

**Minutes of Meeting**  
**Alabama Medicaid Agency**  
**Pharmacy and Therapeutics Committee**

**November 13, 2013**

**Members Present:** Chairperson-Ms. Janet Allen, Dr. Julia Boothe, Dr. Frances Cohenour, Dr. David Harwood, Dr. Elizabeth Jacobson, Dr. Kelli Littlejohn, and Dr. Melinda Rowe

**Members Absent:** Vice chairperson-Ms. LaTouge Porter

**Patient Care Networks of Alabama (PCNA) Staff Present:** Dr. Joshua Lee and Dr. Kristian Testerman

**Patient Care Networks of Alabama (PCNA) Staff Absent:** Dr. Amy Donaldson and Dr. Holley Rice

**Presenters:** Dr. James Gagnon and Dr. Mark Tesell

**Presenters Present via Teleconference:** None

**1. OPENING REMARKS**

Chairperson Allen called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:07 a.m.

**2. APPROVAL OF MINUTES**

Chairperson Allen asked if there were any corrections to the minutes from the August 14, 2013 P&T Committee Meeting.

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

**3. PHARMACY PROGRAM UPDATE**

Dr. Littlejohn provided an overview of the changes to the Alabama Medicaid Pharmacy program effective October 1, 2013. Changes that were discussed include the discontinuation of coverage of most over-the-counter (OTC) products (it was noted that OTC insulins, syringes, nutritionals, and second generation antihistamines remain covered); the reduction of reimbursement from WAC+9.2% to WAC+0% for drugs with no AAC price on Medicaid's file; the phase-in of three month supply of Agency specified maintenance medications (this will be mandatory on January 1,

2014); and the phase-in of five prescription limit (up to 4 may be brands) per month for adults (this will be mandatory on January 1, 2014).

Dr. Littlejohn noted that children and long term care recipients are excluded from the prescription limit. She also noted that there are allowances for up to 10 prescriptions per month for antiretrovirals, antipsychotics, and antiepileptic medications. Dr. Littlejohn stated that educational efforts for the above mentioned changes include provider and recipient notices, face-to-face academic detailing, and various online publications (to include online instructional videos).

Dr. Littlejohn stated that the Alabama Medicaid Pharmacy Commission has held three of its four meetings; the next meeting is scheduled for November 14, 2013, and will follow with a report to the Governor of its findings. More information can be found at the Agency website.

**4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES**

None

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

The pharmacotherapy class reviews began at approximately 9:25 a.m. There were a total of eleven re-reviews. The classes were previously reviewed in May 2011.

**Centrally Acting Skeletal Muscle Relaxants: American Hospital Formulary Service (AHFS) 122004**

Manufacturer comments on behalf of these products:

None

Dr. Tesell commented that the centrally acting skeletal muscle relaxants that are included in this review are listed in Table 1. All of the products are available in a generic formulation. These agents are approved to relieve discomfort associated with acute, painful musculoskeletal conditions, as well as for the management of spasticity. 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 January 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 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 should not be placed in preferred status regardless of cost.

There were no further discussions on the agents in this class. Chairperson Allen 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. Tesell 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 Allen 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. Tesell 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 Allen 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. Tesell commented that orphenadrine and orphenadrine/aspirin/caffeine are the only miscellaneous skeletal muscle relaxants that are currently available and both 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.

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.

Dr. Jacobson inquired if the P&T Committee Members should take “off-label” uses into consideration. Dr. Littlejohn replied that the P&T is charged to review the agents based on Food and Drug Administration (FDA) approved indications.

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

**Opiate Agonists: AHFS 280808**

Manufacturer comments on behalf of these products:

None

Dr. Tesell commented that the opiate agonists that are included in this review are listed in Table 1. 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 as single entity agents, as well as in combination with acetaminophen, aspirin, butalbital, caffeine and ibuprofen. 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. Several new branded dosage formulations have been approved by the FDA since this class was last reviewed and these products are noted in Table 1. The majority of these products were previously available in immediate or extended-release generic preparations.

In September 2013, the FDA announced labeling changes for all extended-release and long-acting opioids. Once these requirements are finalized, safety labeling across the class will include an updated indication stating that these agents are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or otherwise inadequate. The FDA will require a new boxed warning regarding the risk of neonatal opioid withdrawal syndrome when these agents are used during pregnancy and will also require the manufacturers of extended-release and long-acting opioids to conduct postmarket studies further assessing the known risks of misuse, abuse, hyperalgesia, addiction, overdose, and death. These changes will be incorporated into the existing Risk Evaluation and Mitigation Strategy (REMS) program.

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. For the prevention of withdrawal, opiates have been shown to reduce craving and the effects of illicit opioids; therefore the opioid-dependent patient is able to focus more readily on recovery activities.

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.

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

**Opiate Partial Agonists: AHFS 280812**

Manufacturer comments on behalf of these products:

None

Dr. Tesell commented that the opiate partial agonists that are included in this review are listed in Table 1. Since the previous review, Butrans<sup>®</sup> (buprenorphine) transdermal patch has been FDA approved for the management of moderate to severe chronic pain. Another noteworthy event impacting this class was the notification to the FDA in September 2012, that Reckitt Benckiser Pharmaceuticals was voluntarily discontinuing production of Suboxone<sup>®</sup> (buprenorphine and naloxone) sublingual tablets as a result of increasing concerns over accidental or unsupervised pediatric exposure with the tablets compared to the film formulation which is available in a child-resistant, unit dose packaging. Distribution of Suboxone<sup>®</sup> (buprenorphine and naloxone) sublingual tablets was discontinued in March 2013; however, the generic formulation remains available. All of the products are available in a generic formulation with the exception of buprenorphine transdermal patch and pentazocine.

Current treatment guidelines that incorporate the use of the opiate partial agonists are summarized in Table 2. As stated previously, guidelines recommend the use of an opiate agonist in patients with moderate to severe cancer pain or chronic noncancer pain.

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.

As previously mentioned, Butrans<sup>®</sup> (buprenorphine) transdermal patch is the newest partial opioid agonist and has been FDA approved for the management of moderate to severe chronic pain. Similar to full opioid agonists, this agent has a boxed warning for the risks of abuse potential, respiratory depression and accidental exposure, especially in children. In clinical trials of patients with chronic pain syndromes, this agent was observed to be associated with greater reduction in pain from baseline compared to placebo. In addition, the agent was found to be non-inferior to

active comparator treatment with other scheduled analgesics including codeine/acetaminophen and tramadol. Adverse events observed were generally consistent with those expected from opioid treatment.

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.

Dr. Elizabeth Jacobson inquired if clinical trials have demonstrated Butrans<sup>®</sup> (buprenorphine) transdermal patch to be associated with a lower risk of abuse compared to other oral analgesics. Dr. Tesell replied that based upon clinical trials, Butrans<sup>®</sup> (buprenorphine) transdermal patch has not been conclusively found to have a lower abuse potential. The illicit use of the agent was then discussed.

Dr. Littlejohn commented that Alabama Medicaid has been successful in the management of the agents in this class and it is likely due to the management strategies that were implemented when the class was first reviewed by the P&T Committee.

Dr. Boothe inquired if Alabama Medicaid required an X-DEA for practitioners to prescribe Butrans<sup>®</sup> (buprenorphine) transdermal patch. Dr. Littlejohn replied that they did not.

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

### **Selective Serotonin Agonists: AHFS 283228**

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the selective serotonin agonists (triptans) that are included in this review are listed in Table 1. 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. Naratriptan rizatriptan, sumatriptan and zolmitriptan are available in a generic formulation.

Current treatment guidelines that incorporate the use of the selective serotonin agonists are summarized in Table 2. For the acute treatment of migraine headaches, guidelines recommend the use of a non-steroidal anti-inflammatory drug (NSAID) or triptan, depending on the severity of pain. NSAIDs are generally recommended for patients with mild pain, while the triptans are recommended for patients with moderate to severe pain. In very severe attacks, the use of subcutaneous sumatriptan is recommended as initial therapy. Patients experiencing nausea and vomiting may be better candidates for intranasal or subcutaneous formulations. The use of a second dose of a triptan is effective if a patient experiences a reoccurrence of their headache (new onset pain after symptoms had resolved); however, a second dose has not been shown to be useful if the first dose was ineffective.

Although triptans can be taken any time during a migraine attack, evidence suggests they are more efficacious when taken early compared to later use. Combining an NSAID with a triptan reduces headache recurrence. Guidelines also suggest that a triptan can be efficacious even if another triptan was not. For the treatment of cluster headaches, the use of subcutaneous sumatriptan or intranasal zolmitriptan is recommended as initial therapy. For the prophylaxis of menstrual migraines, guidelines recommend the use of an NSAID; however, studies support the cyclical use of a triptan as well. In general, guidelines do not give preference to one triptan over another.

Numerous clinical trials have evaluated the efficacy and safety of the triptans for the treatment of migraine headaches, cluster headaches and menstrual migraines. Several studies have demonstrated similar efficacy among the agents. However, other studies have demonstrated greater efficacy with one agent over another. Sumatriptan/naproxen has been shown to be more effective than either drug administered alone. However, there is no data to suggest that the fixed-dose combination product is more efficacious than the coadministration of the individual components as separate formulations. Some minor differences exist between the triptans with regards to their pharmacokinetic properties (e.g., onset and duration of action); however, this has not consistently resulted in differences in clinical outcomes.

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 Allen asked the P&T Committee Members to mark their ballots.

**Antiemetics, Antihistamines: AHFS 562208**

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the antihistamine antiemetics that are included in this review are listed in Table 1. Since the last review the fixed dose combination product consisting of doxylamine and pyridoxine was approved. The antihistamine antiemetics are approved for the treatment of postoperative nausea and vomiting, general nausea and vomiting, motion sickness and vertigo. Prochlorperazine is also approved for the treatment of schizophrenia, as well as for the short term treatment of generalized non-psychotic anxiety. Conversely, the doxylamine and pyridoxine combination product is indicated for the treatment of nausea and vomiting in pregnancy. All of the products with the exception of the new fixed dose combination product are available in a generic formulation.

Current treatment guidelines that incorporate the use of the antihistamine antiemetics are summarized in Table 2. There have been no major changes to the treatment guidelines since the class was last reviewed.

There have been no major changes to the clinical trials since the class was last reviewed. The agents in the class have been shown to be efficacious for their FDA approved indications. The fixed dose combination product consisting doxylamine and pyridoxine has been shown to be efficacious compared to placebo.

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 Allen asked the P&T Committee Members to mark their ballots.

**Antiemetics, 5-HT<sub>3</sub> Receptor Antagonists: AHFS 562220**

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the 5-HT<sub>3</sub> receptor antagonists that are included in this review are listed in Table 1. 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.

Current treatment guidelines that incorporate the use of the 5-HT<sub>3</sub> 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-HT<sub>3</sub> receptor antagonists (in combination with aprepitant and/or dexamethasone) to prevent acute nausea and vomiting associated with moderately or highly emetogenic chemotherapy. The 5-HT<sub>3</sub> 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-HT<sub>3</sub> 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-HT<sub>3</sub> receptor antagonist over another.

For the prevention of RINV, guidelines recommend the use of a 5-HT<sub>3</sub> receptor antagonist (with or without dexamethasone) before each fraction. Granisetron and ondansetron have demonstrated similar efficacy in one clinical trial.

Nausea and vomiting of pregnancy is a common condition that can significantly impact a woman's quality of life. Mild symptoms can often be treated with lifestyle and dietary modifications. However, some women may experience severe nausea and vomiting (hyperemesis gravidarum), which may require hospitalization. Despite the paucity of data, the 5-HT<sub>3</sub> receptor antagonists have been used to treat nausea and vomiting of pregnancy. The American College of Obstetricians and Gynecologists (ACOG) and the Society of Obstetricians and Gynecologists of Canada (SOGC) guidelines recommend the use of vitamin B6, with or without doxylamine, as first-line therapy for the treatment of nausea and vomiting of pregnancy. If there is no improvement, the addition of promethazine, dimenhydrinate, metoclopramide or trimethobenzamide is recommended. Ondansetron is considered an alternative treatment option for women who are dehydrated and have symptoms that are not relieved by other treatments. One randomized trial demonstrated that intravenous ondansetron was as effective as intravenous promethazine for the treatment of hyperemesis gravidarum.

According to the International Anesthesia Research Society (IARS) guidelines, not all surgical patients will benefit from prophylactic antiemetic therapy. Prophylaxis is only recommended for patients who are at moderate or high-risk for PONV. These patients should receive treatment with two or three antiemetic agents from different classes. The 5-HT<sub>3</sub> receptor antagonists can effectively be combined with droperidol, dexamethasone or promethazine. For patients who do not receive prophylaxis, a small-dose of a 5-HT<sub>3</sub> receptor antagonist should be administered upon the first signs of PONV. Clinical trials have demonstrated similar efficacy and safety among the 5-HT<sub>3</sub> receptor antagonists for the prevention and treatment of PONV.

There is insufficient evidence to support that one brand 5-HT<sub>3</sub> 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-HT<sub>3</sub> 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-HT<sub>3</sub> 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 was a discussion concerning the assigned quantity limits to the agents in the class. The P&T Committee recommended that Alabama Medicaid review the quantity limits for a possible increase in the limit. Alabama Medicaid is to conduct a review of the quantity limits.

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

**Antiemetics, Miscellaneous: AHFS 562292**

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the miscellaneous antiemetics that are included in this review are listed in Table 1. 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.

Current treatment guidelines that incorporate the use of the miscellaneous antiemetics are summarized in Table 2. Guidelines recommend the use of aprepitant or fosaprepitant to prevent acute nausea and vomiting associated with moderately or highly emetogenic chemotherapy (in combination with a 5-HT<sub>3</sub> receptor antagonist and dexamethasone). Clinical trials have demonstrated greater efficacy using a triple therapy regimen (aprepitant/fosaprepitant, 5-HT<sub>3</sub> receptor antagonist, and dexamethasone) compared to a dual therapy regimen (5-HT<sub>3</sub> receptor antagonist and dexamethasone). Guidelines also recommend the use of aprepitant to prevent delayed nausea and vomiting when administering highly emetogenic or anthracycline/cyclophosphamide chemotherapy regimens.

There have been no major changes in the relevant treatment guidelines, the prescribing information or clinical trials related to the miscellaneous antiemetics since the class was last reviewed.

There is insufficient evidence to support that one brand miscellaneous antiemetic is safer or more efficacious than another. Aprepitant is considered 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 aprepitant through the medical justification portion of the prior authorization process, as well as automatic approval through the electronic 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 Allen asked the P&T Committee Members to mark their ballots.

**Proton-Pump Inhibitors: AHFS 562836**

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the proton-pump inhibitors (PPI) that are included in this review are listed in Table 1. Omeclamox-Pak<sup>®</sup> (omeprazole, amoxicillin, and clarithromycin) is the most recently FDA-approved PPI-containing product and this agent was approved in 2011. This product contains omeprazole and is packaged with amoxicillin and clarithromycin with the intent of providing an entire eradication therapy course for H Pylori within one package. Lansoprazole, omeprazole, omeprazole/sodium bicarbonate and pantoprazole are available as generic prescription products. The combination product, Prevpac<sup>®</sup>, contains lansoprazole, amoxicillin and clarithromycin, which are packaged separately on daily administration cards. The individual components are all available in a generic formulation.

Current treatment guidelines that incorporate the use of the PPIs are summarized in Table 2. Guidelines recognize that the PPIs are more effective than histamine H<sub>2</sub>-receptor antagonists for the treatment of erosive esophagitis and symptomatic GERD. In general, clinical trials have demonstrated similar efficacy among the PPIs for these indications and guidelines do not give preference to one PPI over another for the treatment of erosive esophagitis or symptomatic GERD. Guidelines recommend the use of a PPI in combination with antibiotics as first-line therapy for the treatment of patients with *H. pylori* infection and duodenal ulcer disease to eradicate *H. pylori*. Clinical trials have demonstrated similar efficacy among the PPIs for this indication. Guidelines do not give preference to one PPI over another for the eradication of *H. pylori*.

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 Allen 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 was no new business.

**8. NEXT MEETING DATE**

The next P&T Committee Meeting is scheduled for February 12, 2014 at the Medicaid Building in the Commissioner's Board Room.

**9. ADJOURN**

There being no further business, Dr. Harwood moved to adjourn and Dr. Boothe seconded. The meeting adjourned at 10:45 a.m.

Appendix

RESULTS OF THE BALLOTING  
Alabama Medicaid Agency  
Pharmacy and Therapeutics Committee  
November 13, 2011

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

**Amendment:** None

**Vote:** Unanimous to approve as recommended

M. Spone, MD  Approve  Approve as amended  Disapprove  No action  
Medical Director

Kathy Kelly  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie  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

M. Spone, MD  Approve  Approve as amended  Disapprove  No action  
Medical Director

Kathy Kelly  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

Stephanie  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

*M. Rouse, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Spief*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A.*  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

*M. Rouse, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Hall*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie A.*  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

*M. P. Ponce, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Kelly*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie H.*  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

*M. P. Ponce, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Kelly*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie H.*  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

*M. Malone, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Hall*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie H.*  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

*M. Malone, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Hall*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

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

**I. Recommendation:** No brand 5-HT<sub>3</sub> 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

*M. P. Moore, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Kelly*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

*Stephanie H.*  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

*M. P. Moore, MD*  Approve  Approve as amended  Disapprove  No action  
Medical Director

*Kathy Kelly*  Approve  Approve as amended  Disapprove  No action  
Deputy Commissioner

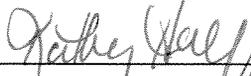
*Stephanie H.*  Approve  Approve as amended  Disapprove  No action  
Commissioner

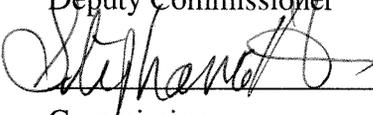
**K. Recommendation:** No brand proton-pump inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

**Amendment:** None

**Vote:** Unanimous to approve as recommended

  
\_\_\_\_\_  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

Respectfully submitted,



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James Gagnon, Pharm.D., BCPS

November 13, 2013

Date