicated for the treatment of relapsing forms of MS. Similar to Vumerity[®], because of its similarity to Tecfidera[®], Bafiertam's approval was based largely on the FDA's findings of safety and efficacy for Tecfidera[®] and bioavailability studies in healthy subjects comparing dimethyl fumarate to Bafiertam[®].

Ofatumumab (Kesimpta[®]) is a recombinant human monoclonal immunoglobulin G1 (IgG1) antibody that binds to human CD20 expressed on B-cells. Following cell surface binding to B lymphocytes, ofatumumab results in antibody-dependent cellular cytotoxicity and complement-mediated lysis. Kesimpta[®] is the first B-cell therapy that can be self-administered once monthly at home. It is a subcutaneous injection indicated for the treatment of relapsing forms of MS.

Ozanimod (Zeposia[®]) is a sphingosine-1-phosphate (S1P) receptor modulator approved by the FDA for the treatment of relapsing forms of MS in adults. The mechanism by which S1P modulators exert their therapeutic effects in MS is unknown, but is hypothesized to reduce lymphocyte migration into the central nervous system (CNS) via binding to the S1P-1 receptor subtype. Siponimod (Mayzent[®]) is indicated for the treatment of adults with relapsing forms of MS, and it is also a S1P receptor modulator. Ponesimod (Ponvory[®]) is the fourth S1P receptor modulator approved by the FDA for the treatment of relapsing forms of MS in adults. In addition to ponesimod (Ponvory[®]), there are currently three other S1P modulators approved for RMS, fingolimod (Gilenya[®]), siponimod (Mayzent[®]) and ozanimod (Zeposia[®]). The primary difference between agents is their affinity to different S1P receptor subtypes. Fingolimod binds with high affinity to four S1P subtypes (1, 3, 4 and 5), siponimod and ozanimod to two subtypes (1 and 5) and ponesimod to one subtype (1). While binding of S1P-1 is thought to be therapeutic in RMS, binding of S1P-3 is suspected to increase the risk of cardiac adverse events such as bradyarrhythmia and atrioventricular blocks. Because fingolimod binds S1P-3 with high affinity, the risk of cardiac adverse events is increased, particularly after the first dose. As such, first dose monitoring is required and fingolimod is contraindicated in patients with certain preexisting cardiac disease. Ponesimod, siponimod, and ozanimod bind to S1P-3 with very low affinity, although some binding does still occur and thus potential for cardiac adverse events continue to exist. For siponimod and ponesimod, first dose cardiac monitoring is recommended only in higher-risk patients while first-dose monitoring is not required for ozanimod. Differences in cardiac adverse events have not been directly compared and potential differences are not well defined. Serious, non-cardiac adverse events that are common among MS Agents (e.g., infections, fetal risks) and S1P receptor modulators (e.g., liver injury, respiratory effects, macular edema, rebound exacerbation after discontinuation, increased risk of malignancy) remain potential issues.

Current clinical guidelines generally recommend the immunomodulatory agents as first line agents. All available agents have been shown to decrease MRI lesion activity, prevent relapses, delay disease progression, and ultimately reduce disability from MS. The goals of MS therapy include slowing disease progression, reducing relapse rate and preventing or postponing long-term disability. Guidelines from the American Academy of Neurology (AAN) and the MS Coalition recommend patient specific factors guide therapy. Specifically, the AAN guideline recommends alemtuzumab, fingolimod, or natalizumab for patients with highly-active RRMS. Revised guidance from the Association of British Neurologists categorize therapies for relapsing remitting MS into two groups including agents of moderate efficacy (β -interferons, glatiramer acetate, teriflunomide,

dimethyl fumarate, and fingolimod) and agents of high efficacy (alemtuzumab and natalizumab). They recommend starting with a moderate efficacy therapy given the improved safety profile. Clinical guidelines do not currently recommend therapy for individuals with PPMS, though it should be noted that at the time the draft guidelines were published, the FDA had not issued a decision on ocrelizumab. Guidelines have not been updated to incorporate specific recommendations for the newly approved agents. Guidelines recommend the use of alemtuzumab in highly active MS; however, because of its safety profile, the use of alemtuzumab should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

The most frequently reported adverse events associated with IFN β therapy are influenza-type symptoms, injection site reactions, headache, nausea, and *musculoskeletal* pain. Rare cases of hepatic toxicity have occurred in patients who were treated with IFN therapy. Therapy with IFN β should be used cautiously in patients with depression or other mood disorders. Patients receiving glatiramer acetate therapy may experience a transient, self-limiting, post-injection systemic reaction (flushing, chest pain, palpitations, anxiety, dyspnea, throat constriction, and/or urticaria) immediately following drug administration. Ocrelizumab may cause infusion reactions and has been associated with an increased risk of infections and malignancies. Similarly, ofatumumab has also been associated with an increased risk of infections as has been observed with other anti-CD20 B-cell depleting therapies. Fingolimod has been associated with cardiac-related death and thus requires cardiac monitoring. It is contraindicated in patients with certain pre-existing cardiovascular conditions. There are now four S1P modulators available that have differing affinities to the S1P receptor subtypes. Ponesimod, siponimod and ozanimod bind to S1P-3 with very low affinity, although some binding does still occur and thus potential for cardiac adverse events continue to exist. Teriflunomide has boxed warnings regarding hepatotoxicity and its risk of teratogenicity. Dimethyl fumarate appears to have the most mild side effect profile with its most common adverse events being flushing and gastrointestinal effects. There are now multiple fumarate therapies available, and diroximel fumarate has been shown to have less gastrointestinal side effects than dimethyl fumarate. Natalizumab increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with natalizumab, physicians should consider whether the expected benefit is sufficient to offset this risk. Natalizumab is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TOUCH[®] Prescribing Program because of the risk of PML. Because of the risks of autoimmune conditions, stroke, and increased risk of malignancies, alemtuzumab is also available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the LEMTRADA REMS Program. Because of its safety profile, the use of alemtuzumab should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

There is insufficient evidence to support that one brand immunomodulatory agent used to treat multiple sclerosis is safer or more efficacious than another within its given indication, with the exception of safety concerns associated with alemtuzumab use. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process. Because of its safety profile, the use of alemtuzumab should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Therefore, all brand immunomodulatory agent used to treat multiple sclerosis, with the exception of alemtuzumab, within the class reviewed are comparable to each other and to the generic products in the class (if applicable) within their given indications and offer no significant clinical advantage over other alternatives in general use.

No brand immunomodulatory agent used to treat multiple sclerosis 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.

Alemtuzumab should not be placed in preferred status regardless of cost.

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

First Generation Antihistamines: Ethanolamine Derivatives, AHFS 040404; Ethylenediamine Derivatives AHFS 040408; and Propylamine Derivatives AHFS 040420

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the first generation antihistamines included for this review are listed in Table 1 on page 10. The first generation antihistamines are approved for use in several allergic and nonallergic conditions; however, these agents are primarily utilized for the treatment of allergic rhinitis, urticaria, and angioedema. The majority of these agents 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 first generation antihistamine is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

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

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

Estrogens: AHFS 681604

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the estrogens that are included in this review are listed in Table 1 beginning on page 75. Estradiol, estradiol valerate, estradiol-norethindrone, and norethindrone-ethinyl estradiol are available in a generic formulation. Bijuva® (estradiol and progesterone) has been approved since the last review in woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause. The estrogens are available in a variety of dosage forms, including injectable, oral, topical, transdermal, and vaginal preparations. 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 estrogen is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

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

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

Alpha Glucosidase Inhibitors: AHFS 682002

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the alpha-glucosidase inhibitors are approved for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The alpha-glucosidase inhibitors that are included in this review are listed in Table 1 on page 183. Acarbose and miglitol are both 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 alpha-glucosidase inhibitor is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

No brand alpha-glucosidase 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. Chairperson Carter asked the P&T Committee members to mark their ballots.

Amylinomimetics: AHFS 682003

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that pramlintide is the only amylinomimetic agent currently available. It is approved for use as an adjunctive treatment in patients with type 1 and type 2 diabetes mellitus who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy. 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 amylinomimetic is safer or more efficacious than another within its given indication. Since pramlintide is only approved for use as an adjunctive treatment in patients with type 1 and type 2 diabetes mellitus, it should be managed through the existing medical justification portion of the prior authorization process.

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

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

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

Biguanides: AHFS 682004

Manufacturer comments on behalf of these products:

None

Dr. Anderson commented that metformin remains the only biguanide that is currently available. It is FDA-approved as adjunct therapy to diet and exercise to improve glycemic control in patients with type 2 diabetes. Metformin is available as an immediate release tablet, extended-release tablet, and solution. Both the immediate- and extended-release tablets are available generically.

Metformin remains the recommended first-line therapy for most antidiabetic treatment regimens and remains the cornerstone to most combination dual and triple therapy regimens. Among current treatment guidelines, preference of one formulation of metformin over another is not stated.

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

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

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

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

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: AHFS 682005

Manufacturer comments on behalf of these products:

None

Dr. Anderson commented that the DPP-4 inhibitors included in this review are listed in Table 1 on page 373. Alogliptin and alogliptin combination products are available in a generic formulation; metformin and pioglitazone are also available generically in separate formulations. 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 DPP-4 inhibitor is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process. Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand DPP-4 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. Chairperson Carter asked the P&T Committee members to mark their ballots.

Insulins: AHFS 682008

Manufacturer comments on behalf of these products:

None

Dr. Anderson commented that the insulins that are included in this review are listed in Table 1 on page 600. There are no generic formulations of insulin; however, there are several products available over-the-counter. Additionally, an authorized generic formulation of Humalog® (insulin lispro injection) is available.

Three new formulations have been approved since the last review. Lyumjey® (insulin lispro injection) is a rapid-acting human insulin analog. This agent can be dosed at the beginning of a

meal or within 20 minutes after starting a meal. It is designed to have a quicker onset of action and shorter duration of action overall compared to Humalog® (insulin lispro). Myxredlin® (insulin regular) is a short-acting insulin and is the first ready-to-use insulin for IV infusion. Semglee® (insulin glargine-yfgn) is the first interchangeable biosimilar product and is interchangeable with Lantus® (insulin glargine).

In general, insulin is FDA-approved for use in type 1 and 2 diabetes. Essentially all insulin products act the same and have comparable efficacy among them; the primary differences between the products revolve around pharmacokinetic and pharmacodynamic properties. Insulin is the standard of care for patients with type 1 diabetes.

Insulin analogs have been shown to be at least as effective, or more effective, than human insulin. In several studies, there was a lower risk of hypoglycemia with the insulin analogs compared to human insulin. There is insufficient evidence to conclude that one rapid-acting insulin analog is safer or more efficacious than another. There is also insufficient evidence to conclude that one long-acting insulin analog is safer or more efficacious than another.

Therefore, all brand products within the class reviewed, with the exception of rapid-acting and long-acting insulin analogs, are comparable to each other and to the generics and over-the-counter products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Rapid-acting insulin analogs offer significant clinical advantages in general use over short-acting human insulin but are comparable to each other. Long-acting insulin analogs offer significant clinical advantages in general use over intermediate-acting human insulin but are comparable to each other.

No brand insulin, with the exception of rapid-acting and long-acting insulin analogs, 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 rapid-acting insulin analog is selected as a preferred agent.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand long-acting insulin analog is selected as a preferred agent.

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

Meglitinides: AHFS 682016

Manufacturer comments on behalf of these products:

None

Dr. Anderson commented that the meglitinides included in this review are listed in Table 1 on page 768. Nateglinide and repaglinide 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 meglitinide is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process. Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

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

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

Sodium-glucose Cotransport 1 Inhibitors: AHFS Class 682017

Manufacturer comments on behalf of these products:

None

Dr. Anderson commented that currently there are no prescription medications classified by AHFS as Sodium-glucose Cotransport 1 Inhibitors. No SGLT1 inhibitor is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 682017 in the Preferred Drug List screening process. If new prescription sodium-glucose cotransport 1 inhibitors are added, it is recommended that this class be re-reviewed.

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

Sodium-glucose Cotransport 2 Inhibitors: AHFS Class 682018

Manufacturer comments on behalf of these products:

None

Dr. Anderson commented that the sodium-glucose cotransport 2 (SGLT2) inhibitors included in this review are listed in Table 1 on page 817. There are no generic products available. One new agent has been included since the last review, Trijardy XR® (empagliflozin, linagliptin, and metformin). All SGLT2 inhibitors are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin, dapagliflozin, and empagliflozin also have cardiovascular indications, and canagliflozin and dapagliflozin also have renal indications.

According to current clinical guidelines for the management of type 2 diabetes, metformin remains the cornerstone to most antidiabetic treatment regimens. Additionally, patients with a high glycosylated hemoglobin (HbA1c) will most likely require combination or triple therapy in order to achieve glycemic goals. At this time, uniform recommendations on the best agent to be

combined with metformin cannot be made; therefore, advantages and disadvantages of specific antidiabetic agents for each patient should be considered. SGLT2 inhibitors are recommended as a potential first, second, or third-line treatment option to be added as an alternative to or in combination with metformin in patients not achieving glycemic goals. SGLT2 inhibitors are acceptable therapeutic alternatives that reduce glucose without weight gain or hypoglycemia. According to the 2021 update of the American Diabetes Association Standards of Medical Care in Diabetes, in patients with type 2 diabetes who have established atherosclerotic cardiovascular disease (ASCVD), heart failure, or chronic kidney disease, choose a SGLT2 inhibitor or GLP-1 receptor agonist that has demonstrated cardiovascular disease benefit for add-on therapy with metformin. According to the 2019 update of the Management of Hyperglycemia in Type 2 Diabetes and the 2020 Consensus Statement on the Comprehensive Type 2 Diabetes Management Algorithm, in appropriate high-risk individuals with established type 2 diabetes, the decision to treat with a GLP-1 receptor agonist or SGLT2 inhibitor to reduce MACE, hospitalization for HF, CV death, or CKD progression should be considered independently of baseline HbA1c or individualized HbA1c target.

Based on an FDA review of new data from three clinical trials, the Boxed Warning about amputation risk was removed from canagliflozin products prescribing information.

Dapagliflozin demonstrated benefit compared to placebo in a composite renal outcome, which occurred in 197 participants (9.2%) in the dapagliflozin group and 312 participants (14.5%) in the placebo group (HR, 0.61; $P < 0.001$) in the DAPA-CKD trial. Dapagliflozin has gained the indication to reduce the risk of sustained eGFR decline, end stage kidney disease cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. The CREDENCE trial compared canagliflozin to placebo for a composite renal outcome in patients with type 2 diabetes mellitus and chronic kidney disease, demonstrating that a relative risk of the primary outcome was 30% lower in the canagliflozin group than in the placebo group, with event rates of 43.2 and 61.2 per 1000 patient-years, respectively (HR, 0.70; $P = 0.00001$). Canagliflozin gained approval to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria.

Dapagliflozin and empagliflozin have both demonstrated benefit compared to placebo in composite cardiovascular outcomes. Dapagliflozin gained approval to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV) and to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors. Empagliflozin is also approved to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

A variety of warnings and precautions are listed in the package inserts for the SGLT2 inhibitors, including risks for hypotension, ketoacidosis, acute kidney injury, urosepsis and pyelonephritis, hypoglycemia, necrotizing fasciitis of the perineum (Fournier's Gangrene), genital mycotic infections, hypersensitivity reactions, bone fracture, and increased LDL-C. During clinical trials, common adverse side effects associated with the SGLT2 inhibitors included increased incidence of female genital mycotic infections, urinary tract infection, and increased urination.

There is insufficient evidence to support that one brand sodium-glucose cotransport 2 inhibitor is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process. The SGLT2 inhibitors that have demonstrated cardiovascular disease benefit (currently canagliflozin, dapagliflozin, and empagliflozin) should be available for treatment of patients with type 2 diabetes and atherosclerotic cardiovascular disease (or for heart failure with reduced ejection fraction for dapagliflozin and empagliflozin), and agents that have demonstrated kidney disease benefit (currently canagliflozin and dapagliflozin) should be available for treatment of patients with (canagliflozin) or without (dapagliflozin) type 2 diabetes and end-stage kidney disease.

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

No brand sodium-glucose cotransport 2 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. Chairperson Carter asked the P&T Committee members to mark their ballots.

Sulfonylureas: AHFS 682020

Manufacturer comments on behalf of these products:

None

Dr. Anderson commented that the sulfonylureas included in this review are listed in Table 1 on page 883. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed. The sulfonylureas are FDA-approved for use as an adjunct therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes. All sulfonylureas are available in a generic formulation, including the fixed-dose combination products.

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

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

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

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

Thiazolidinediones: AHFS 682028

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the thiazolidinediones that are included in this review are listed in Table 1 on page 1002. Pioglitazone, pioglitazone-glimepiride, and pioglitazone-metformin are available in generic formulations. Metformin and glimepiride are also available generically in separate formulations. 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 thiazolidinedione 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 products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

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

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

Antidiabetic Agents, Miscellaneous: AHFS 682092

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that Mifepristone (Korlym[®]) is classified as an antidiabetic agent, miscellaneous by the American Hospital Formulary Service. Mifepristone is a cortisol receptor blocker that the Food and Drug Administration (FDA)-approved to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and have failed surgery or are not candidates for surgery.

The Endocrine Society Clinical Practice Guidelines for the Treatment of Cushing's Syndrome suggests administering mifepristone in patients with diabetes or glucose intolerance who are not surgical candidates or who have persistent disease after transsphenoidal selective adenomectomy.

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

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

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

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

Multivitamin Preparations: Prenatal Vitamins: AHFS 882800

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the prenatal vitamins that are included in this review are listed in Table 1 on page 1126. It should be noted that the products included in this review contain an extensive ingredient list, which can be found separately in the prescribing information. The term “prenatal vitamins” in Table 1 collectively refers to all active vitamin and mineral ingredients. Additional ingredients, including folic acid and iron, have been listed out separately. Many of the prenatal vitamins are available in a generic formulation, including products which contain omega-3 fatty acids. 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 prenatal vitamin is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

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

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

Antigout Agents: AHFS 921600

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the antigout agents that are included in this review are listed in Table 1 on page 1271. All products are currently available in a generic formulation, with the exception of

pegloticase. Gloperba® is a new oral solution formulation of colchicine. 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 antigout agent is more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand antigout agents within the class reviewed, with the exception of the febuxostat and pegloticase, 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. Febuxostat and pegloticase possess extensive adverse effect profiles compared to the other brands and generics in the class (if applicable) and should be managed through the medical justification portion of the prior authorization process.

No brand antigout 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.

Febuxostat and pegloticase should not be placed in preferred status, regardless of cost.

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

Genitourinary Smooth Muscle Relaxants- Antimuscarinics: AHFS 861204

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the genitourinary smooth muscle relaxants- antimuscarinics included in this review are listed in Table 1 on page 1325. All of the agents with the exception of fesoterodine are available in a generic formulation. A solifenacin oral suspension has become available. Fesoterodine has gained approval for the treatment of neurogenic detrusor overactivity in pediatric patients six years of age and older with a body weight greater than 25 kg. There have been no other 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 antimuscarinic genitourinary smooth muscle relaxant is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

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

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

Genitourinary Smooth Muscle Relaxants- Beta-3 Adrenergic Agonists: AHFS 861208

Manufacturer comments on behalf of these products:

None

Dr. Bacon noted that the beta-3 adrenergic agonist genitourinary smooth muscle relaxants included in this review are listed in Table 1 on page 1438. Mirabegron (Myrbetriq[®]) is the first beta-3 adrenergic receptor agonist to be approved for the treatment of overactive bladder, and vibegron (Gemtesa[®]) is the second. Beta-3 adrenergic receptor agonists relax the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle which increases bladder capacity. Because they act via the beta-3 adrenergic receptor rather than through muscarinic cholinergic receptors, these agents may have a better tolerability profile compared to other urinary antispasmodics. Mirabegron is also approved for the treatment of neurogenic detrusor overactivity in pediatric patients aged three years and older.

The FDA approval of vibegron was based on the 12-week, double-blind, placebo- and active-controlled, phase III EMPOWUR randomized controlled trial including 1,518 patients with overactive bladder. At 12 weeks micturitions decreased by an adjusted mean of 1.8 episodes per day for the vibegron group compared to 1.3 for the placebo group (P<0.001) and 1.6 for the tolterodine group. Among incontinent patients urge urinary incontinence episodes decreased by an adjusted mean 2.0 episodes per day for the vibegron group compared to 1.4 for the placebo group (P<0.0001) and 1.8 for the tolterodine group. Specific recommendations for vibegron have not been added into guidelines.

There is insufficient evidence to support that one brand beta-3 adrenergic agonist genitourinary smooth muscle relaxant is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand beta-3 adrenergic agonist genitourinary smooth muscle relaxants within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand beta-3 adrenergic agonist genitourinary smooth muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson 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 will be communicated via e-mail. Results of voting are described in the Appendix to the minutes.

7. NEW BUSINESS

Voting results for the Vice-chairperson will also be sent via e-mail.

8. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for February 9, 2022 at the Medicaid Building in the Commissioner's Board Room.

9. ADJOURN

There being no further business, Dr. Nevels moved to adjourn and Dr. Hughes seconded. The meeting adjourned at 2:56 p.m.

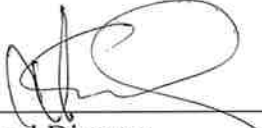
Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
November 3, 2021

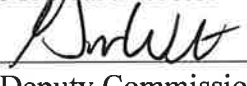
- A. Recommendation:** No brand allylamine is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

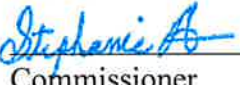
Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action

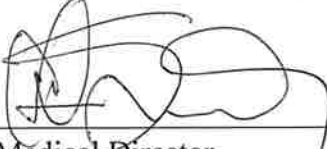


Commissioner Approve Approve as amended Disapprove No action


- 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



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

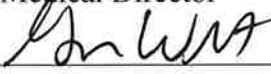
C. Recommendation: No brand echinocandin is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None


Vote: Unanimous to approve as recommended



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

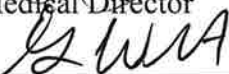
D. Recommendation: No brand polyene is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

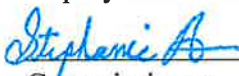
Vote: Unanimous to approve as recommended



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

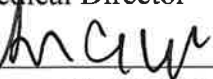
E. Recommendation: No brand pyrimidine is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None


Vote: Unanimous to approve as recommended



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

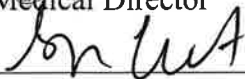
F. Recommendation: No brand miscellaneous antifungal is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

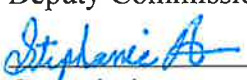
Vote: Unanimous to approve as recommended



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


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



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



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

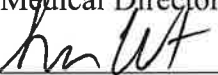
I. **Recommendation:** No brand adamantane is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

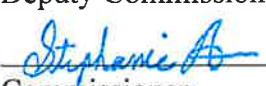
Vote: Unanimous to approve as recommended



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

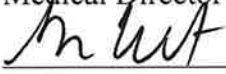
J. **Recommendation:** No brand interferon alfa product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

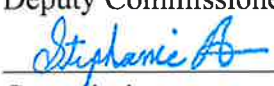
Vote: Unanimous to approve as recommended



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

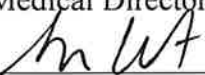
K. Recommendation: Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products (brand or generic) of oseltamivir (Tamiflu®) and zanamivir (Relenza®), along with baloxavir (Xofluza®), and designate one or more preferred products contingent upon statewide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

Amendment: None


Vote: Unanimous to approve as recommended



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

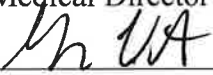
L. Recommendation: No brand nucleoside or nucleotide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None


Vote: Unanimous to approve as recommended



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


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

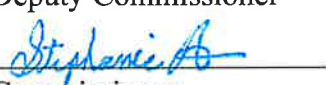
Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action



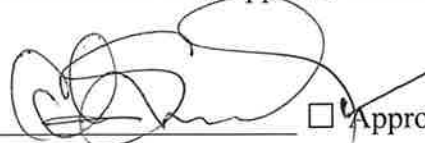
Commissioner Approve Approve as amended Disapprove No action

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.

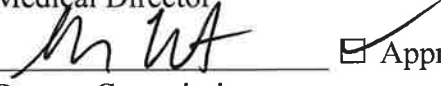
None of the remaining brand miscellaneous antivirals are recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

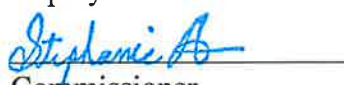
Vote: Unanimous to approve as recommended



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


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

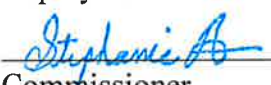
Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action

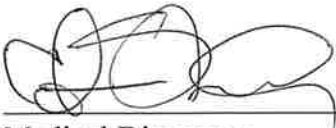


Commissioner Approve Approve as amended Disapprove No action


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

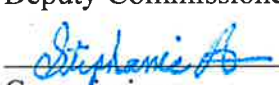
Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action

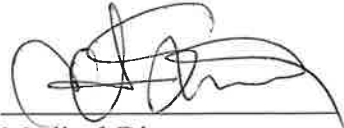


Commissioner Approve Approve as amended Disapprove No action

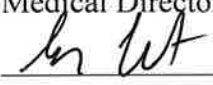
Q. Recommendation: No brand miscellaneous antiprotozoal is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

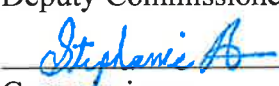
Vote: Unanimous to approve as recommended



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

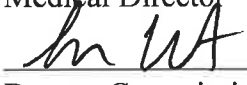
R. Recommendation: No brand urinary anti-infective is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

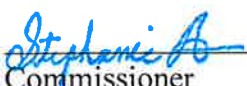
Vote: Unanimous to approve as recommended



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


S. **Recommendation:** No brand first generation antihistamine 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

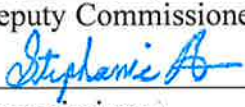
Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action

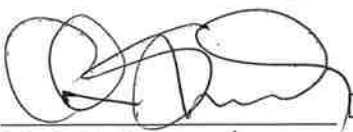


Commissioner Approve Approve as amended Disapprove No action

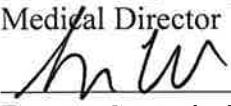
T. **Recommendation:** No brand estrogen is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

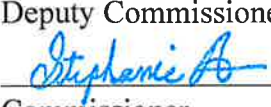
Vote: Unanimous to approve as recommended



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


U. **Recommendation:** No brand alpha glucosidase 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

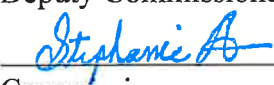
Vote: Unanimous to approve as recommended



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

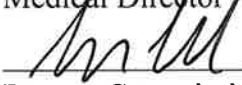
V. **Recommendation:** No brand amylinomimetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

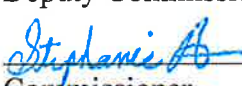
Vote: Unanimous to approve as recommended



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

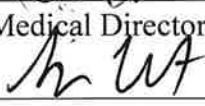
W. Recommendation: No brand biguanide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

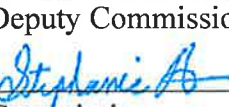
Vote: Unanimous to approve as recommended



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

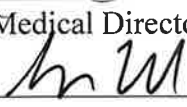
X. Recommendation: No brand dipeptidyl peptidase-4 inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

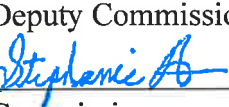
Vote: Unanimous to approve as recommended



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

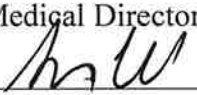
Y. Recommendation: No brand incretin mimetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

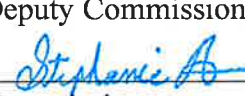
Vote: Unanimous to approve as recommended



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


Z. Recommendation: No brand insulin, with the exception of rapid-acting and long-acting insulin analogs, 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 rapid-acting insulin analog is selected as a preferred agent.

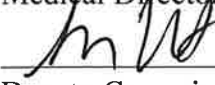
Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand long acting insulin analog is selected as a preferred agent.

Amendment: None

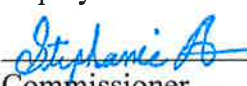
Vote: Unanimous to approve as recommended



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

AA. Recommendation: No brand meglitinide 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


_____ Approve Approve as amended Disapprove No action

Medical Director

_____ Approve Approve as amended Disapprove No action

Deputy Commissioner

_____ Approve Approve as amended Disapprove No action

Commissioner

BB. Recommendation: No sodium-glucose cotransport 1 inhibitor is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 682017 in the Preferred Drug List screening process. If new prescription sodium-glucose cotransport 1 inhibitors are added, it is recommended that this class be re-reviewed.

Amendment: None

Vote: Unanimous to approve as recommended


_____ Approve Approve as amended Disapprove No action

Medical Director

_____ Approve Approve as amended Disapprove No action

Deputy Commissioner


_____ Approve Approve as amended Disapprove No action

Commissioner

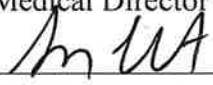
CC. Recommendation: No brand sodium-glucose cotransport 2 inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

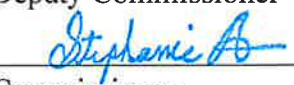
Vote: Unanimous to approve as recommended



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

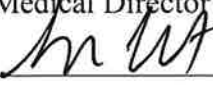
DD. Recommendation: No brand sulfonylurea is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

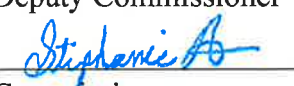
Vote: Unanimous to approve as recommended



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


EE. Recommendation: No brand thiazolidinedione 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



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


FF. Recommendation: No brand antidiabetic agent, miscellaneous 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

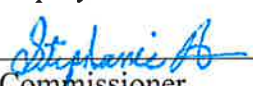
Vote: Unanimous to approve as recommended



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


GG. Recommendation: No brand prenatal vitamin 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



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action



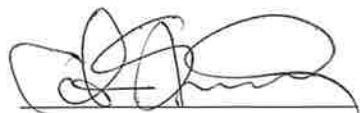
Commissioner Approve Approve as amended Disapprove No action

HH. Recommendation: No brand immunomodulatory agent used to treat multiple sclerosis 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.

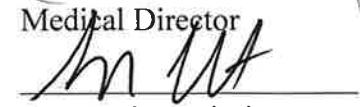
Alemtuzumab should not be placed in preferred status regardless of cost.

Amendment: None


Vote: Unanimous to approve as recommended



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

II. Recommendation: No brand antigout 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.


Febuxostat and pegloticase should not be placed in preferred status, regardless of cost.

Amendment: None

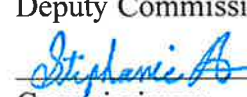
Vote: Unanimous to approve as recommended



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

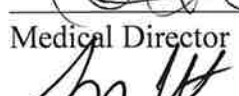
JJ. Recommendation: No brand genitourinary smooth muscle relaxant: antimuscarinic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

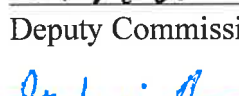
Vote: Unanimous to approve as recommended



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

KK. Recommendation: No brand genitourinary smooth muscle relaxant: beta-3 agonist 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

 _____ Medical Director	<input checked="" type="checkbox"/> Approve	<input type="checkbox"/> Approve as amended	<input type="checkbox"/> Disapprove	<input type="checkbox"/> No action
 _____ Deputy Commissioner	<input checked="" type="checkbox"/> Approve	<input type="checkbox"/> Approve as amended	<input type="checkbox"/> Disapprove	<input type="checkbox"/> No action
 _____ Commissioner	<input checked="" type="checkbox"/> Approve	<input type="checkbox"/> Approve as amended	<input type="checkbox"/> Disapprove	<input type="checkbox"/> No action

Respectfully submitted,

Rachel Bacon

11/04/2021

Rachel Bacon, Pharm.D.

Date