

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

May 14, 2014

Members Present: Dr. Julia Boothe, Dr. Lee Carter, Dr. Frances Cohenour, Dr. David Harwood, Dr. Elizabeth Jacobson, Dr. Kelli Littlejohn Newman, Vice chairperson-Ms. LaTonage Porter and Dr. Melinda Rowe

Members Absent: Chairperson-Ms. Janet Allen and Dr. Weily Soong

Patient Care Networks of Alabama (PCNA) Staff Present: Dr. Amy Donaldson, Dr. Tammy Dubuc, Dr. Lydia Rather, Dr. Holley Rice, and Dr. Kristian Testerman

Presenters: Dr. James Gagnon, Dr. Neha Kashalikar and Dr. Mito Takeshita

Presenters Present via teleconference: None

1. OPENING REMARKS

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

2. APPROVAL OF MINUTES

Vice chairperson Porter asked if there were any corrections to the November 13, 2013 P&T Committee Meeting's minutes.

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

3. PHARMACY PROGRAM UPDATE

Dr. Littlejohn Newman oriented the Committee members to the Provider Alerts that are available on the Agency's website and provided the following updates:

- In January of 2014 Alabama Medicaid implemented a monthly prescription limit for adults and a mandatory maintenance three month supply. (The maintenance supply mandate only applies to medications specified by the Alabama Medicaid Agency. A complete listing of the included medications is on the Agency's website.) However, as of May 2014 all

applicable maintenance medications, even the first 60 days of stable therapy, will be excluded from the monthly prescription limit for adults.

- As of the April 2014 Preferred Drug List update, the proton pump inhibitors were added to the maintenance three month supply list. This information was included with quarterly PDL updates effective April 1, 2014.
- In May 2014, the Agency's Regional Care Organization (RCO) statewide meetings were held; see the Agency's website for more information.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations were explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were a total of six 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 9:15 a.m. There were a total of 23 drug class re-reviews. The Skin and Mucous Membrane Antibacterials, Skin and Mucous Membrane Antivirals, Skin and Mucous Membrane Antifungals, Skin and Mucous Membrane Scabicides and Pediculicides, Skin and Mucous Membrane Local Anti-infectives, Miscellaneous, Skin and Mucous Membrane Anti-inflammatory Agents, Skin and Mucous Membrane Antipruritics and Local Anesthetics, Skin and Mucous Membrane Astringents, Skin and Mucous Membrane Keratolytic Agents, Skin and Mucous Membrane Keratoplastic Agents, Skin and Mucous Membrane Agents, Miscellaneous were all last reviewed in November 2011. The Alzheimer's Agents, Antidepressants, Cerebral Stimulants/Agents Used for ADHD, Wakefulness Promoting Agents, Anxiolytics, Sedatives, and Hypnotics – Barbiturates, Anxiolytics, Sedatives, and Hypnotics – Benzodiazepines, Anxiolytics, Sedatives, and Hypnotics – Miscellaneous, Genitourinary Smooth Muscle Relaxants were all last reviewed in August 2012.

Skin and Mucous Membrane Antibacterials: American Hospital Formulary Service (AHFS) 840404

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane antibacterials included in this review are listed in Table 1. Most of the agents within this class are available in a generic formulation. The antibacterial agents are approved for the treatment and/or prevention of various skin infections and bacterial vaginosis. 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 skin and mucous membrane antibacterial 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 skin and mucous membrane antibacterials 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 skin and mucous membrane antibacterial 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Antivirals: AHFS 840406

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane antivirals included in this review are listed in Table 1. Since the last review acyclovir ointment has become available generically. There have been no other 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 skin and mucous membrane antiviral 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 skin and mucous membrane antivirals within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

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

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Antifungals: AHFS 840408

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane antifungals included in this review are listed in Table 1. There have been no other 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 skin and mucous membrane antifungal 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 skin and mucous membrane antifungals within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

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

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Scabicides and Pediculicides: AHFS 840412

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane scabicides and pediculicides included in this review are listed in Table 1. The skin and mucous membrane scabicides and pediculicides are approved to treat pediculosis and scabies. When treating scabies and lice, the goal of therapy is to eradicate the parasite. The agents in this class achieve this goal via different mechanisms of action. The newest agent in the class, ivermectin, is pediculicidal but not ovicidal and it is approved as a single application product only. All of the products are available in a generic formulation, with the exception of benzyl alcohol, crotamiton and ivermectin.

Permethrin is recommended as first-line therapy and lindane as second-line in the guidelines by the Centers for Disease Control (CDC) and the American Academy of Pediatrics. Crotamiton also has a role as an antipruritic for those with scabies. All patients treated for scabies should expect the rash and itching to continue for approximately two weeks after treatment. The CDC recommends permethrin for pediculosis pubis.

None of the pediculicides are 100% ovicidal and resistance has been reported with lindane, pyrethrins and permethrin. Overall, the comparative success rates of topical pediculicides have been shown to be approximately 57 to 99% with permethrin, 45 to 95% with piperonyl butoxide and pyrethrins, 60 to 88% with lindane and 78% with malathion. The newer agents which include benzyl alcohol, ivermectin and spinosad, have shown cure rates of 75%, 71 to 75% and 93 to 94%, respectively, although there is limited published literature confirming these results.

Therefore, all brand skin and mucous membrane scabicides and pediculicides 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. Lindane possesses an extensive adverse effect profile compared to the other brands and generics in the class (if applicable).

No brand skin and mucous membrane scabicide or pediculicide 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.

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

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Local Anti-infectives, Miscellaneous: AHFS 840492

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane miscellaneous local anti-infectives included in this review are listed in Table 1. 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 skin and mucous membrane miscellaneous local anti-infective is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane miscellaneous local anti-infectives 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 skin and mucous membrane miscellaneous local anti-infective is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Local Anti-inflammatory Agents: AHFS 840600

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane anti-inflammatory agents included in this review are listed in Table 1. The skin and mucous membrane anti-inflammatory agents are approved for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Since the last review generic formulations of Luxiq[®], Lokara[®], Topicort Spray[®], Dermasmooth FS[®], and Synalar[®] have become available. Additionally the branded product Ultravate X[®], a combination package consisting of halobetasol and lactic acid has become available.

This review encompasses all dosage forms and strengths. There is at least one topical corticosteroid available in a generic formulation in each potency category and hydrocortisone is

available over the counter. There have been no other 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 skin and mucous membrane anti-inflammatory agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane anti-inflammatory 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 skin and mucous membrane anti-inflammatory 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Antipruritics and Local Anesthetics: AHFS 840800

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane antipruritics and local anesthetics included in this review are listed in Table 1. This review encompasses all topical dosage forms and strengths. Several of the products are available in a generic formulation. The most noteworthy generic to recently become available is lidocaine transdermal patch. Since the last review, Pre-attached LTA[®] also became available. This agent is a sterile disposable kit for producing rapid topical anesthesia to the interior of the larynx and trachea. There have been no other 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 skin and mucous membrane antipruritic or local anesthetic 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 skin and mucous membrane antipruritics and local anesthetics 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 skin and mucous membrane antipruritic or local anesthetic 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Astringents: AHFS 841200

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that aluminum chloride is the only skin and mucous membrane astringent that is currently available. It is approved for the treatment of hyperhidrosis and is available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane astringent 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 skin and mucous membrane astringents 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 skin and mucous membrane astringent 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Keratolytic Agents: AHFS 842800

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the skin and mucous membrane keratolytic agents included in this review are listed in Table 1. 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 skin and mucous membrane keratolytic agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane keratolytic 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 skin and mucous membrane keratolytic 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Keratoplastic Agents: AHFS 843200

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that as of October 1, 2013, Alabama Medicaid no longer covers most over-the-counter (OTC) medications for adults and children. The only exceptions are insulin, 2nd generation antihistamines and specialized nutritional products. Currently there are no prescription medications classified by American Hospital Formulary Service (AHFS) as keratoplastic agents.

No brand skin and mucous membrane keratoplastic agent is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 843200 in the Preferred Drug List (PDL) screening process. If new prescription keratoplastic agents are added, it is recommended that this class be re-reviewed.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Agents, Miscellaneous: AHFS 849200

Manufacturer comments on behalf of these products:

None

Dr. Gagnon commented that the miscellaneous skin and mucous membrane agents included in this review are listed in Table 1. The miscellaneous skin and mucous membrane class includes a diverse group of products used to treat many skin conditions, including actinic keratoses, atopic dermatitis, basal cell carcinoma, cutaneous T-cell lymphoma, Kaposi's sarcoma, mucositis, pain associated with anal fissure, postherpetic neuralgia, psoriasis, warts and wounds. This review encompasses all dosage forms and strengths of the agents included in this review. Acitretin, calcipotriene, calcitriol, fluorouracil, imiquimod and podofilox are available in a generic formulation.

Since the last review, a generic formulation has become available for soriatane and vestical. Also since the last review, three new agents have become available and include: Sorilux[®], a foam formulation of calcipotriene that is approved for the treatment of plaque psoriasis of the scalp and body; Picato[®], a gel formulation of ingenol mebutate which is approved for the treatment of actinic keratosis; and Rectiv[®], an ointment formulation of nitroglycerine that is approved for the treatment of moderate to severe pain associated with chronic anal fissure. There were no other major changes in the prescribing information since the class was last reviewed.

Due to the wide variety of products, as well as the range of Food and Drug Administration-approved indications, direct comparisons are difficult. Several guidelines have been updated since this class was last reviewed, which are summarized in Table 2.

Clinical trials evaluating the safety and efficacy of the miscellaneous skin and mucous membrane agents were summarized. A small number of placebo controlled trials were identified that demonstrated the efficacy of the new agents included in this review. There were no other major changes in the clinical studies since this class was last reviewed.

At this time, there is not a role for the miscellaneous skin and mucous membrane agents in general use. Because these agents have narrow indications with limited usage, they should be available for special needs/circumstances that require medical justification through the prior authorization process.

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

No brand miscellaneous skin and mucous membrane 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Alzheimer's Agents: Parasympathomimetic (Cholinergic) Agents, AHFS 120400; and Central Nervous System Agents, Miscellaneous, AHFS 289200

Manufacturer comments on behalf of these products:

Exelon Patch[®] - Novartis

Dr. Takeshita noted that there are four agents approved for the treatment of Alzheimer's disease, including cholinesterase inhibitors (donepezil, galantamine and rivastigmine) and an N-methyl-D-aspartate (NMDA) receptor antagonist (memantine). Although none of the agents delay the progression of neurodegeneration, these agents do delay the progression of symptoms. Since the last review, an extended release capsule of memantine was approved by the FDA. Additionally, in February of 2014, Forest Laboratories notified the prescriber community of its plan to discontinue the sale of Namenda[®] tablets on August 15, 2014. However, the Namenda[®] oral solution and Namenda XR[®] extended release capsules will continue to be sold.

The Alzheimer's agents included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. Donepezil, galantamine and rivastigmine are available in a generic formulation.

There have been no significant changes in treatment guidelines since the previous therapeutic class review.

Recently published clinical trials evaluating the Alzheimer's agents in the treatment of Alzheimer's disease have not produced clinically different results compared to trials included in the previous therapeutic class review. Overall, evidence still supports that no one agent in the class is more efficacious than another. A published placebo-controlled study supporting the efficacy of the memantine extended-release formulation, in which active treatment significantly improved cognition rating scale scores compared to placebo was discussed.

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

Therefore, all brand Alzheimer's 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 Alzheimer's 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Antidepressants: AHFS 281604

Manufacturer comments on behalf of these products:

Pristiq[®] - Pfizer

Dr. Takeshita 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 are categorized into six different American Hospital Formulary Service (AHFS) subclasses, including monoamine oxidase inhibitors (MAOIs), selective serotonin- and norepinephrine-reuptake inhibitors (SNRIs), selective serotonin-reuptake inhibitors (SSRIs), serotonin modulators, tricyclic antidepressants (TCAs) and miscellaneous agents. Since the last review, a generic has become available for Cymbalta[®] (duloxetine). New formulations of desvenlafaxine extended-release have been approved as Dexvenlafaxine ER[®] and Khedezla[®], and a new formulation consisting of 450 mg of bupropion extended-release has been approved as Forfivo XL[®]. In addition, three new agents have become available, including Brintellix[®] (vortioxetine), Brisdelle[®] (paroxetine mesylate capsule) and Fetzima[®] (levomilnacipran). The antidepressants included in this review are listed in Table 1. This review encompasses all dosage forms and strengths. 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 have been no major changes in the treatment guidelines since this class was last reviewed. Treatment guidelines from the American Psychiatric Association regarding the treatment of major depressive disorder still recommend the use of antidepressants as first line therapy. Subclasses of antidepressants are thought to be equally efficacious, and for most patients a selective serotonin reuptake inhibitor, serotonin norepinephrine reuptake inhibitor, mirtazapine, or bupropion are optimal as initial therapy.

Recently published clinical trials evaluating the antidepressants have not produced clinically different results compared to trials included in the previous class review. With regards to the antidepressant agents approved since the last review of this class, data supporting the efficacy of Brintellix[®] (vortioxetine) and Fetzima[®] (levomilnacipran) for the treatment of major depressive disorder are derived from limited placebo-controlled trials in which active treatment significantly improved depression rating scale scores compared to placebo.

In conclusion, numerous clinical trials have been conducted with the antidepressants and comparative studies have demonstrated similar efficacy in patients with major depressive disorder. Guidelines do not give preference to one agent over another. Rather, the selection of an antidepressant should be based on safety, adverse events, drug interactions, prior response to treatment, comorbid conditions and patient preference.

In general, the monoamine oxidase inhibitors are not routinely used compared to the other subclasses of antidepressants due to their safety profile and associated drug interactions. These agents are typically reserved for patients not responding to other antidepressant therapies.

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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Cerebral Stimulants/Agents Used for ADHD: Central Alpha-Agonists, AHFS 240816; Amphetamines, AHFS 282004; Anorexigenic Agents and Respiratory and Cerebral Stimulants, Miscellaneous, AHFS 282032; and Central Nervous System Agents, Miscellaneous, AHFS 289200

Manufacturer comments on behalf of these products:

Intuniv[®] - Shire

Quillivant[®] - Pfizer

Strattera[®] - Eli Lilly

Dr. Kashalikar noted that all of the medications used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) were last reviewed in August 2012. ADHD is a common psychiatric disorder that is often diagnosed during childhood; however, children with ADHD may continue to manifest symptoms into adulthood. The key diagnostic feature is a persistent pattern of inattention and/or hyperactivity-impulsivity that is more frequent/severe than seen in individuals at a comparable level of development. Since the last review, new generics have become available for Kapvay[®] (clonidine extended-release) and Metadate CD[®] (methylphenidate). In addition, two new agents have become available, including Zenedi[®] (dextroamphetamine) which offers two unique

dosage strengths of dextroamphetamine and Quillivant XR[®] (methylphenidate extended-release) which offers an extended release oral suspension formulation. The cerebral stimulants/agents used for ADHD included in this review are listed in Table 1. Many of the products are available in a generic formulation.

There have been no significant changes in prescribing information since the class was last reviewed.

In 2012, guidelines from the Institute for Clinical Systems Improvement for Diagnosis and Management of ADHD in children and adolescents were updated. Guidelines note stimulant and non-stimulant agents may be used for the treatment of ADHD. Response to one stimulant does not predict response to the others. If a child is a non-responder to one stimulant, it is advisable to attempt a second or third trial with other stimulants. Atomoxetine is a good option for patients with comorbid anxiety, sleep initiation disorder, substance abuse, or tics, or if initially preferred by parents and/or physician. Additionally, extended-release guanfacine and extended-release clonidine are the first ADHD medications to achieve FDA approval as adjunctive therapy with stimulant medications.

Quillivant has been shown to be effective versus placebo as have other agents in this class; however, there are no head to head trials for this agent compared to other stimulant agents.

There is insufficient evidence to support that one brand cerebral stimulant/agent used for ADHD 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 cerebral stimulants/agents used for ADHD 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 cerebral stimulant/agent used for ADHD 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Wakefulness Promoting Agents: AHFS 282080

Manufacturer comments on behalf of these products:

None

Dr. Kashalikar noted that all of the wakefulness promoting agents were last reviewed in August 2012. Narcolepsy is a sleep disorder characterized by excessive daytime sleepiness and intermittent manifestations of rapid eye movement sleep during wakefulness. Obstructive sleep apnea is the most common form of breathing-related sleep disorder, which is caused by obstruction of the airway. The wakefulness promoting agents included in this review are listed in Table 1. Modafinil is currently the only wakefulness promoting agent that is available generically.

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

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

Therefore, all brand wakefulness promoting 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 wakefulness promoting 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Anxiolytics, Sedatives, and Hypnotics-Barbiturates: AHFS 282404

Manufacturer comments on behalf of these products:

None

Dr. Kashalikar noted that the barbiturates are approved for the treatment of insomnia and for the induction of sedation. Some of the agents are also approved for use as an adjunct to anesthesia, as well as for the treatment of seizure disorders. The barbiturates included in this review are listed in Table 1. Phenobarbital is the only agent available in a generic formulation.

There have been no significant changes in prescribing information or clinical studies since the class was last reviewed. Some of the treatment guidelines have been updated since the last review. However, these updates do not contain changes that are significantly different than the other guidelines included.

There is insufficient evidence to support that one brand barbiturate 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 barbiturates 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 barbiturate 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Anxiolytics, Sedatives, and Hypnotics-Benzodiazepines: AHFS 282408

Manufacturer comments on behalf of these products:

None

Dr. Kashalikar noted that the benzodiazepines are approved for a variety of indications including treatment of anxiety, insomnia, seizures and alcohol withdrawal. The benzodiazepines included in this review are listed in Table 1. Prior to January 1, 2014 benzodiazepines were an excludable/optional drug class in accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA 90). All of the benzodiazepines are available in a generic formulation, with the exception of clobazam and quazepam.

There have been no significant changes in prescribing information or clinical studies since the class was last reviewed. Some of the treatment guidelines have been updated since the last review. However, these updates do not contain changes that are significantly different than the other guidelines included.

There is insufficient evidence to support that one brand benzodiazepine 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 benzodiazepines within the class reviewed, with the exception of diazepam rectal gel, 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. Diazepam rectal gel provides a beneficial route of administration compared to other agents in this class. Therefore, patients should be allowed approval for this agent through the medical justification portion of the prior authorization process.

No brand benzodiazepine 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Anxiolytics, Sedatives, and Hypnotics-Miscellaneous: AHFS 282492

Manufacturer comments on behalf of these products:

None

Dr. Kashalikar noted that the miscellaneous anxiolytics, sedatives, and hypnotics are used primarily for the treatment of anxiety disorders and insomnia. Some of the miscellaneous agents are also approved for the management of acute alcohol withdrawal, for use as a sedative (e.g., preoperative, prior to procedures, and in intubated or mechanically ventilated patients), for the management of nausea/vomiting from surgical/diagnostic procedures and for the treatment of pruritus.

Since the last review, Intermezzo[®] (zolpidem)- a sublingual zolpidem formulation, was approved by the FDA for the as needed treatment of insomnia when a middle of the night awakening is followed by difficulty returning to sleep. Also in January 2013, the FDA released new recommendations that the dose of zolpidem be lowered due to new data suggesting that blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. Women appear to be more susceptible, as they eliminate zolpidem more slowly than men. The FDA required the manufacturers of Ambien[®], Ambien CR[®], Edluar[®], and Zolpimist[®] to lower the recommended dose. The miscellaneous anxiolytics, sedatives, and hypnotics included in this review are listed in Table 1. All of the products are available in a generic formulation, with the exception of dexmedetomidine and ramelteon. Since this clinical review document was finalized, a generic formulation of eszopiclone has become available.

Some of the treatment guidelines have been updated since the last review. However, these updates do not contain changes that are significantly different than the other guidelines included in this review.

There is insufficient evidence to support that one brand miscellaneous anxiolytic/sedative/hypnotic agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

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

No brand miscellaneous anxiolytic, sedative, or hypnotic 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.

Vice-chairperson Porter asked the P&T Committee members to mark their ballots.

Genitourinary Smooth Muscle Relaxants: AHFS 861200

Manufacturer comments on behalf of these products:

Toviaz[®] - Pfizer

Dr. Takeshita noted that the genitourinary smooth muscle relaxants are primarily antimuscarinic agents utilized in the treatment of urinary incontinence and overactive bladder. Since the last review of this class, mirabegron has been added to this class as the first beta-3 adrenergic receptor agonist to be approved for the treatment of overactive bladder. Mirabegron relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle which increases bladder capacity. Because it acts via the beta-3 adrenergic receptor rather than through muscarinic cholinergic receptors, mirabegron may have a better tolerability profile compared to other urinary antispasmodics.

The genitourinary smooth muscle relaxants included in this review are listed in Table 1. This review encompasses all dosage forms and strengths of the agents reviewed in this class. Flavoxate, oxybutynin, tolterodine and trospium are available in a generic formulation.

Four new guidelines regarding the management of urinary incontinence were updated since the last review. Updated treatment guidelines still recognize antimuscarinics as the mainstay of treatment for urinary incontinence and overactive bladder. In addition, they state that there is no consistent evidence to support that one antimuscarinic agent is more efficacious than another. Overall, the guidelines do not identify a single preferred agent for initial therapy. However, several recent guidelines provide general recommendations. For example, two guidelines from the American Urological Association and the European Association of Urology favor the use of extended-release preparations. In addition, guidelines from the National Institute of Health and Clinical Excellence recommend immediate-release oxybutynin, immediate-release tolterodine or once-daily darifenacin as initial therapy. Several guidelines also recommend the use of transdermal oxybutynin if anticholinergic side effects are experienced with initial therapy.

Recently published clinical trials evaluating the genitourinary smooth muscle relaxants have not produced clinically different results compared to trials included in the previous class review. With regards to mirabegron that was approved since the last review, data supporting its efficacy for the treatment of overactive bladder were derived from limited placebo controlled trials.

A few trials have found significant reduction of overactive bladder symptoms and rating scales with fesoterodine compared to the tolterodine group. However, other trials have found there to be no significant difference in terms of efficacy for the treatment of overactive bladder between the two treatment groups.

There is insufficient evidence to support that one brand genitourinary smooth muscle relaxant 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 genitourinary smooth 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 genitourinary smooth 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.

Vice-chairperson Porter 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. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for August 13, 2014 at the Medicaid Building in the Commissioner's Board Room.

8. ADJOURN

There being no further business, Dr. Harwood moved to adjourn and Dr. Cohenour seconded. The meeting adjourned at 11:05 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
May 14, 2014

A. **Recommendation:** No brand skin and mucous membrane antibacterial 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

Mey Rouse, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Kelly Approve Approve as amended Disapprove No action
Deputy Commissioner

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

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

Amendment: None

Vote: Unanimous to approve as recommended

Mey Rouse, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Kelly Approve Approve as amended Disapprove No action
Deputy Commissioner

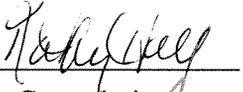
Stephanie A. ... Approve Approve as amended Disapprove No action
Commissioner

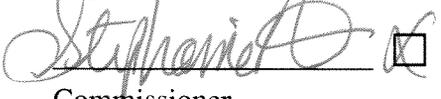
C. Recommendation: No brand skin and mucous membrane antifungal is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

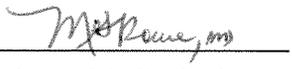
 Approve Approve as amended Disapprove No action
Commissioner

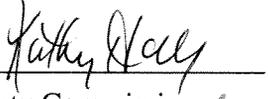
D. Recommendation: No brand skin and mucous membrane scabicide or pediculicide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

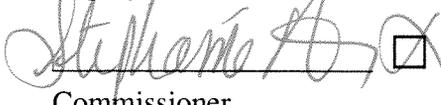
Lindane should not be placed in preferred status regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

E. Recommendation: No brand skin and mucous membrane miscellaneous local anti-infective is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McKone, ms Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie H Approve Approve as amended Disapprove No action
Commissioner

F. Recommendation: No brand skin and mucous membrane anti-inflammatory 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

McKone, ms Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

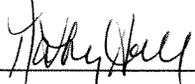
Stephanie H Approve Approve as amended Disapprove No action
Commissioner

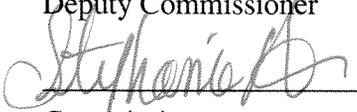
G. Recommendation: No brand skin and mucous membrane antipruritic or local anesthetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

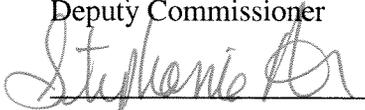
H. Recommendation: No brand skin and mucous membrane astringent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

I. Recommendation: No brand skin and mucous membrane keratolytic 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

M. K. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Steel Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A. Approve Approve as amended Disapprove No action
Commissioner

J. Recommendation: No brand skin and mucous membrane keratoplastic agent is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 843200 in the Preferred Drug List (PDL) screening process. If new prescription keratoplastic agents are added, it is recommended that this class be re-reviewed.

Amendment: None

Vote: Unanimous to approve as recommended

M. K. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Steel Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A. Approve Approve as amended Disapprove No action
Commissioner

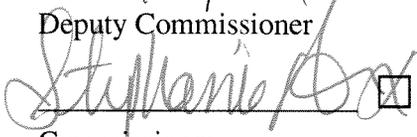
K. Recommendation: No brand miscellaneous skin and mucous membrane agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

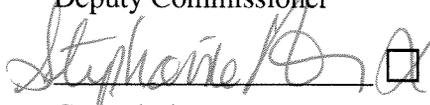
L. Recommendation: No brand Alzheimer's agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

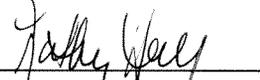
M. Recommendation: No brand antidepressant is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

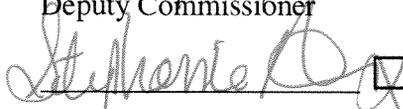
No brand monoamine oxidase inhibitor is recommended for preferred status, regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

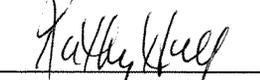
 Approve Approve as amended Disapprove No action
Commissioner

N. Recommendation: No brand cerebral stimulant/agent used for ADHD 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
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

O. Recommendation: No brand wakefulness promoting 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

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

T. Kelly Approve Approve as amended Disapprove No action
Deputy Commissioner

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

P. Recommendation: No brand barbiturate 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. Rowley, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

T. Kelly Approve Approve as amended Disapprove No action
Deputy Commissioner

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

Q. Recommendation: No brand benzodiazepine 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. Spore, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Kelly Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Commissioner

R. Recommendation: No brand miscellaneous anxiolytic, sedative, or hypnotic 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. Spore, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Kathy Kelly Approve Approve as amended Disapprove No action
Deputy Commissioner

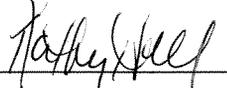
Stephanie Approve Approve as amended Disapprove No action
Commissioner

S. **Recommendation:** No brand genitourinary smooth 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

 Approve Approve as amended Disapprove No action
Assistant Medical Director

 Approve Approve as amended Disapprove No action
Deputy Commissioner

 Approve Approve as amended Disapprove No action
Commissioner

Respectfully submitted,



May 28, 2014

James Gagnon, Pharm.D., BCPS

Date