

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

August 19, 2015

Members Present: Ms. Janet Allen, Dr. Lee Carter, Dr. David Harwood (Chair), Dr. Kelli Littlejohn Newman, Dr. Melinda Rowe, and Dr. Robert Smith

Members Absent: Dr. Frances Cohenour (Vice-chair), Dr. Elizabeth Jacobson, Dr. Pilar Murphy

Health Home/Probationary RCO Pharmacists Present via Teleconference: Lisa Channell, Angela Lowe, Michelle Richard, Machelle Stiles, Kristian Testerman, Lauren Ward

Presenters: Ms. Amy Levy

Presenters Present via Teleconference: Dr. Rachel Bastien and Dr. Pavel Lavitas

1. OPENING REMARKS

Chairperson Harwood called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:05 a.m.

2. APPROVAL OF MINUTES

Chairperson Harwood asked if there were any corrections to the minutes from the May 20, 2015 P&T Committee Meeting.

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

3. PHARMACY PROGRAM UPDATE

Dr. Littlejohn Newman commented that ALERTS are included in your packets, which clarify IUD billing and outline the new male contraceptive coverage policy. The Agency still does not have a budget for the upcoming financial year. Governor Bentley is expecting to announce another special session in September to pass a budget. Recent changes in Remittance Advice (RAs) were announced in a recent Provider Insider. Probationary RCOs/Health Homes are up and working; a Medical Management meeting is being held later this week.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations were explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were a total of two manufacturer verbal presentations at the meeting.

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

The pharmacotherapy class reviews began at approximately 9:10 a.m. There were a total of 19 drug class re-reviews. The central alpha-agonists; direct vasodilators; peripheral adrenergic inhibitors; hypotensive agents, miscellaneous; alpha-adrenergic blocking agents; beta-adrenergic blocking agents; dihydropyridines; calcium-channel blocking agents, miscellaneous; angiotensin-converting enzyme inhibitors; angiotensin II receptor antagonists; mineralocorticoid (aldosterone) receptor antagonists; renin inhibitors; loop diuretics; potassium-sparing diuretics; thiazide diuretics; thiazide-like diuretics; vasopressin antagonists; and diuretics, miscellaneous were last reviewed in May 2013. The HCV Antivirals were last reviewed in November 2014.

Central alpha-agonists, AHFS 240816

Manufacturer comments on behalf of these products:

None

Dr. Bastien stated that the central alpha-agonists included in the review are listed in Table 1. They are approved for the treatment of hypertension and all of the agents are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

Therefore, all brand central alpha-agonists 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 central alpha-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.

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

Direct vasodilators: AHFS 240820

Manufacturer comments on behalf of these products:

None

Dr. Bastien stated that the direct vasodilators are approved for the treatment of heart failure and hypertension, as well as for the treatment of hypoglycemia due to hyperinsulinism. The direct vasodilators that are included in the review are listed in Table 1 and hydralazine and minoxidil are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

Therefore, all brand direct vasodilators 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. The fixed-dose combination of isosorbide dinitrate and hydralazine (BiDil[®]) should be available through the medical justification portion of the prior authorization process as an adjunct to standard heart failure therapy in self-identified black patients. Due to its limited FDA-approved indications, diazoxide (Proglycem[®]) should be managed through the existing medical justification portion of the prior authorization process.

No brand direct vasodilator 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 Harwood asked the P&T Committee members to mark their ballots.

Peripheral adrenergic inhibitors: AHFS 240832

Manufacturer comments on behalf of these products:

None

Dr. Bastien stated that the peripheral adrenergic inhibitors that are included in the review are listed in Table 1. Reserpine is the only agent in the class and it is available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

Therefore, all brand peripheral adrenergic inhibitors 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 peripheral adrenergic 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 Harwood asked the P&T Committee members to mark their ballots.

Hypotensive agents, miscellaneous: AHFS 240892

Manufacturer comments on behalf of these products:

None

Dr. Bastien stated that mecamlamine is currently the only covered agent in the miscellaneous hypotensive agents. Mecamlamine was one of the first oral antihypertensive agents, introduced in the mid-1950s under the trade name Inversine[®]. It was withdrawn from the market in 2009 due to increased competition of antihypertensive drugs and decreasing use of the agent. In March 2013, mecamlamine was issued FDA approval and re-entered the market under the name of Vecamyl[®] for management of moderately severe to severe essential hypertension and uncomplicated cases of malignant hypertension. The miscellaneous

hypotensive agents are not included in the treatment guidelines and there are no specific recommendations for this drug.

Although the clinical literature reports that mecamlamine is effective for the management of moderate-to-severe hypertension, its clinical utility is minimal due to its adverse events profile and the availability of newer and more effective agents. Current hypertension treatment guidelines do not mention mecamlamine as a first-line or alternative agent for the treatment of hypertension. Therefore, all brand miscellaneous hypotensive agents 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 hypotensive agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

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

Alpha-adrenergic blocking agents: AHFS 2420000

Manufacturer comments on behalf of these products:

None

Dr. Bastien stated that the alpha-adrenergic blocking agents are approved for the treatment of benign prostatic hyperplasia and hypertension. All agents in the class are available in a generic dosage form and Cardura XL[®] is only available as a branded agent. 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 alpha-adrenergic blocking 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.

Therefore, all brand alpha-adrenergic blocking agents 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-adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

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

Beta-adrenergic blocking agents: AHFS 2424000

Manufacturer comments on behalf of these products:

Hemangeol[®] - Pierre Fabre

Dr. Bastien stated that the beta-adrenergic blocking agents that are included in the review are listed in Table 1. All of the agents are available in a generic formulation, with the exception of nebivolol and penbutolol. Since the last review, Hemangeol[®], an oral solution formulation of propranolol, was approved for the treatment of proliferating infantile hemangioma requiring systemic therapy. Aside from this new indication, 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 beta-adrenergic blocking 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.

Therefore, all brand beta-adrenergic blocking agents 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-adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

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

Dihydropyridines: AHFS 242808

Manufacturer comments on behalf of these products:

None

Dr. Bastien stated that the dihydropyridines included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. All of the products with the exception of clevidipine and amlodipine-olmesartan 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 dihydropyridine 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 dihydropyridines 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 dihydropyridine 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 Harwood asked the P&T Committee members to mark their ballots.

Calcium-channel blocking agents, miscellaneous: AHFS 242892

Manufacturer comments on behalf of these products:

None

Dr. Bastien stated that the miscellaneous calcium-channel blocking agents include diltiazem and verapamil which are approved for the treatment of angina, arrhythmias, and hypertension. There have been no major changes in the prescribing information, treatment guidelines, or clinical trials since the last time the class was reviewed.

Therefore, all brand miscellaneous calcium-channel blocking agents 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 calcium-channel blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

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

Angiotensin-converting enzyme inhibitors: AHFS 243204

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the ACE (angiotensin-converting enzyme) inhibitors that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. All of the products are available in a generic formulation, many in combinations with hydrochlorothiazide or verapamil. This class was last reviewed in May 2013. There have been no major changes in the prescribing information, treatment guidelines, or clinical trials since the last time the class was reviewed.

There is insufficient evidence to support that one brand angiotensin-converting enzyme inhibitor 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 angiotensin-converting enzyme inhibitors 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 angiotensin-converting enzyme 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 Harwood asked the P&T Committee members to mark their ballots.

Angiotensin II receptor antagonists: AHFS 243208

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the angiotensin II receptor antagonists also known as angiotensin II receptor blockers (ARBs) that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. All single entity products with the exception of azilsartan and olmesartan are available generically. Fixed-dose combination products candesartan and hydrochlorothiazide, irbesartan and hydrochlorothiazide, losartan and hydrochlorothiazide, telmisartan and amlodipine, telmisartan and hydrochlorothiazide, and valsartan and hydrochlorothiazide are available in a generic formulation. This class was last reviewed in May 2013. There have been no major changes in the prescribing information, treatment guidelines, or clinical trials since the last time the class was reviewed.

Several studies comparing ARBs and ACE inhibitors have demonstrated similar efficacy with regards to cardiovascular events, heart failure and the rate of progression of nephropathy. ACE inhibitors inhibit the breakdown of bradykinin, which may lead to the development of a persistent non-productive cough. The ARBs do not increase bradykinin and may be better tolerated in some patients.

At this time, there is insufficient evidence to conclude that the angiotensin II receptor antagonists offer a significant clinical advantage over other alternatives in general use. Therefore, all brand angiotensin II receptor antagonists 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 angiotensin II receptor antagonist 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 Harwood asked the P&T Committee members to mark their ballots.

Mineralocorticoid (aldosterone) receptor antagonists: AHFS 243220

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the mineralocorticoid (aldosterone) receptor antagonists that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. All of the products are available in a generic formulation. This class was last reviewed in May 2013. Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There is insufficient evidence to support that one brand mineralocorticoid (aldosterone) receptor antagonist 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 mineralocorticoid (aldosterone) receptor antagonists 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 mineralocorticoid (aldosterone) receptor antagonist 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 Harwood asked the P&T Committee members to mark their ballots.

Renin inhibitors: AHFS 243240

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the renin inhibitors that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. There are no generic renin inhibitor products currently available; however, amlodipine and hydrochlorothiazide as separate agents are available generically. This class was last reviewed in May 2013. Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

At this time, there is insufficient evidence to conclude that the renin inhibitors offer a significant clinical advantage over other alternatives in general use. Therefore, all brand renin inhibitors 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 renin 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 Harwood asked the P&T Committee members to mark their ballots.

Loop diuretics: AHFS 402808

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the loop diuretics that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. Bumetanide, furosemide, and torsemide are available in a generic formulation. This class was last reviewed in May 2013. Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There is insufficient evidence to support that one brand loop diuretic 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 loop diuretics 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 loop diuretic 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 Harwood asked the P&T Committee members to mark their ballots.

Potassium-sparing diuretics: AHFS 402816

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the potassium-sparing diuretics that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. All of the products are available in a generic formulation. This class was last reviewed in May 2013. Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There is insufficient evidence to support that one brand potassium-sparing diuretic 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 potassium-sparing diuretics 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 potassium-sparing diuretic 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 Harwood asked the P&T Committee members to mark their ballots.

Thiazide diuretics: AHFS 402820

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the thiazide diuretics that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. All of the agents are available in a generic formulation. This class was last reviewed in May 2013. Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There is insufficient evidence to support that one brand thiazide diuretic 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 thiazide diuretics 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 thiazide diuretic 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 Harwood asked the P&T Committee members to mark their ballots.

Thiazide-like diuretics: AHFS 402824

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the thiazide-like diuretics that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. All of the agents are available in a generic formulation. This class was last reviewed in May 2013. Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products.

There is insufficient evidence to support that one brand thiazide-like diuretic 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 thiazide-like diuretics 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 thiazide-like diuretic 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 Harwood asked the P&T Committee members to mark their ballots.

Vasopressin antagonists: AHFS 402828

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that the vasopressin antagonists that are included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. There are no generic products currently available. This class was last reviewed in May 2013.

Although there have been some updates to the existing treatment guidelines in table 2, there have been no major or clinically significant updates to the treatment of conditions using these products. That being said, there are limited guidelines available that discuss the management of hyponatremia. An expert panel provided treatment recommendations in 2013, which includes fluid restriction, sodium chloride administration, and diuresis. The panel concluded that the current role for vasopressin antagonists in SIADH (Syndrome of Inappropriate Antidiuretic Hormone) is in treating mild to moderate hyponatremia and asymptomatic severe hyponatremia. Because there is a paucity of data for patients with severely symptomatic hyponatremia, hypertonic saline remains the treatment of choice in this group until more evidence-based data are available. In patients with heart failure, a vasopressin antagonist is recommended if serum sodium does not correct to the desired level with hypertonic saline or fluid restriction. The fluid restriction should be lifted before starting these agents.

There is insufficient evidence to conclude that tolvaptan offers a significant clinical advantage over other alternatives in general use. Since tolvaptan is not indicated as first-line therapy for the management of hyponatremia, it should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand vasopressin antagonists 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 vasopressin antagonist 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 Harwood asked the P&T Committee members to mark their ballots.

Diuretics, miscellaneous: AHFS 402892

Manufacturer comments on behalf of these products:

None

Ms. Levy stated that there are no drugs available in the miscellaneous diuretics class.

No brand miscellaneous diuretic is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 402892 in the PDL screening process. If new outpatient miscellaneous diuretics are added, it is recommended that this class be re-reviewed at that time.

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

HCV Antivirals: AHFS 081840

Manufacturer comments on behalf of these products:

Viekira Pak™ - Abbvie

Dr. Lavitas stated that the HCV antivirals were last reviewed in November 2014. The products included in this review are listed in Table 1. This review includes all dosage forms and strengths. There are no generic products in this class. In late 2014, two new combination products were FDA-approved and included in this review: A once daily combination of ledipasvir (NS5A inhibitor) & sofosbuvir (NS5B polymerase inhibitor), with the brand name Harvoni® and a regimen consisting of fixed-dose ombitasvir, an HCV NS5A inhibitor, paritaprevir, a protease inhibitor and ritonavir, a pharmacokinetic booster agent with twice daily dasabuvir, an HCV non-nucleoside NS5B polymerase inhibitor; with the brand name Viekira Pak®.

These two combination products join single-agent protease inhibitors (boceprevir & simeprevir) as well as a sofosbuvir (an HCV NS5B polymerase inhibitor), which were already available on the market. Of note, boceprevir (Victrelis®) is being voluntarily discontinued by the manufacturer and will no longer be available after December 31, 2015.

Chronic Hepatitis C infection is the most common blood born infection in the United States. At least 6 viral genotypes have been identified, of which genotype 1 is the most common. The goal of treatment is to eradicate the virus and prevent liver related complications and death. Sustained Virologic Response (SVR) Rates amongst HCV Antivirals in Genotype 1 Patients are summarized in Table 2 for your reference. SVR rates observed with Harvoni® and Viekira Pak® were generally between 90 to 100%.

Treatment guidelines are summarized in Table 3 for your reference. Several treatment guidelines have been updated since the last review. While guidelines recommend treatment for all patients with hepatitis C infection, treatment should be prioritized based on risk of developing severe complications, so that highest priority is assigned to those with advanced fibrosis, liver transplant recipients, and patients with severe extrahepatic manifestations.

In general, all-oral combination regimens that include newer direct hepatitis C antivirals are preferred over older peginterferon-containing regimens due to a higher SVR rate, improved side effects profile, and reduced pill burden. Many treatment regimens are available, but not all are FDA-approved. The selection of treatment regimen should take into account viral genotype and subtype, previous treatment and response, presence of cirrhosis, drug interactions and special populations (e.g., post liver transplant, decompensated cirrhosis). While the FDA-approved labeling for the newer direct antivirals does not include stopping rules, treatment guidelines generally recommend treatment discontinuation based on expert opinion if patient does not respond to treatment based on viral loads at treatment weeks 4 and 6. Additional updates were also made to the AASLD/IDSA guideline after the packet was written and were not included in the packet. The impact of the update is expected to be limited.

Turning to page 1154, Table 4 summarizes FDA-approved indications. All products included in this review are FDA-approved in the treatment of chronic hepatitis C genotype 1 infection in adults. In addition, combination therapy with sofosbuvir is FDA-approved in genotypes 2, 3, and 4.

Drug Interactions are summarized in Table 6, 7, and 8 for your reference. There are many drug interactions associated with agents included in this review that must be managed prior to the start of treatment. Sofosbuvir does not have as many drug interactions as some of the other agents.

Adverse reactions are summarized in Table 9 on page 1159. Harvoni® and Viekira Pak® are generally better tolerated than the older peginterferon-containing regimens.

Dosing and Administration information begins on page 1161. Harvoni® is given once daily, whereas Viekira Pak® requires administration of four tablets per day. Most patients taking Viekira Pak® will also need to take ribavirin.

Several new trials have been summarized in Table 11, beginning on page 1163. Direct antivirals have not been compared to each other in clinical trials.

The safety and efficacy of Harvoni® has been evaluated in multiple large clinical trials in adults with chronic HepC infection, including treatment-naïve patients and those who have failed peginterferon and ribavirin with or without protease inhibitor. Cure rates were generally 90 to 100%. Treatment-naïve patients without cirrhosis achieved high cure rates with the 8-week treatment. Of note, treatment-experienced cirrhotics (one of the hardest populations to cure) had lower cure rates (82 to 86%) with 12-week regimen of Harvoni; however, adding RBV or extending treatment duration to 24 weeks led to significant improvements in cure rates (resulting in 96 to 100% cure). Treatment with Harvoni has also resulted in high SVR rates in patients with HIV-coinfection, s/p liver transplant, and decompensated cirrhotics; there is small body of evidence that also supports use in HCV genotypes 3, 4 and 6. In some of these patient populations the addition of RBV to 12 week regimen of Harvoni improved cure rates.

The safety and efficacy of Viekira Pak® with or without RBV has been evaluated in multiple large clinical trials in adults with chronic HepC infection, including treatment-naïve patients and those who have failed peginterferon and ribavirin dual therapy. As was the case with Harvoni®, cure rates with Viekira Pak® were generally very high 90 to 100%. Of note, SVR rates with the 12-weeks treatment were lower (80%) in genotype 1a patients who were cirrhotic and had prior null response to PEG/RBV (this population is historically more difficult to cure); however, extending treatment duration to 24 weeks led to significant improvements in cure rates (resulting in 93% cure), suggesting that longer treatment duration may improve cure rates in difficult to treat populations. High cure rates with Viekira Pak® plus RBV were also observed in patient s/p liver transplant, HIV-coinfection and genotype 4 infection.

In conclusion, of the agents included in this review, Sovaldi, Harvoni, and Viekira Pak offer significant clinical advantages over the other brand and generic products in the same class (if applicable). Boceprevir in any combination and simeprevir except when used in combination with sofosbuvir offer a clinical disadvantage to the other brand and generic products in the same class (if applicable). Because these agents have narrow indications with limited usage, and very specific criteria must be met prior to initiating therapy, these agents should be managed through the medical justification portion of the prior authorization process.

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

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

6. RESULTS OF VOTING ANNOUNCED

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

7. NEW BUSINESS

There is a conflict with the currently scheduled November meeting date and the committee will be polled on other possible meeting dates.

Dr. Cohenour will be the new Chairperson, and ballots were distributed for members to vote on Dr. Smith or Dr. Carter as Vice-chairperson.

8. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for November 4, 2015 at the Medicaid Building in the Commissioner's Board Room.

9. ADJOURN

There being no further business, Dr. Carter moved to adjourn and Ms. Allen seconded. The meeting adjourned at 10:05 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
August 19, 2015

- A. **Recommendation:** No brand central alpha-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

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Heell Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Heell Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Kruz, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Gabby Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie H Approve Approve as amended Disapprove No action
Acting Commissioner

D. Recommendation: No brand miscellaneous hypotensive agent is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 240892 in the PDL screening process. If new outpatient miscellaneous hypotensive agents are added, it is recommended that this class be re-reviewed at that time.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Kruz, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Gabby Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie H Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie H. Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie H. Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Pous, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie B Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Pous, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie B Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rouzma Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rouzma Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

K. Recommendation: No brand mineralocorticoid (aldosterone) receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda L. Rome, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda L. Rome, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Ponce, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Heel Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie [Signature] Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Ponce, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Heel Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie [Signature] Approve Approve as amended Disapprove No action
Acting Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda H. Rowles Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

R. Recommendation: No brand miscellaneous diuretic is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 402892 in the PDL screening process. If new outpatient miscellaneous diuretics are added, it is recommended that this class be re-reviewed at that time.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowles Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hull Approve Approve as amended Disapprove No action
Deputy Commissioner

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

S. **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

Melinda A. King, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Johnny Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

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

Respectfully submitted,

Rachel Bastien

August 31, 2015

Rachel Bastien, Pharm.D.

Date

Amy Levy

August 31, 2015

Amy Levy, R.Ph., MHP

Date