Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

August 6, 2025

Members Present: Dr. Lee Carter (Chairperson), Dr. Frances Heinze (Vice-Chairperson), Terri Madry, RPh, Dr. Kelli Newman, Dr. Alivia Price, Dr. Melinda Rowe, Dr. Chandler Stisher, Dr. George Sutton, Dr. Blake Tennant, Dr. Darlene Traffanstedt, and Dr. Jack Wanschek

Members Absent: Dr. Ashley Lane and Dr. Kenny Murray

Presenters: Dr. Rachel Bacon and Dr. Thomas Pomfret

1. OPENING REMARKS

Chairperson Carter called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 1:12 p.m.

2. APPROVAL OF MINUTES

Chairperson Carter asked if there were any corrections to the May 7, 2025, P&T Committee Meeting's minutes.

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

3. PHARMACY PROGRAM UPDATE

Dr. Newman stated that the Agency is already beginning work on next year's budget and is keeping up with any changes occurring at the federal level. The new PA Interoperability Rule is a large project the Agency is working on associated with non-pharmacy PAs which will reduce response times to recipients. At Stephanie Azar's exit, Timothy Bo Offord has been appointed as the new Alabama Medicaid Agency Commissioner. He was previously General Counsel for the Alabama Medicaid Agency and has served in various legal capacities within the Agency.

The supplemental rebate offer form on the Agency website is very simple, including drug name, NDC, offer (usually Guaranteed Net Unit Price (GNUP)), and any notes. Detailed notes submitted to the Agency by drug manufacturers are becoming increasingly lengthy and difficult to manage. Manufacturers were requested at a previous P&T meeting to simplify offer details/notes and focus on the financial data. This Committee reviews clinical information, and the financial review comes

after the P&T Committee review. The Agency's goal is to have as many preferred products as possible, and manufacturers are encouraged to simplify the language included in their offers. The Agency is considering removing the notes section or limiting the character count, much like other states and third parties. We appreciate your understanding and cooperation. We are thankful for our P&T Board and the manufacturers, who allow us to have numerous preferred agents for our recipients.

We are working towards approval for moving this meeting to a virtual platform so Committee members would no longer need to travel to the P&T meetings, while still participating and voting. The state law was changed last year and now allows virtual meetings for voting purposes, with some specifications. The Agency is considering modifying its policy to align with the updated law. The Committee discussed options so that Medicaid could follow the updated law and allow the virtual platform for Committee members to participate.

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 three manufacturer verbal presentations at the meeting.

5. NEW DRUG REVIEWS (Please refer to the website for full text reviews.)

The new drug reviews began at approximately 1:35 p.m. There were a total of two new drug reviews.

Nemluvio® (nemolizumab-ilto)
Manufacturer comments on behalf of these products:
Galderma –Nemluvio®

Dr. Bacon commented that Nemluvio® (nemolizumab-ilto) is the first FDA-approved interleukin (IL)-31 receptor antagonist. Nemluvio® is indicated for the treatment of adults and children 12 years of age and older with moderate to severe atopic dermatitis (AD) in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies. Nemluvio® is also indicated for the treatment of adults with prurigo nodularis (PN).

Atopic dermatitis is a chronic, pruritic, inflammatory skin condition. Current treatment modalities include the avoidance of triggers, skin hydration, phototherapy, topical agents, oral antihistamines, and systemic immunomodulatory agents. Additionally, patients with moderate to severe AD may be treated with the subcutaneous IL-4 and IL-13 inhibitor Dupixent® (dupilumab), the IL-13 antagonists Adbry® (tralokinumab-ldrm) or Ebglyss® (lebrikizumab-lbkz), or the oral JAK inhibitors Rinvoq® (upadacitinib) and Cibinqo® (abrocitinib). However, JAK inhibitors come with

a boxed warning for the potential risk of serious infections, mortality, malignancy, major cardiovascular events, and thrombosis.

Prurigo nodularis (PN) is a rare, chronic dermatologic condition that primarily affects middle-aged and older adults. It is characterized by intensely pruritic, raised, hyperkeratotic nodular lesions symmetrically distributed across the arms, legs, and trunk. While PN can occur independently, it is often associated with atopic dermatitis and other pruritic skin conditions. Prior to FDA approval of Dupixent® (dupilumab) for the treatment of adults with PN in 2022, only off-label treatments were available.

The ARCADIA-1 and ARCADIA -2 trials demonstrated the superiority of nemolizumab-ilto over topical therapies in achieving clear or almost clear skin in patients with atopic dermatitis. The OLYMPIA-1 and OLYPMIA-2 trials demonstrated the superiority of nemolizumab-ilto over placebo in reducing average peak pruritus numerical rating scale in patients with prurigo nodularis. Nemolizumab-ilto was generally well tolerated in clinical trials, with headaches as the most notable adverse effect. The FDA-approved labeling carries a warning to avoid the use of live vaccines during treatment with nemolizumab-ilto.

Consensus guidelines have not yet incorporated recommendations regarding the use of nemolizumab-ilto in the treatment of prurigo nodularis and/or atopic dermatitis. In general, treatment guidelines that incorporate the use of other biological agents recommend their use in patients who have not responded to conventional therapies. Agent selection should be individualized based on patient-specific factors such as co-morbid conditions, prior treatment trials, disease severity, and safety considerations.

There is insufficient evidence to demonstrate that the brand nemolizumab-ilto product is safer or more efficacious than other agents within its given indications. 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 nemolizumab-ilto 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.

Journavx® (suzetrigine)
Manufacturer comments on behalf of these products:
Vertex – Journavx®

Dr. Bacon commented that acute pain is caused by injury, surgery, illness, trauma, or painful medical procedures and generally lasts up to seven days, with prolongations from seven to 30 days

in duration common. Acute pain usually resolves when the underlying cause is treated or healed. Pain is a subjective experience that is unique to the individual. There are numerous etiologies of pain, and successful pain management can be difficult to achieve.

Journavx® (suzetrigine) was FDA-approved in January 2025 and is indicated for the treatment of moderate to severe acute pain in adults. It is an oral medication designed to selectively inhibit the voltage-gated sodium channel 1.8 (Nav 1.8), which plays a crucial role in transmitting pain signals in peripheral nociceptors. Journavx® has maintenance dosing of one tablet every 12 hours: it should be used for the shortest duration, consistent with individual patient treatment goals. Use of Journavx® for the treatment of acute pain has not been studied beyond 14 days. Dosage adjustments should be made for patients with hepatic impairment and with concomitant use of CYP3A inhibitors.

In the acute pain setting, effective pain management focuses on quickly relieving pain while preventing it from becoming chronic. The approach is typically multimodal, using a combination of medications and non-pharmacologic methods to alleviate pain. Non-opioid pain relievers, such as acetaminophen, NSAIDs, and local anesthetics, are often first-line treatments, as they help reduce inflammation and pain without the risks of opioids. When necessary, opioids may be used for more severe pain, but are to be prescribed at the lowest effective dose and for the shortest duration to minimize the risk of dependence. In addition to medications, physical therapy, cognitive-behavioral therapy, and other non-drug treatments like cold or heat therapy can play a role in managing acute pain. Regular assessments of pain levels are essential to adjust treatment and ensure that the pain is managed effectively, promoting recovery and preventing long-term issues. Clinical trial data comparing treatments for acute pain are available although heterogeneous in design and comparisons. A systematic review of 183 randomized controlled trials on the comparative effectiveness of interventions for acute pain found that opioid therapy was associated with decreased or similar effectiveness for pain versus an NSAID for surgical dental pain, kidney stone pain, and low back pain. For the treatment of postoperative pain, the study found no difference in pain in the first day for opioid vs NSAID, single dose, and opioid vs acetaminophen, single dose, although data was limited. Multimodal analgesia (using a combination of different methods and medications) is recommended as the preferred approach for managing postoperative pain. This includes the use of non-opioid medications (e.g., acetaminophen, NSAIDs), local anesthetics, and regional anesthesia techniques. The use of suzetrigine has not yet been incorporated into the published clinical guidelines.

Suzetrigine is a novel small molecule and a highly selective inhibitor of the voltage-gated sodium channel 1.8, marking the first new mechanism of action in pain treatment in over twenty years. This agent offers a potential new option for patients requiring short-term pain control. Furthermore, this agent is a non-opioid and reportedly non-addictive, so it has potential to address longstanding challenges in the field of pain management. Longer term data will help define the appropriate role of suzetrigine in practice.

Clinical trial data demonstrated that treatment with suzetrigine resulted in statistically significant improvements in pain compared to placebo, along with a reduction in acute pain from baseline in both the abdominoplasty and bunionectomy randomized controlled trials. Ibuprofen was permitted as rescue medication in both trials. In the bunionectomy trial, 85.4% of patients in the suzetrigine

group and 85.6% of patients in the placebo group used rescue medication, with a mean time to first rescue of 157 minutes in the suzetrigine group and 185 minutes in the placebo group. Use of rescue medication in the hydrocodone/acetaminophen arm was not reported. In the abdominoplasty trial, 81.0% of patients in the suzetrigine group and 87.9% of patients in the placebo group used rescue medication, with a mean time to first rescue of 186 minutes in the suzetrigine group and 115 minutes in the placebo group. Use of rescue medication in the hydrocodone/acetaminophen arm was not reported. Suzetrigine did not achieve a key secondary endpoint of sum of the pain intensity difference from 0 to 48 hours (SPID48) compared to hydrocodone/acetaminophen. In the abdominoplasty trial, there were no significant differences in SPID48 between the active treatment arms, but in the bunionectomy trial, hydrocodone/acetaminophen demonstrated a statistically significant improvement in pain compared to suzetrigine (least squares mean difference, -20.2; P=0.0016). Additionally, suzetrigine demonstrated effectiveness in a single-arm study across a range of surgical and non-surgical pain conditions, providing relief for up to 14 days. The majority of participants used rescue medication (73%), and had a favorable rating of suzetrigine for pain management.

There is insufficient evidence to support that the brand analgesics and antipyretics, miscellaneous product reviewed is safer or more efficacious than other alternatives used for acute pain. 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. Suzetrigine does offer an advantage in pain management by providing pain reduction while potentially being non-addictive; however, long-term safety and efficacy data and its place within clinical guidelines has yet to be established. Use of suzetrigine should be limited to 14 days.

No brand suzetrigine 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.

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

The pharmacotherapy class reviews began at approximately 1:53 p.m. There were a total of 25 drug class re-reviews. The Allylamines, Azoles, Echinocandins, Triterpenoids, Polyenes, Pyrimidines, Miscellaneous Antifungals, Antituberculosis Agents, Antileprosy Agents, Adamantanes, Interferons, Neuraminidase Inhibitors, Nucleosides and Nucleotides, HCV Antivirals, Endonuclease Inhibitors, CMV Antivirals, Coronavirus (COVID-19), Miscellaneous Antivirals, Amebicides, Antimalarials, Pneumocystis jirovecii Pneumonia Antiprotozoals, Nitroimidazole-derivative Antiprotozoals, Cryptosporidiosis Antiprotozoals, Miscellaneous

Antiprotozoals, and Urinary Anti-infectives were all last reviewed in August 2023. Some of the classes are newly added by AHFS but comprise of agents previously included in other classes.

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

Dr. Bacon commented that the HCV antivirals that are included in this review are listed in Table 1 on page 821. Since the preparation of the clinical packet, Mavyret® (glecaprevir and pibrentasvir) has gained the indication for the treatment of acute hepatitis C.

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

There is insufficient evidence to support that one HCV antiviral is safer or more efficacious than another. The drugs in this AHFS class are used in a specific patient population. Because these agents have narrow indications with limited usage, and very specific criteria must be met prior to initiating therapy, these agents should be managed through the existing medical justification portion of the prior authorization process.

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

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

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

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

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

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

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

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

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

Dr. Bacon commented that the azoles that are included in this review are listed in Table 1 on page 35. All of the products are available in a generic formulation, with the exception of isavuconazonium and oteseconazole. Isavuconazonium has gained approval for use in pediatric patients.

The azoles are generally well tolerated with gastrointestinal symptoms being the most frequently reported adverse event. Treatment with an azole may lead to hepatic function abnormalities, which range from mild elevations in transaminases to severe hepatotoxicity. There are also numerous drug interactions reported with these agents due to oxidative drug metabolism via the cytochrome P450 enzyme system.

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.

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

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

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

Dr. Bacon commented that the echinocandins that are included in this review are listed in Table 1 on page 175. Caspofungin and micafungin are available in a generic formulation. Rezzayo® (rezafungin) is a new agent, approved in 2023 for patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Rezafungin is dosed weekly, while other echinocandins are dosed daily. In the ReSTORE trial, rezafungin demonstrated statistical non-inferiority versus caspofungin.

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.

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.

Triterpenoids: AHFS 081420
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that ibrexafungerp is the only agent included in the triterpenoids class, which is a subclass newly added by AHFS. Ibrexafungerp (Brexafemme®) is approved for the treatment of vulvovaginal candidiasis and reduction in the incidence of recurrent vulvovaginal candidiasis in adult and post-menarchal pediatric females. Ibrexafungerp inhibits glucan synthase, an enzyme necessary to produce fungal cell walls. Ibrexafungerp has concentration-dependent fungicidal activity against Candida species, including most Candida species resistant to treatment with fluconazole. Ibrexafungerp has a boxed warning stating that it is contraindicated in pregnancy because it may cause fetal harm based on findings from animal reproductive studies.

There is insufficient evidence to support that one brand triterpenoid 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.

No brand triterpenoid 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 270. Amphotericin B (conventional and liposome) and nystatin are available in a generic formulation. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand polyene is more efficacious than another. Since amphotericin B is not indicated as first-line therapy for the management of common infectious diseases that would be seen in general use, formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

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

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

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

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

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

Dr. Bacon commented that the miscellaneous antifungals are listed in Table 1 on page 409. Griseofulvin is available in generic formulations. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

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 439. Most of the agents are available in a generic formulation. Successful treatment and cure of tuberculosis (TB) improves individual health and reduces *Mycobacterium tuberculosis* transmission. Historically, treatment of TB, particularly of drug-resistant TB (DR-TB), has involved prolonged courses of multiple medications and frequent adverse reactions. Individuals with drug-susceptible (DS)-TB may be eligible for effective regimens that reduce treatment duration by one-third. Previously, only patients with smear- and culture-negative "nonsevere" pulmonary TB were recommended to receive four months of treatment. Adults and adolescents with DS-TB may now be offered four months of a rifapentine and moxifloxacin-based regimen. Most children with nonsevere TB can now be treated with four months of standard medications. For DR-TB, new all-oral six-month regimens are more effective and safer than standard of care regimens used for decades and may reduce morbidity and mortality. The bedaquiline, pretomanid, and linezolid-based regimens can also be considered applicable to those with intolerance of rifampin.

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.

Antileprosy Agents: AHFS 081608
Manufacturer comments on behalf of these products:
None

Dr. Pomfret commented this review begins on page 508 and that dapsone is the only antileprosy agent that is currently available. It is approved for the treatment of leprosy and dermatitis herpetiformis and is available in a generic formulation. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

All brand antileprosy agents within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use.

No brand antileprosy 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.

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

Dr. Pomfret commented that the adamantanes that are included in this review are listed in Table 1 on page 527. 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 considered not effective. There have been no major changes in the prescribing information or clinical studies since this class was last reviewed.

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

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

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

Dr. Pomfret commented that the interferons that are included in this review are listed in Table 1 on page 565. None of the interferons are available in a generic formulation. The Food and Drug Administration (FDA)-approved indications vary among the products; however, the interferons are primarily used for the treatment of chronic hepatitis B.

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

Interferon alfa-2b is approved for the treatment of condylomata acuminata. However, the interferons are considered an alternative treatment option by the Centers for Disease Control and Prevention (CDC). Interferon alfa-2b is also approved for the treatment of select 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.

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 616. 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. Guidelines recommend the use of oseltamivir, zanamivir, peramivir, or baloxavir for the treatment of all influenza subtypes.

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 679. 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, respiratory syncytial virus, and COVID-19.

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.

Endonuclease Inhibitors: AHFS 081830
Manufacturer comments on behalf of these products:
None

Dr. Pomfret commented that Baloxavir (Xofluza®) has been moved to the endonuclease inhibitors class which begins on page 908. Guidelines recommend the use of oseltamivir, zanamivir, peramivir, or baloxavir for the treatment of all influenza subtypes.

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.

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

CMV Antivirals: AHFS 081844
Manufacturer comments on behalf of these products:
None

Dr. Pomfret commented that the cytomegalovirus (CMV) antivirals included in this review are listed in Table 1 on page 922. Neither agent is available in a generic formulation. Letermovir (Prevymis®) is indicated for prophylaxis of CMV infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant. It is also indicated for prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]). Maribavir (Livtencity®) is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients 12 years of age and older and weighing at least 35 kg with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

All brand CMV antivirals within the class reviewed are comparable to each other and to the generic products in the class (if applicable) for their labeled indication(s) and offer no significant clinical advantage over other alternatives in general use.

No brand CMV 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 agents.

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

Coronavirus (COVID-19): AHFS 081848
Manufacturer comments on behalf of these products:
None

Dr. Pomfret commented that nirmatrelvir and ritonavir (Paxlovid®) is the only agent currently included in the COVID-19 antivirals, which is a new subclass created by AHFS. Paxlovid® is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Guidelines recommend the use of this agent in-line with its FDA-approved indication.

The brand COVID-19 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 COVID-19 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 agents.

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 950. Currently the only agent is foscarnet, which is available in a generic formulation. Foscarnet is approved for the treatment of cytomegalovirus (CMV) retinitis in patients with the acquired immunodeficiency syndrome (AIDS). It is also approved for the treatment of acyclovir-resistant mucocutaneous herpes simplex virus infections in immunocompromised patients.

The 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.

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

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

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

Dr. Bacon commented that paromomycin is the only amebicide that is currently available. It is approved for the treatment of amebiasis, as well as an adjunctive agent for the treatment of hepatic coma, and is available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

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

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

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

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

Dr. Bacon commented that the antimalarials that are included in this review are listed in Table 1 on page 991. These agents are approved for the prevention and treatment of malaria. Most of the agents are available in a generic formulation. In 2024, the Centers for Disease Control (CDC) updated guidelines for the treatment of malaria based on drugs currently available in the United States. In the United States, most cases of malaria occur among individuals who have traveled to endemic regions without receiving appropriate prophylactic therapy. Treatment for malaria should not be initiated until the diagnosis has been confirmed by laboratory investigations. Once the diagnosis of malaria has been confirmed, appropriate antimalarial treatment must be initiated immediately. Treatment decisions are based upon the infecting *Plasmodium* species, the clinical status of the patient, and the drug susceptibility of the infecting parasites as determined by the geographic area where the infection was acquired.

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

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

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

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

Antiprotozoals, Pneumocystis jirovecii Pneumonia: AHFS 083012
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that the Pneumocystis jirovecii pneumonia antiprotozoals that are included in this review are listed in Table 1 on page 1065. The antiprotozoals have been broken into 3 additional subclasses by AHFS. Atovaquone and pentamidine are both available in a generic formulation.

There is insufficient evidence to support that one brand Pneumocystis jirovecii pneumonia antiprotozoal agent 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.

No brand Pneumocystis jirovecii pneumonia 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.

Antiprotozoals, Nitroimidazole-derivative: AHFS 083016
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that the nitroimidazole-derivative antiprotozoals that are included in this review are listed in Table 1 on page 1086. Benznidazole, metronidazole, and tinidazole are available in a generic formulation. The nitroimidazole-derivative antiprotozoals are approved for the treatment of various infectious diseases, including amebiasis, anaerobic bacterial infections, bacterial vaginosis, Chagas disease, giardiasis, and trichomoniasis.

There is insufficient evidence to support that one brand nitroimidazole-derivative 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.

No brand nitroimidazole-derivative 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.

Antiprotozoals, Cryptosporidiosis: AHFS 083020
Manufacturer comments on behalf of these products:
None

Dr. Bacon commented that currently, the only cryptosporidiosis antiprotozoal is nitazoxanide and it is approved for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*. Cryptosporidiosis is a parasitic infection caused by *Cryptosporidium* which results in self-limiting diarrhea in immunocompetent persons but may lead to potentially life-threatening complications in immunocompromised persons. Giardiasis is a parasitic infection caused by *Giardia lamblia*, which may result in acute self-limiting diarrhea or chronic diarrhea associated with malabsorption and weight loss.

There is insufficient evidence to support that one brand Cryptosporidiosis antiprotozoal agent 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.

No brand Cryptosporidiosis 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.

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

Dr. Bacon commented that nifurtimox is currently the only miscellaneous antiprotozoal and it is 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*. Chagas disease is transmitted by a number of reduviid bug species. The major manifestations of chronic Chagas disease are Chagas cardiomyopathy and gastrointestinal disease.

There is insufficient evidence to support that one brand miscellaneous antiprotozoal agent 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.

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

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

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

Dr. Bacon commented that the urinary anti-infectives that are included in this review are listed in Table 1 on page 1183. 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.

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.

7. RESULTS OF VOTING ANNOUNCED

The results of voting for each of the therapeutic classes were announced; all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

8. NEW BUSINESS

There was no new business.

9. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for November 5th at the Medicaid Building in the Commissioner's Board Room.

10. ADJOURN

There being no further business, Dr. Carter moved to adjourn and Dr. Stisher seconded. The meeting adjourned at 2:35 p.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
August 6, 2025

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

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

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

D. **Recommendation:** No brand triterpenoid 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

E. **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

F. **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

G. **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

H. **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

I. **Recommendation:** No brand antileprosy 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

J. **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

K. **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

L. **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

M. **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

N. **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

O. **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.

Amendment: None

Vote: Unanimous to approve as recommended

P. **Recommendation:** No brand CMV 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 agents.

Amendment: None

Vote: Unanimous to approve as recommended

Q. **Recommendation:** No brand COVID-19 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 agents.

Amendment: None

Vote: Unanimous to approve as recommended

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

Amendment: None

Vote: Unanimous to approve as recommended

S. **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

T. **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

U. **Recommendation:** No brand Pneumocystis jirovecii pneumonia 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

V. **Recommendation:** No brand nitroimidazole-derivative 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

W. **Recommendation:** No brand Cryptosporidiosis 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

X. **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

Y. **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

Z. **Recommendation:** No brand nemolizumab-ilto 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

AA. **Recommendation:** No brand suzetrigine 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

J. Darlene Draffenstedt, MD
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

Respectfully submitted,

Rachel Bacon

Rachel Bacon, PharmD, MPH — August 11, 2025 Date