

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

February 10, 2016

Members Present: Ms. Janet Allen, Dr. Lee Carter (Vice-chair), Dr. Frances Cohenour (Chair), Dr. Elizabeth Dawson, Dr. David Harwood, Dr. Elizabeth Jacobson, Dr. Kelli Littlejohn Newman, Dr. Melinda Rowe, and Dr. Robert Smith

Members Absent: Dr. Pilar Murphy

Health Home/Probationary RCO Pharmacists Present via Teleconference: Amy Donaldson, Joshua Lee, Lydia Rather, Machel Stiles, Kristian Testerman, Lauren Ward

Presenters: Dr. Rachel Bacon

Presenters Present via teleconference: None

1. OPENING REMARKS

Chairperson Cohenour called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:09 a.m.

2. APPROVAL OF MINUTES

Chairperson Cohenour asked if there were any corrections to the minutes from the November 11, 2015 P&T Committee Meeting.

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

3. PHARMACY PROGRAM UPDATE

It was announced yesterday that the RCO waiver has been approved by CMS. Lynn Abrell has retired from the State; Heather Vega and Allison Scott will be taking over the drug rebate duties. The legislative session began last week. The next quarterly PDL update will be in April.

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 was explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were a total of three 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 9:18 a.m. There were a total of 11 drug class re-reviews. The centrally acting skeletal muscle relaxants, direct-acting skeletal muscle relaxants, GABA-derivative skeletal muscle relaxants, miscellaneous skeletal muscle relaxants, opiate agonists, opiate partial agonists, selective serotonin agonists, antihistamine antiemetics, 5-HT₃ receptor antagonist antiemetics, miscellaneous antiemetics, and proton-pump inhibitors were last reviewed in November 2013. There were two new drug reviews: Savaysa[®] and Toujeo[®].

Centrally Acting Skeletal Muscle Relaxants: American Hospital Formulary Service (AHFS) 122004 Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the centrally acting skeletal muscle relaxants that are included in this review are listed in Table 1 on page 12. All 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. The prolonged use of carisoprodol has been associated with dependence, withdrawal, and abuse. Therefore, carisoprodol products were placed on prior authorization in 2007 through P&T and DUR review due to the abuse potential.

There is insufficient evidence to support that one brand centrally acting skeletal muscle relaxant is safer or more efficacious than another. Due to the potential risk of abuse, carisoprodol-containing products should be managed through the medical justification portion of the prior authorization process.

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

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

Carisoprodol and carisoprodol-containing products should not be placed in preferred status regardless of cost.

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

Direct-Acting Skeletal Muscle Relaxants: AHFS 122008

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that dantrolene is the only direct-acting skeletal muscle relaxant that is currently available in this class and the capsules 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-acting skeletal muscle relaxants within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

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

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

GABA-Derivative Skeletal Muscle Relaxants: AHFS 122012

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that baclofen is the only gamma aminobutyric acid (GABA)-derivative skeletal muscle relaxant that is currently available and the tablets 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 GABA-derivative skeletal muscle relaxants within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand gamma aminobutyric acid (GABA)-derivative skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

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

Skeletal Muscle Relaxants, Miscellaneous: AHFS 122092

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that orphenadrine is the only miscellaneous skeletal muscle relaxant that is currently available 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 miscellaneous skeletal muscle relaxants within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

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

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

Opiate Agonists: AHFS 280808

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the opiate agonists that are included in this review are listed in Table 1 on page 83. These agents are considered to be the most potent analgesics available and are frequently prescribed for the treatment of acute pain, chronic pain, and palliative care. They are available in a variety of dosage forms and combination products available. All of the products are available in a generic formulation, with the exception of remifentanyl and tapentadol. The oral sustained-release opiate agonists are not included in this review as they are included in the Alabama Medicaid Prior Authorization Program, which is outside of the Preferred Drug Program. Since the last review, new dosage formulations of fentanyl and oxycodone-acetaminophen have been approved by the FDA. In October 2014 the DEA re-scheduled hydrocodone and acetaminophen combination products from schedule III to schedule II.

Current treatment guidelines that incorporate the use of the opiate agonists are summarized in Table 2. For the treatment of cancer pain, guidelines recommend the use of an opiate agonist in patients with moderate to severe pain that is not controlled on acetaminophen therapy and non-steroidal anti-inflammatory drugs alone. For patients with continuous pain who have not received adequate analgesia from other interventions, it is appropriate to prescribe opioids around-the-clock and provide supplemental doses for breakthrough pain. Long-acting formulations are recommended in patients whose pain is controlled on stable doses of short-acting opioids. For the treatment of chronic noncancer pain, guidelines recommend the use of an opiate agonist in patients with moderate to severe pain. The selection of therapy should be based on patient preference, ease of administration, prior treatment trials, adverse events, and risk for misuse or abuse. Guidelines do not give preference to one opiate agonist over another. For the maintenance treatment of opioid dependence, guidelines recommend the use of methadone or buprenorphine-naloxone as first-line therapy.

Opiate agonists have been evaluated in a variety of pain indications, including chronic cancer and non-cancer pain syndromes. These agents have been associated with decreases in baseline pain scale scores compared to placebo. In head to head trials, opiate agonists have generally been associated with similar decreases in pain from baseline. Although some studies have demonstrated one agent to be associated with

improved pain control compared to another agent, these results have not been consistently demonstrated and may be attributable to variability in the dosing of the agents or the treated indication.

There is insufficient evidence to support that one brand opiate agonist 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 opiate 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 opiate 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.

Dr. Cohenour asked for clarification on opiate dosage limits and Dr. Littlejohn Newman reviewed the policies. The committee discussed unit limits, overrides, and the hydrocodone-acetaminophen switch from C-III to C-II, and the impact of these issues on their practices.

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

Opiate Partial Agonists: AHFS 280812

Manufacturer comments on behalf of these products:

Bunavail[®] – BioDelivery Sciences International

Dr. Bacon commented that the opiate partial agonists included in this review are listed in Table 1. Since the previous review, newly FDA-approved buprenorphine-naloxone formulations include Bunavail[®], a buccal film, and Zubsolv[®], a sublingual tablet with enhanced bioavailability as compared to Suboxone[®], thus requiring a lower dosage.

For the maintenance treatment of opioid dependence, guidelines recommend the use of methadone or buprenorphine/naloxone as first-line therapy. Qualified office-based physicians may prescribe buprenorphine-containing products for the treatment of opioid dependence, which has significantly expanded access to treatment. Clinical trials have demonstrated that buprenorphine (with or without naloxone) reduces opioid use, retains patients in treatment and is associated with minimal adverse events when used for the detoxification and maintenance treatment of opioid dependence. Studies directly comparing buprenorphine (with or without naloxone) to methadone have shown mixed results, which is thought to be due to differences in the dosing regimens used. Compared to methadone, buprenorphine has a lower potential for abuse and is safer in an overdose situation. However, it can still produce euphoria and physical dependence. The fixed-dose combination of buprenorphine/naloxone has less potential for abuse and diversion than buprenorphine monotherapy.

There is insufficient evidence to support that one brand opiate partial agonist is safer or more efficacious than another. Due to the potential risk of abuse, buprenorphine and buprenorphine and naloxone should be managed through the medical justification portion of the prior authorization process. Approval should only

be granted for patients with a diagnosis of opioid dependence. Treatment should only be prescribed by a licensed physician who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a DEA 'X' number.

Therefore, all brand opiate partial 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 opiate partial 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.

Buprenorphine and buprenorphine-naloxone should not be placed in preferred status regardless of cost.

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

Selective Serotonin Agonists: AHFS 283228

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the selective serotonin agonists (triptans) that are included in this review are listed in Table 1 on page 291. They are all approved for the treatment of acute treatment of migraine attacks with or without aura. The subcutaneous formulation of sumatriptan is also approved for the treatment of cluster headaches. Several 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 selective serotonin agonist is safer or more efficacious than another when administered at equipotent doses. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand selective serotonin 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 selective serotonin 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 Cohenour asked the P&T Committee Members to mark their ballots.

Antiemetics, Antihistamines: AHFS 562208

Manufacturer comments on behalf of these products:

Diclegis[®] – Duchesnay Inc

Dr. Bacon commented that the antihistamine antiemetics included in this review are listed in Table 1 on page 391. All of the products with the exception of the fixed dose combination product are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies regarding these agents since this class was last reviewed.

There is insufficient evidence to support that one brand antihistamine antiemetic 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 antihistamine antiemetics 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 antihistamine antiemetic 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 Cohenour asked the P&T Committee Members to mark their ballots.

Antiemetics, 5-HT₃ Receptor Antagonists: AHFS 562220

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the 5-HT₃ receptor antagonists included in this review are listed in Table 1 on page 430. They are approved for the prevention and treatment of chemotherapy-induced nausea and vomiting (CINV), postoperative nausea and vomiting (PONV), and radiation-induced nausea and vomiting (RINV). Granisetron and ondansetron are both available in a generic formulation. A new oral soluble film formulation of ondansetron, Zuplenz[®], has been included since the last review.

Current treatment guidelines that incorporate the use of the 5-HT₃ receptor antagonists are summarized in Table 2. The use of multiple antiemetic agents is generally required for the prevention of CINV. The selection of therapy depends on the emetogenic potential of the chemotherapy regimen. Guidelines recommend the use of 5-HT₃ receptor antagonists (in combination with a neurokinin-1 antagonist and dexamethasone) to prevent acute nausea and vomiting associated with highly emetogenic chemotherapy. The 5-HT₃ receptor antagonists are also recommended as one of several options to prevent delayed nausea and vomiting, as well as to treat breakthrough nausea and vomiting. Clinical trials have demonstrated similar efficacy and safety with the 5-HT₃ receptor antagonists for the prevention of CINV. Intravenous and oral formulations are equally effective when used at the appropriate dose. Guidelines do not give preference to one 5-HT₃ receptor antagonist over another.

There is insufficient evidence to support that one brand 5-HT₃ 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 5-HT₃ 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 5-HT₃ 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 Cohenour asked the P&T Committee Members to mark their ballots.

Antiemetics, Miscellaneous: AHFS 562292

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the miscellaneous antiemetics that are included in this review are listed in Table 1 on page 510. The miscellaneous antiemetics are approved for the prevention and treatment of CINV, PONV, motion sickness, and acquired immunodeficiency syndrome-related anorexia. Dronabinol is the only agent that is available in a generic formulation. A combination product containing netupitant and palonosetron was Food and Drug Administration (FDA)-approved in October 2014. Netupitant is a neurokinin-1 antagonist and palonosetron is a 5-HT₃ antagonist; Palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

Current treatment guidelines that incorporate the use of the miscellaneous antiemetics are summarized in Table 2. Guidelines recommend the use of a neurokinin-1 antagonist to prevent acute nausea and vomiting associated with highly emetogenic chemotherapy (in combination with a 5-HT₃ receptor antagonist and dexamethasone). Clinical trials have demonstrated greater efficacy using a triple therapy regimen (neurokinin-1 antagonist, 5-HT₃ receptor antagonist, and dexamethasone) compared to a dual therapy regimen (5-HT₃ receptor antagonist and dexamethasone). Guidelines also recommend the use of a neurokinin-1 antagonist to prevent delayed nausea and vomiting when administering highly emetogenic or anthracycline/cyclophosphamide chemotherapy regimens.

There is insufficient evidence to support that one brand miscellaneous antiemetic is safer or more efficacious than another. NK1 antagonists are considered a component of first-line therapy in certain clinical settings, such as in patients receiving moderately or highly emetogenic chemotherapy. Patients with a cancer diagnosis should be allowed approval for an oral NK1 antagonist through the medical justification portion of the prior authorization process.

Therefore, all brand miscellaneous antiemetics 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 antiemetic 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 Cohenour asked the P&T Committee Members to mark their ballots.

Proton-Pump Inhibitors: AHFS 562836

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the proton-pump inhibitors (PPI) that are included in this review are listed in Table 1 on page 569. All agents with the exception of dexlansoprazole are available in a generic formulation. Esomeprazole strontium was FDA-approved in August 2013 without a proprietary name; it was approved based on bioequivalence of esomeprazole strontium 24.65 mg and 49.3 mg delayed-release capsules to esomeprazole magnesium 20 and 40 mg delayed-release capsules. Esomeprazole strontium will be included in Table 1, but no additional references to esomeprazole strontium will be made in this review as all data are similar between esomeprazole magnesium and esomeprazole strontium.

There have been no major changes in the prescribing information, treatment guidelines, or clinical studies regarding these agents since this class was last reviewed. Of note, in November 2014 the prescribing information for PPIs was updated to include information on the risk of acute interstitial nephritis and vitamin B12 deficiency. Acute interstitial nephritis is generally attributed to an idiopathic hypersensitivity reaction, and vitamin B12 deficiency occurs rarely in patients taking acid-suppressing medications longer than three years.

There is insufficient evidence to support that one brand proton-pump 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 proton-pump 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 proton-pump 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 Cohenour asked the P&T Committee Members to mark their ballots.

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

Savaysa®

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that edoxaban (Savaysa®) is a factor Xa inhibitor approved by the Food and Drug Administration (FDA) for the reduction in the risk of stroke and systemic embolism in nonvalvular atrial fibrillation (NVAf) as well as for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant. This agent is the fourth new oral anticoagulant (NOAC) to reach the market.

The major advancement with all of the NOAC agents, including edoxaban, is that they do not have the same extensive food and drug interactions as warfarin nor do they require the same monitoring as warfarin therapy. The lack of therapeutic monitoring, however, may make it difficult for physicians to objectively assess adherence to therapy. Another important consideration is the lack of available reversal agents for many of the NOACs like there is with the use of vitamin K for warfarin. A specific reversal agent for dabigatran was recently FDA-approved, and development of an agent for the reversal of factor Xa inhibitors is underway.

Edoxaban is predominately cleared by the kidneys. Recommendations per the package insert are to decrease the dose if creatinine clearance (CrCl) is <50 mL/min and to avoid use altogether in AF patients with normal renal function (CrCl is >95 mL/min). Avoiding edoxaban use in patients with CrCL >95 mL/min is included in the boxed warning. In the ENGAGE AF-TIMI 48 study, nonvalvular atrial fibrillation patients with CrCL >95 mL/min had an increased rate of ischemic stroke with edoxaban 60 mg once daily compared to patients treated with warfarin. For the treatment of nonvalvular AF, the ENGAGE AF-TIMI 48 study also demonstrated that high dose edoxaban (60 mg or 30 mg dose adjusted) was noninferior to adjusted dose warfarin for the reduction of the primary composite endpoint of stroke (ischemic or hemorrhagic) or systemic embolic event (P<0.001 for noninferiority). The rate of ischemic stroke was similar with high-dose edoxaban and warfarin but was higher with the low-dose edoxaban regimen. Results from the HOKUSAI-VTE study demonstrated noninferiority of edoxaban to adjusted dose warfarin for the reduction of recurrent, symptomatic DVT and PE in patients treated up to 12 months. Edoxaban has demonstrated a favorable bleeding profile compared to warfarin except for more reports of gastrointestinal hemorrhages with the 60 mg dose.

Although the use of this new anticoagulant has not been addressed in the most recent consensus guidelines, the guidelines do mention that all the other NOAC agents are appropriate alternatives to warfarin for the management of individuals with AF. The 2014 American Heart Association/American College of Cardiology guidelines state that antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute relative risks of stroke and bleeding and the patient's values and preferences.

Due to the lack of unanimous recommendations from guidelines preferring one of the newer agents over another, the reports of significant adverse drug reactions reported to the FDA, and the lack of long-term safety data, it is recommended that edoxaban be managed via the prior authorization process.

No brand edoxaban 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 this agent. Chairperson Cohenour asked the P&T Committee members to mark their ballots.

Toujeo[®]

Manufacturer comments on behalf of these products:

Toujeo[®] - Sanofi

Dr. Bacon commented that insulins stimulate peripheral glucose uptake by skeletal muscle and fat, decrease hepatic glucose production, inhibit lipolysis and proteolysis, and enhance protein synthesis. Insulin therapy is usually administered by subcutaneous injection, which allows for prolonged absorption and less pain compared to intramuscular injection. All insulin products have at least one formulation with a concentration of 100 units/mL (U-100). Two agents are also formulated with a higher concentration, regular insulin as 500 units/mL (U-500; Humulin[®] R U-500) and insulin glargine as 300 units/mL (U-300; Toujeo[®]). Toujeo[®] shows a more flat-line pharmacokinetic profile and prolonged duration of activity versus insulin glargine U-100 (Lantus[®]).

According to current clinical guidelines regarding the management of type 1 diabetes, initiation of individualized, intensive insulin therapy at the time of diagnosis is recommended. According to the American Diabetes Association, insulin analogs should be utilized in most patients. Some patients treated with basal, or long-acting, insulin may require twice-daily dosing to achieve greater control. In general, no one specific insulin product among the various classifications is recommended or preferred over another. Again, insulin therapy must be individualized as the products within the different classifications play specific roles in achieving adequate glycemic control in patients with type 1 diabetes. Insulin therapy may also be appropriate in the management of type 2 diabetes; however, traditionally oral antidiabetic agents are utilized. Of note, many patients with type 2 diabetes will ultimately require insulin therapy, alone or in combination with other agents, to maintain glucose control. Insulin is recognized as a potential option to be added to current oral antidiabetic agent regimens in patients not achieving glycemic goals. It may also be appropriate to initiate insulin therapy at the time of diagnosis in certain clinical settings, particularly in patients with a high baseline glycosylated hemoglobin (HbA1c) ($\geq 9.0\%$), or in patients presenting with significant hyperglycemic symptoms and/or has dramatically elevated plasma glucose concentrations or HbA1c. Furthermore, such therapy is mandatory when catabolic features are exhibited or if ketonuria is demonstrated. There is insufficient evidence to conclude that one long-acting insulin analog is safer or more efficacious than another.

The safety and efficacy of insulin glargine U-300 (Toujeo[®]) was evaluated in the EDITION trials. Each study compared insulin glargine U-300 to insulin glargine U-100. The EDITION studies evaluated the safety and effectiveness of insulin glargine U-300 in patients with type 2 diabetes. EDITION 1 evaluated insulin glargine U-300 in combination with mealtime insulin, while EDITION 2 and 3 evaluated combination therapy with non-insulin oral antidiabetic agents; in EDITION 3, patients were also insulin-naïve. In all three studies, insulin glargine U-300 was shown to be non-inferior to insulin glargine U-100. Additionally, the dose of basal glargine insulin required was higher in all three studies for U-300, requiring

11, 12, and 15% more units. Generally, both U-100 and U-300 had similar rates of adverse events, including hypoglycemia and all three studies showed similar changes in weight.

At this time, there is insufficient data to conclude that insulin glargine U-300 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.

No brand insulin glargine U-300 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 this agent. Chairperson Cohenour 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 BUISNESS

The dates for the 2016 Alabama Medicaid P&T Meetings were provided and are as follows: May 11, 2016, August 10, 2016, and November 9, 2016.

9. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for May 11, 2016 at the Medicaid Building in the Commissioner's Board Room.

10. ADJOURN

There being no further business, Dr. Harwood moved to adjourn and Dr. Carter seconded. The meeting adjourned at 10:18 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
February 10, 2016

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

Carisoprodol and carisoprodol containing products should not be placed in preferred status regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Ponce, MD Approve Approve as amended Disapprove No action

Assistant Medical Director

Kathy Veil Approve Approve as amended Disapprove No action

Deputy Commissioner

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

Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

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

Assistant Medical Director

Kathy Steel Approve Approve as amended Disapprove No action

Deputy Commissioner

Stephanie Fox Approve Approve as amended Disapprove No action
Commissioner

C. Recommendation: No brand gamma aminobutyric acid (GABA)-derivative skeletal muscle relaxant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

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

Assistant Medical Director

Kathy Steel Approve Approve as amended Disapprove No action

Deputy Commissioner

Stephanie Fox Approve Approve as amended Disapprove No action
Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Poma, MD Approve Approve as amended Disapprove No action

Assistant Medical Director

Kathy Heel Approve Approve as amended Disapprove No action

Deputy Commissioner

Stephanie Dyer Approve Approve as amended Disapprove No action
Commissioner

E. Recommendation: No brand opiate 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. Poma, MD Approve Approve as amended Disapprove No action

Assistant Medical Director

Kathy Heel Approve Approve as amended Disapprove No action

Deputy Commissioner

Stephanie Dyer Approve Approve as amended Disapprove No action
Commissioner

F. Recommendation: No brand opiate partial 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.

Buprenorphine and buprenorphine-naloxone should not be placed in preferred status regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rome, MD Approve Approve as amended Disapprove No action

Assistant Medical Director

Kathy Skelley Approve Approve as amended Disapprove No action

Deputy Commissioner

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

G. Recommendation: No brand selective serotonin 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 S. Rome, MD Approve Approve as amended Disapprove No action

Assistant Medical Director

Kathy Skelley Approve Approve as amended Disapprove No action

Deputy Commissioner

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

H. Recommendation: No brand antihistamine antiemetic 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. Ponce, 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

Commissioner

I. Recommendation: No brand 5-HT₃ 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. Ponce, 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

Commissioner

J. Recommendation: No brand miscellaneous antiemetic 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. Roney, MD Approve Approve as amended Disapprove No action

Assistant Medical Director

Gabby Healy Approve Approve as amended Disapprove No action

Deputy Commissioner

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

K. Recommendation: No brand proton-pump 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. Roney, MD Approve Approve as amended Disapprove No action

Assistant Medical Director

Gabby Healy Approve Approve as amended Disapprove No action

Deputy Commissioner

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

L. Recommendation: No brand edoxaban 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

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

Nathly Steel Approve Approve as amended Disapprove No action
Deputy Commissioner

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

M. Recommendation: No brand insulin glargine U-300 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

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

Nathly Steel Approve Approve as amended Disapprove No action
Deputy Commissioner

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

Respectfully submitted,

Rachel Bacon

Rachel Bacon, PharmD

February 16, 2016

Date