

Minutes of Meeting
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
February 9, 2022

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

Members Absent: Dr. Albert Holloway and Dr. Tiffany Lyght

Presenters: Dr. Thomas Pomfret

1. OPENING REMARKS

Chairperson Heinze called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 1:10 p.m. CST.

2. APPROVAL OF MINUTES

Chairperson Heinze asked if there were any corrections to the minutes from the November 3, 2021 P&T Committee Meeting.

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

3. PHARMACY PROGRAM UPDATE

Dr. Newman noted that Alabama is currently in legislative session. She also noted that Covid-19 at-home tests are covered through pharmacy billing effective 1/1/2022. Dr. Newman clarified that the Federal Public Health Emergency (PHE) Declaration is still in effect, whereas the State Public Health Emergency Declaration expired in July 2021. The Agency will follow the Federal PHE on a monthly basis until the expiration, at which time notice will be provided to the public.

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 was one (1) manufacturer verbal presentation at the meeting.

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

The pharmacotherapy class reviews began at approximately 1:22 p.m. CST. There were a total of fourteen (14) drug class re-reviews. The oral anticoagulants; platelet aggregation inhibitors; antiarrhythmics; cardiotonic agents; cardiac drugs, miscellaneous; bile acid sequestrants; cholesterol absorption inhibitors; fibric acid derivatives; HMG-CoA reductase inhibitors; Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) inhibitors; antilipemic agents, miscellaneous; nitrates and nitrites; and renin-angiotensin-aldosterone system inhibitors, miscellaneous were all last reviewed in November 2019. The antidepressants were last reviewed in November 2020.

Antidepressants: AHFS 281604

Manufacturer comments on behalf of these products:

Spravato® (esketamine); Janssen Pharmaceuticals, Inc.

Dr. Pomfret noted that the antidepressants are approved to treat a variety of mental disorders, including anxiety disorders, depressive disorders, eating disorders, and premenstrual dysphoric disorder. The antidepressants included in this review are listed in Table 1 on page 1089. The majority of the products are available in a generic formulation, and there is at least one generic product available in each antidepressant subclass.

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

Therefore, all brand antidepressants within the class reviewed, with the exception of the monoamine oxidase inhibitors, 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. The monoamine oxidase inhibitors possess an extensive adverse effect profile compared to the other brands and generics in the class (if applicable) and should be managed through the existing medical justification portion of the prior authorization process.

No brand antidepressant 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.

No brand monoamine oxidase inhibitor is recommended for preferred status, regardless of cost.

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

Oral Anticoagulants: AHFS 201204

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the oral anticoagulants included in this review are listed in Table 1 on page 10. This review encompasses only oral dosage forms and strengths within the AHFS class. Warfarin is the only product available in a generic formulation.

Since the last review, rivaroxaban has gained prophylactic indications related to specific venous thromboembolism and thrombotic vascular events. Dabigatran has gained indications in pediatric patients 8 to 18 years of age.

The novel (non-vitamin K) oral anticoagulants (NOACs) have been shown to be at least as effective as vitamin K antagonist (VKA) therapy. Guidelines recommend NOACs over warfarin for initial and long-term treatment of Venous thromboembolism (VTE) in patients without cancer. Atrial fibrillation guidelines recommend NOACs over warfarin in NOAC-eligible patients with atrial fibrillation (excluding those with moderate-to-severe mitral stenosis or a mechanical heart valve). VKA therapy is recommended for stroke prevention in patients with atrial fibrillation with moderate-to-severe mitral stenosis or a mechanical heart valve. There is insufficient evidence to conclude that one NOAC is safer or more efficacious than another for its approved indications.

NOACs may offer significant clinical advantages in VTE patients, but are comparable to each other. VKA products may offer significant clinical advantages in AF patients with mitral stenosis or mechanical heart valves, but are comparable to each other. In other patient populations with FDA-approved indications for an oral anticoagulant, 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 oral anticoagulant, with the exception of a non-vitamin K oral anticoagulant (NOAC) 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.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand apixaban, dabigatran, edoxaban, or rivaroxaban product is selected as a preferred agent.

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

Platelet Aggregation Inhibitors: AHFS 201218

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the platelet-aggregation inhibitors included in this review are listed in Table 1 on page 135. Cilostazol, clopidogrel, dipyridamole, prasugrel, and aspirin-dipyridamole are available generically. The newest platelet inhibitor to be approved by the Food and Drug Administration, vericiguat, increases levels of cyclic guanosine monophosphate (cGMP) by stimulating soluble guanylate cyclase (sGC), causing smooth muscle relaxation and vasodilation. It is indicated to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics in adults with symptomatic chronic heart failure and ejection fraction <45%.

There is insufficient evidence to support that one brand platelet-aggregation 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 platelet-aggregation 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 platelet-aggregation 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 Heinze asked the P&T Committee members to mark their ballots.

Antiarrhythmics: AHFS 240404

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the antiarrhythmic agents included in the review are listed in Table 1 on page 287. All of the antiarrhythmic agents are available in a generic formulation with the exception of dronedarone. 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 one brand antiarrhythmic agent is more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

No brand antiarrhythmic 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 Heinze asked the P&T Committee members to mark their ballots.

Cardiotonic Agents: AHFS 240408

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the only cardiotonic agent is digoxin as outlined in Table 1 on page 348. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

All brand cardiotonic 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 cardiotoxic 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 Heinze asked the P&T Committee members to mark their ballots.

Cardiac Drugs, Miscellaneous: AHFS 240492

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the miscellaneous cardiac drugs included in this review are listed in Table 1 on page 401. Ranolazine is available in a generic formulation. Tafamidis (Vyndaqel[®] and Vyndamax[®]) is the first FDA-approved treatment for cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults. Vyndamax[®] is a once-daily oral capsule developed for patient convenience. A single Vyndamax[®] 61 mg capsule is bioequivalent to Vyndaqel[®] 80 mg (four 20 mg capsules) and is not interchangeable on a mg-per-mg basis.

There is insufficient evidence to support that one brand miscellaneous cardiac drug is safer or more efficacious than other agents commonly used for the approved indication. Due to their limited FDA-approved indications, ivabradine (Corlanor[®]) and tafamidis should be made available through the medical justification portion of the prior authorization process for their respective indications.

Therefore, all brand miscellaneous cardiac therapies 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 cardiac drug 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 Heinze asked the P&T Committee members to mark their ballots.

Bile Acid Sequestrants: AHFS 240604

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the bile acid sequestrants included in this review are listed in Table 1 on page 438. All agents are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand bile acid sequestrant 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 bile acid sequestrants 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 bile acid sequestrant 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 Heinze asked the P&T Committee members to mark their ballots.

Cholesterol Absorption Inhibitors: AHFS 240605

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that ezetimibe is the only cholesterol absorption inhibitor and it is available in a generic formulation as outlined in Table 1 on page 492. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

All brand cholesterol absorption 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 cholesterol absorption 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 Heinze asked the P&T Committee members to mark their ballots.

Fibric Acid Derivatives: AHFS 240606

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the fibric acid derivatives that are included in this review are listed in Table 1 on page 583. All fibric acid derivatives are available in a generic formulation. A warning/precaution for hepatotoxicity has been added to the labeling of the fibric acid derivatives. Serious drug-induced liver injury, including liver transplantation and death, have been reported postmarketing with these agents. Drug-induced liver injury has been characterized as hepatocellular, chronic active, and cholestatic hepatitis, and cirrhosis has occurred in association with chronic active hepatitis. These agents are contraindicated in patients with active liver disease, including those with primary biliary cirrhosis and unexplained persistent liver function abnormalities. Liver function, including serum ALT, AST, and total bilirubin should be routinely monitored.

There is insufficient evidence to support that one brand fibric acid derivative 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 fibric acid derivatives 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 fibric acid derivative 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 Heinze asked the P&T Committee members to mark their ballots.

HMG-CoA Reductase Inhibitors: AHFS 240608

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the HMG-CoA reductase inhibitors, or statins, included in this review are listed in Table 1 on page 656. 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 HMG-CoA Reductase Inhibitors 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 HMG-CoA Reductase 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 HMG-CoA Reductase Inhibitors 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 Heinze asked the P&T Committee members to mark their ballots.

Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors: AHFS 240624

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the proprotein convertase subtilisin kexin 9 (PCSK9) inhibitors included in this review are listed in Table 1 on page 905. Both Praluent[®] (alirocumab) and Repatha[®] (evolocumab) are FDA-approved as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe) for the treatment of adults with primary hyperlipidemia (including heterozygous and homozygous familial hypercholesterolemia) to reduce LDL-C. Praluent[®] (alirocumab) is also indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease. Repatha[®] (evolocumab) is also indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease and as an adjunct to

diet and other lipid lowering therapies (statins, ezetimibe, LDL-C apheresis) in pediatric patients ≥ 10 years of age with homozygous familial hypercholesterolemia (HoFH) or heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of LDL-C.

At this time, there is insufficient data to conclude that one PCSK9 inhibitor is safer or more efficacious than other brand or generic products within its class and that it offers a significant clinical advantage over other alternatives in general use. 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 made available 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 PCSK9 inhibitor 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.

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

Antilipemic Agents, Miscellaneous: AHFS 240692

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the miscellaneous antilipemic agents included in this review are listed in Table 1 on page 948. Icosapent ethyl, niacin, and omega-3 acid ethyl esters are available in a generic formulation. Three drugs have been added since the last review.

Bempedoic acid is an adenosine triphosphate-citrate lyase (ACL) inhibitor that is FDA-approved as a monotherapy (Nexletol[®]) or a combination therapy with ezetimibe (Nexlizet[®]) for the treatment of heterozygous familial hypercholesterolemia (HeFH) and atherosclerotic cardiovascular disease as an adjunct to diet and maximally tolerated statin therapy. Inhibition of ACL results in decreased cholesterol synthesis in the liver and lowers LDL-C in the blood via upregulation of LDL receptors. Ezetimibe reduces blood cholesterol by inhibiting the absorption of cholesterol by the small intestine thus leading to a decrease in the delivery of intestinal cholesterol to the liver, reduction of hepatic cholesterol stores, and clearance of cholesterol from the blood.

Evinacumab-dgnb (Evkeeza[®]) is a monoclonal antibody that inhibits angiopoietin-like protein 3 (ANGPTL3) and is indicated as an adjunct to other low-density lipoprotein-cholesterol lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH). Inhibition of ANGPTL3 leads to reduction of LDL-C by promoting VLDL processing and clearance upstream of LDL formation as well as a reduction in TG and HDL-C by rescuing lipoprotein lipase and endothelial lipase activities, respectively.

Bempedoic acid, bempedoic acid/ezetimibe, and evinacumab-dgnb are recently approved medications that are not yet addressed in clinical guidelines. Clinical trials have demonstrated that,

when compared to placebo, bempedoic acid can effectively lower LDL-C and reduce other lipid/lipoprotein parameters in patients with HeFH. The CLEAR Wisdom trial demonstrated the efficacy of bempedoic acid in patients stable on maximally tolerated lipid-lowering therapy while the CLEAR Serenity trial demonstrated the efficacy of bempedoic acid in statin intolerant patients. Studies of bempedoic acid in combination with ezetimibe have shown that bempedoic acid/ezetimibe can reduce LDL-C and other lipid/lipoprotein parameters in patients with HeFH when compared to placebo, bempedoic acid, or ezetimibe alone. The ELIPSE HoFH trial demonstrated that evinacumab-dgnb, as an adjunct therapy in patients with HoFH, can reduce LDL-C and improve lipid/lipoprotein parameters when compared to placebo.

Prescription niacin products offer significant clinical advantages in general use over the other brand, generic, and OTC niacin products in the same class (if applicable) but are comparable to each other. Extended-release niacin is available in a generic formulation. Due to their limited FDA-approved indications, prescription omega-3 acid ethyl esters and icosapent ethyl should be made available through the medical justification portion of the prior authorization process for adults with severe hypertriglyceridemia (≥ 500 mg/dL). Omega-3 acid ethyl esters and icosapent ethyl are available in generic formulations. Due to the limited FDA-approved indications, lomitapide and evinacumab should be made available through the medical justification portion of the prior authorization process for adjunctive use to diet and other lipid-lowering treatments in patients with HoFH. Bempedoic acid and the combination of bempedoic acid/ezetimibe should be available through the medical justification portion of the prior authorization process for adjunctive use to diet and other lipid-lowering therapies in adults with HeFH due to their limited FDA-approved indications.

No brand miscellaneous antilipemic 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 Heinze asked the P&T Committee members to mark their ballots.

Nitrates and Nitrites: AHFS 241208

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that the nitrates and nitrites that are included in this review are listed in Table 1 on page 1034, and all of the products are available in generic formulation. There have been no major changes in prescribing information, treatment guidelines, or clinical trials since this class was last reviewed.

There is insufficient evidence to support that one brand nitrate or nitrite product 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.

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

No brand nitrate or nitrite 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.

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

Miscellaneous Renin-Angiotensin-Aldosterone System Inhibitors: AHFS 243292

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that Entresto® (sacubitril-valsartan) is the only miscellaneous renin-angiotensin-aldosterone system (RAAS) inhibitor in this review as outlined in Table 1 on page 1070.

Entresto® (sacubitril-valsartan) is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an ARB, that is Food and Drug Administration (FDA)-approved to reduce the risk of cardiovascular death and hospitalization for HF in adult patients with chronic heart failure. Benefits are most clearly evident in patients with LVEF below normal. It is also indicated for the treatment of symptomatic HF with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto® reduces NT-proBNP and is expected to improve cardiovascular outcomes. In the phase III PARADIGM-HF trial, this agent was shown to reduce the rate of cardiovascular death, HF hospitalizations, and all-cause mortality compared to enalapril.

Treatment of symptomatic HF typically consists of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) and a β -blocker to reduce morbidity and mortality. In the case of volume overload, a diuretic agent may be added to therapy to improve symptoms. The 2016 and 2017 American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Failure Society of America (HFSA) updates of the 2013 American College of Cardiology (ACCF)/AHA guideline for the management of HF reaffirms the benefits of therapy with an ACEI or ARB in patients with HFrEF, but also recommends replacement of ACEI or ARB with an angiotensin receptor neprilysin inhibitor (ARNI) in patients with chronic symptomatic HFrEF (NYHA class II-IV) who tolerate an ACEI or ARB to further reduce morbidity and mortality. The European Society of Cardiology 2021 Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure recommend sacubitril-valsartan as a replacement for an ACE inhibitor to further reduce the risk of HF hospitalization and death in ambulatory patients with HFrEF who remain symptomatic despite optimal treatment with an ACEI, a beta-blocker, and a mineralocorticoid receptor antagonist.

There is insufficient evidence to support that one brand miscellaneous renin-angiotensin-aldosterone system 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 miscellaneous renin-angiotensin-aldosterone system 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 miscellaneous renin-angiotensin-aldosterone system 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 Heinze 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 and all recommendations were accepted unanimously. Results of voting are described in the Appendix to the minutes.

7. NEW BUSINESS

Chairperson Heinze and Dr. Newman discussed the implications of ensuring treatments for Covid-19 remain accessible and available through the pharmacy benefit on an outpatient basis (i.e., outpatient clinics, provider's office, or outpatient pharmacies) through the Federal PHE period. Dr. Hughes made the following motion, which was seconded by Dr. Carter, and approved unanimously by the full committee: To ensure that any drug with a Food and Drug Administration (FDA)-approved or Emergency Use Authorization (EUA)-authorized indication for the treatment of Covid-19 be made available as preferred through the duration of the Federal Public Health Emergency.

8. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for May 4, 2022 at 1 p.m. CST in the Commissioner's Board Room of the Medicaid Building.

9. ADJOURN

There being no further business, Dr. Hughes moved to adjourn and Dr. Carter seconded the motion. The meeting adjourned at 3:10 p.m. CST.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
February 9, 2022

- A. Recommendation:** No brand antidepressant 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.

No brand monoamine oxidase inhibitor is recommended for preferred status, regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action

Medical Director

 Approve Approve as amended Disapprove No action

Deputy Commissioner

 Approve Approve as amended Disapprove No action

Commissioner

- B. Recommendation:** No brand oral anticoagulant, with the exception of a non-vitamin K oral anticoagulant (NOAC) 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.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand apixaban, dabigatran, edoxaban, or rivaroxaban product is selected as a preferred agent.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action

Medical Director

 Approve Approve as amended Disapprove No action

Deputy Commissioner

 Approve Approve as amended Disapprove No action

Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action



Commissioner Approve Approve as amended Disapprove No action

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

Amendment: None

Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action



Commissioner Approve Approve as amended Disapprove No action


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

Amendment: None

Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action




Commissioner Approve Approve as amended Disapprove No action

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

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner


 Approve Approve as amended Disapprove No action
Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

H. **Recommendation:** No brand cholesterol absorption 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

 Approve Approve as amended Disapprove No action
Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action

Medical Director

 Approve Approve as amended Disapprove No action

Deputy Commissioner


 Approve Approve as amended Disapprove No action

Commissioner

J. Recommendation: No brand HMG-CoA reductase 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

 Approve Approve as amended Disapprove No action

Medical Director

 Approve Approve as amended Disapprove No action

Deputy Commissioner

 Approve Approve as amended Disapprove No action

Commissioner

K. Recommendation: No brand PCSK9 inhibitor 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

 Approve Approve as amended Disapprove No action

Medical Director

 Approve Approve as amended Disapprove No action

Deputy Commissioner

 Approve Approve as amended Disapprove No action

Commissioner

L. **Recommendation:** No brand miscellaneous antilipemic 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


_____ Approve Approve as amended Disapprove No action

Medical Director


_____ Approve Approve as amended Disapprove No action

Deputy Commissioner


_____ Approve Approve as amended Disapprove No action

Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended


_____ Approve Approve as amended Disapprove No action

Medical Director


_____ Approve Approve as amended Disapprove No action

Deputy Commissioner


_____ Approve Approve as amended Disapprove No action

Commissioner

N. No brand miscellaneous renin-angiotensin-aldosterone system 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


_____ Approve Approve as amended Disapprove No action

Medical Director


_____ Approve Approve as amended Disapprove No action

Deputy Commissioner


_____ Approve Approve as amended Disapprove No action

Commissioner


- O. To ensure that any drug with a Food and Drug Administration (FDA)-approved or Emergency Use Authorization (EUA)-authorized indication for the treatment of Covid-19 be made available as preferred through the duration of the Federal Public Health Emergency.

Amendment: None

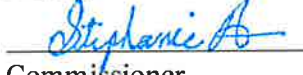
Vote: Unanimous to approve as recommended



Medical Director Approve Approve as amended Disapprove No action



Deputy Commissioner Approve Approve as amended Disapprove No action



Commissioner Approve Approve as amended Disapprove No action

Respectfully submitted,



2/14/2022

Thomas Pomfret, Pharm.D., MPH, BCPS

Date