

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

November 4, 2020

Members Present: Dr. Lee Carter (Vice-Chairperson), Dr. Kimberly Graham, Dr. Albert Holloway, Dr. Frances Heinze (Chairperson), Dr. Peter Hughes, Dr. Charles Nevels, Dr. Kelli Littlejohn Newman, and Dr. Melinda Rowe

Members Absent: None

Presenters: Dr. Thomas Pomfret and Dr. Warren Smith

1. OPENING REMARKS

Chairperson Heinze called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:06 a.m.

2. APPROVAL OF MINUTES

Chairperson Heinze asked if there were any corrections to the minutes from the August 5, 2020 P&T Committee Meeting.

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

3. PHARMACY PROGRAM UPDATE

Dr. Newman discussed that the Agency is finalizing the budget for 2022 and working diligently to determine the COVID impact. The Agency is anticipating an announcement for the public health emergency to be extended another month.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations was explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were a total of 4 manufacturer verbal presentations at the meeting. There were a total of 4 manufacturer written submissions provided to the P&T Committee members as part of the clinical review packet in advance of the meeting.

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

The pharmacotherapy class reviews began at approximately 9:13 a.m. There were a total of 10 drug class reviews. 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 – Antimuscarinics, Genitourinary Smooth Muscle Relaxants – Beta-3 Agonists, and Disease-Modifying Antirheumatic Agents were last reviewed in August 2018. There was one new drug review: Vumerity® (diroximel fumarate).

Cerebral Stimulants/Agents for ADHD: Central Alpha-Agonists – AHFS 240816, Amphetamine Derivatives – AHFS 282004, Respiratory and CNS Stimulants – AHFS 282032, Central Nervous System Agents, Miscellaneous – AHFS 289200

Manufacturer comments on behalf of these products:

Adhansia XR® – Adlon Therapeutics

Jornay PM® – Ironshore Pharmaceuticals

Dr. Pomfret noted that the cerebral stimulants/agents used for ADHD included in this review are listed in Table 1 beginning on page 312. Many of the products are available in a generic formulation. Since the last review, several new extended release formulations of methylphenidate have become available, including Adhansia XR® capsule, Jornay PM® capsule, Relexxii ER® 72 mg tablet, as well as the generic atomoxetine and amphetamine extended-release.

Adhansia XR® and Jornay PM® (methylphenidate extended-release) are CNS stimulants indicated for the treatment of ADHD in patients six years and older. Adhansia XR® is available in capsule formulation and is dosed once-daily (in the morning), either as a whole capsule or sprinkled onto applesauce or yogurt. It utilizes a technology to release both immediate release and extended-release methylphenidate throughout the day to provide a duration of effect for up to 16 hours. Similarly, Jornay PM® is the only agent approved specifically to be dosed once-daily in the evening, and may be given either as a whole capsule or sprinkled onto applesauce. It utilizes a technology that limits the release of the medication overnight and controls the release of the medication throughout the following day. Neither Adhansia XR® or Jornay PM® have been compared in head-to-head studies to other treatment options for ADHD, but have demonstrated clinical improvements compared to placebo. Similar to other CNS stimulants, both agents carry warnings related to abuse and dependence.

Although guideline updates have occurred, 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 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.

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

Wakefulness Promoting Agents – AHFS 282080

Manufacturer comments on behalf of these products:

Sunosi® - Jazz Pharmaceuticals, Inc.

Xyrem® - Jazz Pharmaceuticals, Inc.

Dr. Smith noted that the wakefulness promoting agents included in this review are listed in Table 1 on page 412. Sodium oxybate (Xyrem®), pitolisant (Wakix®), and solriamfetol (Sunosi®) are not available in a generic formulation. There have been two newly Food and Drug Administration (FDA)-approved agents, pitolisant (Wakix®) and solriamfetol (Sunosi®) since the class was last reviewed. Pitolisant is the only approved agent in this class that is not a controlled substance based upon potential for abuse and dependence. Pitolisant is an inverse H3-receptor agonist indicated for excessive daytime sleepiness associated with narcolepsy in adults and is available as 4.45 and 17.8 mg tablets. Solriamfetol is a norepinephrine and dopamine reuptake inhibitor indicated for excessive daytime sleepiness associated with narcolepsy and excessive daytime sleepiness associated with obstructive sleep apnea, both in adult patients, and is available as 75 and 150 mg tablets. Both agents were shown to be superior to placebo in clinical trials with pitolisant being non-inferior to modafinil. Sodium oxybate gained an additional indication for cataplexy in narcolepsy and excessive daytime sleepiness in narcolepsy in patients seven years of age and older since the last review.

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.

There were no further discussions on the agents in this class. Chairperson Heinze 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. Smith noted that the barbiturates included in this review are listed in Table 1 on page 452. Pentobarbital and phenobarbital are available in a generic formulation. Pentobarbital is a new addition since this class was last discussed and is available as a 50 mg/mL injection generally used in an inpatient or controlled institutional setting for anesthesia, sedation, and emergency control of seizures. Efficacy of pentobarbital has been demonstrated in trials comparing it against etomidate, intravenous midazolam, and chloral hydrate for sedation prior to radiographic procedures. Although guidelines updates have occurred, 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 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.

There were no further discussions on the agents in this class. Chairperson Heinze 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. Smith noted that benzodiazepines included in this review are listed in Table 1 beginning on page 483. All are available in a generic formulation. The benzodiazepines are approved for a variety of indications including treatment of anxiety, insomnia, seizures, and alcohol withdrawal. Although guideline updates have occurred, there have been no major changes in the treatment guidelines or clinical studies since this class was last reviewed. However, on September 23, 2020, the FDA released a publication to address labeling changes to the benzodiazepine class to improve the safe use of these agents. This action was taken by the FDA as part of ongoing efforts to promote the public health by minimizing risks associated with inappropriate use of controlled substances. The update requires class-wide labeling changes for benzodiazepines to include the risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions to help improve their safe use. Beyond requiring an update to the Boxed Warning, other required changes to the prescribing information encompass the Warnings and Precautions, Drug Abuse and Dependence, and Patient Counseling Information sections. Revisions to the patient Medication Guide will also be mandated to educate patients and caregivers about the associated risks of these therapies.

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 brand benzodiazepines within the class reviewed are comparable to each other (except for diazepam rectal gel) and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

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.

There were no further discussions on the agents in this class. Chairperson Heinze 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. Smith noted that the miscellaneous anxiolytics, sedatives, and hypnotics included in this review are listed in Table 1 on page 547. All are available in a generic formulation except for suvorexant (Belsomra[®]), lemborexant (Dayvigo[®]), and tasimelteon (Hetlioz[®]). Lemborexant is available as 5 and 10 mg tablets and was newly added since this class was last discussed. It is approved for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adult patients, and in clinical trials was compared to placebo with a zolpidem ER active comparator, showing a statistically significant difference in latency to persistent sleep (-19.5 and -21.5 vs -7.9 minutes for lemborexant 5 mg and 10 mg vs placebo and -7.5 vs -7.9 minutes for zolpidem ER compared to placebo). It was also shown to have improved subjective sleep onset latency compared to placebo in clinical trials. Lemborexant was well tolerated in clinical trials. Although guideline updates have occurred, there have been no major changes in treatment guidelines or clinical studies since this class was last reviewed. In April 2019, the FDA released a safety announcement advising that rare but serious injuries have occurred with certain common prescription insomnia medicines (eszopiclone, zaleplon, and zolpidem) due to complex sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake, which may occur in serious injury or death.

There is insufficient evidence to support that one brand miscellaneous anxiolytic, sedative, and hypnotic 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 anxiolytics, sedatives, and hypnotics 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, and 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.

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

Genitourinary Smooth Muscle Relaxants: Antimuscarinics – AHFS 861204

Manufacturer comments on behalf of these products:

None

Dr. Smith noted that the antimuscarinic genitourinary smooth muscle relaxants included in this review are listed in Table 1 on page 641. A solifenacin (Vesicare[®]) generic has been approved since the last review and all agents within this category are available in a generic formulation except for fesoterodine (Toviaz[®]). Although guideline updates have occurred, 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 antimuscarinic 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 antimuscarinic 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 antimuscarinic 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.

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

Genitourinary Smooth Muscle Relaxants: Beta-3 Adrenergic Agonists – AHFS 861208

Manufacturer comments on behalf of these products:

None

Dr. Smith noted that the beta-3 adrenergic agonist genitourinary smooth muscle relaxants included in this review are listed in Table 1 on page 750. Mirabegron (Myrbetriq®) is not available in a generic formulation. Although guideline updates have occurred, there have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand beta-3 adrenergic agonist 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 beta-3 adrenergic agonist 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 beta-3 adrenergic agonist 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.

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

Alzheimer's Agents: Parasympathomimetic (Cholinergic) Agents – AHFS Class 120400 & Central Nervous System Agents, Miscellaneous – AHFS Class 289200

Manufacturer comments on behalf of these products:

None

Dr. Pomfret noted that the Alzheimer's agents included in this review are listed in Table 1 on page 11. All products with the exception of the memantine-donepezil combination product are available in a generic formulation. Although guideline updates have occurred, 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 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.

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

Antidepressants – AHFS 281604

Manufacturer comments on behalf of these products:

None

Dr. Pomfret commented that noted that the antidepressants included in this review are listed in Table 1 beginning on page 91. The antidepressants are approved to treat a variety of mental health disorders, including anxiety disorders, depressive disorders, eating disorders, premenstrual dysphoric disorder, and postpartum depression. The majority of the products are available in a generic formulation. Since the last review, a new branded duloxetine delayed-release capsule (Drizalma Sprinkle[®]), brexanolone intravenous injection (Zulresso[®]), and esketamine nasal spray (Spravato[®]) have become available.

Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor that is available in a generic formulation. Drizalma Sprinkle[®] is approved for adults with major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathy, and chronic musculoskeletal pain. A potential advantage of this product is the ability to open the capsule and sprinkle the contents on applesauce for oral administration or to administer the contents by nasogastric tube.

Brexanolone is a neuroactive steroid gamma-aminobutyric acid-A receptor positive modulator that is chemically identical to endogenous allopregnanolone, which is a potent neuroactive steroid that rises with progesterone levels during pregnancy. Brexanolone is indicated for the treatment of postpartum depression in adults and is administered via intravenous infusion over a 60-hour timeframe. In clinical trials, brexanolone was shown to have significant improvement in the Hamilton Rating Scale for Depression (HAM-D) total scores at the end of the 60-hour infusion compared to placebo. Due to potentially serious adverse events, brexanolone has a boxed warning for excessive sedation and sudden loss of consciousness, requiring monitoring and continuous pulse oximetry measurement. Patients should also be accompanied during interactions with their children according to the prescribing information. Due to these risks, brexanolone is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

Esketamine nasal spray is indicated in conjunction with an oral antidepressant for the treatment of adults with treatment-resistant depression or depressive symptoms with major depressive disorder with acute suicidal ideation or behavior. It is the S-enantiomer of racemic ketamine, and a non-selective, noncompetitive antagonist of the N-methyl-D-aspartate receptor. The precise mechanism of action of esketamine in major depressive disorder is unknown. Esketamine nasal spray is administered, in conjunction with an oral antidepressant, twice-weekly for four weeks, once-weekly for four weeks, and once-weekly to every two weeks thereafter based upon remission or response. Ongoing need for therapy should be evaluated after four weeks of treatment. Esketamine was evaluated in placebo-controlled trials among adults with major depressive disorder. Results demonstrated that patients treated with esketamine nasal spray plus

an oral antidepressant demonstrated greater improvements in mean Montgomery-Asberg Depression Rating Scale (MADRS) scores compared to those treated with placebo plus an oral antidepressant, and among remitters, fewer patients treated with esketamine plus an oral antidepressant experienced a relapse compared to patients treated with placebo. Due to potentially serious adverse events, esketamine has a boxed warning for sedation, dissociation or perceptual changes after administration, abuse, and misuse. Patients must be monitored for at least two hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting. Due to the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, esketamine is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

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. In addition, brexanolone for intravenous administration and esketamine nasal spray are both indicated for specific patient populations, have significant side effect profiles, and are only available through restricted access programs and; therefore, should also be managed through the medical justification portion of the prior authorization process.

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

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

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

Disease-Modifying Antirheumatic Agents – AHFS 923600

Manufacturer comments on behalf of these products:

None

Dr. Pomfret noted that the disease-modifying antirheumatic drugs (DMARDs) are used for a variety of inflammatory and immunologic conditions which include: rheumatoid arthritis, neonatal-onset multisystem inflammatory disease, psoriatic arthritis, plaque psoriasis, juvenile idiopathic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and hidradenitis suppurativa. Agents included in this review are listed in Table 1 on page 780. Leflunomide is the only product available in a generic formulation. A new infliximab biosimilar product, Avsola[®], has become available, making it the third available biosimilar product. Currently, none of the injectable agents in this class are available generically.

Since the last review, apremilast (Otezla[®]) gained the FDA-approved indication for the treatment of adult patients with oral ulcers associated with Behçet's Disease based on a trial that found greater reduction in the

total number of oral ulcers with apremilast during 12 weeks of treatment compared to placebo. Certolizumab pegol (Cimzia[®]) received the expanded indication for the treatment of adults with active, non-radiographic axial spondyloarthritis with objective signs of inflammation based on trial results of achievement of greater improvement in disease activity scores (ASDAS) at 52 weeks compared to placebo when added to background therapy. Abatacept (Orencia[®]) received the updated indication for juvenile idiopathic arthritis in individuals ≥ 2 years of age.

In addition, the FDA has approved two new Janus kinase inhibitors (JAK) inhibitors, baricitinib (Olumiant[®]) tablet for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies and upadacitinib (Rinvoq[®]) extended-release tablet for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. Baricitinib is dosed 2 mg orally once daily and upadacitinib is dosed 15 mg orally once daily. Concomitant use of these new agents with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

Both baricitinib and upadacitinib have a boxed warning to address the risks associated with serious infection leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections. Pre-treatment tuberculosis testing and ongoing monitoring of active infection during treatment is advised. In addition, lymphoma and other malignancies have been observed and thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have also occurred.

Clinical trials demonstrated efficacy of baricitinib 2 mg as assessed by ACR20 improvement response compared to placebo in conventional DMARD-experienced patients (RA-BUILD) and TNF-blocker-experienced patients (RA-BEACON). Clinical trials demonstrated the efficacy of upadacitinib in the proportion of patients achieving at least 20% improvement in the ACR scores compared to methotrexate and placebo.

There is insufficient evidence to support that one brand disease-modifying antirheumatic agent is safer or more efficacious than another within the FDA-approved indication(s). The drugs in this AHFS class are used in a specific patient population. Because these agents have narrow indications with limited usage and serious adverse events, these agents should be managed through the medical justification portion of the prior authorization process.

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

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

6. New Drug Review

New Drug Review Vumerity® (diroximel fumarate) – AHFS 922000

Manufacturer comments on behalf of these products:

None

Dr. Pomfret noted Vumerity® (diroximel fumarate) is FDA-approved for the treatment of relapsing forms of MS (RMS) in adults, including clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS). Agents included in this review are listed in Table 1 on page 959. Diroximel fumarate was approved as a new dosage form of dimethyl fumarate (Tecfidera®) via the 505(b)(2) drug approval pathway and is a prodrug that is metabolized to active monomethyl fumarate prior to systemic circulation. FDA-approval of Vumerity® was based on bioavailability studies in patients with RMS comparing dimethyl fumarate and diroximel fumarate. The adverse event profile of Vumerity® was consistent with the reported events in the placebo-controlled clinical trials with dimethyl fumarate, including flushing, abdominal pain, diarrhea, nausea, vomiting, pruritis, rash, albuminuria, erythema, dyspepsia, abnormal liver enzymes, and lymphopenia. Available as a 231 mg delayed-release tablet, Vumerity® is administered as one tablet twice daily initially for one week, and then as two tablets (462 mg) twice daily thereafter. This product was designed to reduce the gastrointestinal (GI) side-effects associated with dimethyl fumarate by reducing the methanol biproduct during prodrug metabolism. In general, the GI side-effects associated with dimethyl fumarate are considered relatively mild and typically resolve within the first two months of treatment. The efficacy of Vumerity® was based upon bioavailability studies in patients with relapsing forms of multiple sclerosis and healthy subjects comparing oral dimethyl fumarate and diroximel fumarate. Efficacy of dimethyl fumarate was established in two clinical trials (CONFRIM and DEFINE). Overall, rates of discontinuation due to side effects were low in clinical studies (4%).

The American Academy of Neurology guidelines provide recommendations for managing the various forms of MS. For patients with CIS, disease-modifying therapies may be recommended after assessing the benefits and risks of therapy. For patients with recent clinical relapses or MRI activity, including RRMS or active SPMS forms of the disease, disease-modifying therapies are recommended. Except in certain situations, no disease-modifying therapy is recommended over another and selection of therapy should be based on individual patient factors and preference. Several newer agents, including Vumerity®, are not specifically addressed in the guideline, which has not been updated since 2018.

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

Therefore, all brand diroximel fumarate 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 diroximel fumarate product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

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

7. RESULTS OF VOTING ANNOUNCED

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

8. NEW BUISNESS

Dr. Heinze has been voted to be the Vice-Chair and Dr. Carter will move to the Chair position.

9. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for February 3, 2021.

10. ADJOURN

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

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
November 4, 2020

- A. **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

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

Nathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Cox Approve Approve as amended Disapprove No action
Commissioner

- B. **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

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

Nathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Cox Approve Approve as amended Disapprove No action
Commissioner

C. **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

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

Kathy Bell Approve Approve as amended Disapprove No action
Deputy Commissioner

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

D. **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. Rowe, MD Approve Approve as amended Disapprove No action
Medical Director

Kathy Bell Approve Approve as amended Disapprove No action
Deputy Commissioner

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

E. Recommendation: No brand anxiolytic, sedative, and hypnotic 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. Rowe, MD Approve Approve as amended Disapprove No action
Medical Director

Kathy Hill Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie D. Approve Approve as amended Disapprove No action
Commissioner

F. Recommendation: No brand anxiolytic, sedative, and hypnotic 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. Rowe, MD Approve Approve as amended Disapprove No action
Medical Director

Kathy Hill Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie D. Approve Approve as amended Disapprove No action
Commissioner

G. Recommendation: No brand miscellaneous anxiolytic, sedative, and 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. Rowe, MD Approve Approve as amended Disapprove No action
Medical Director

Kathy Spill Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Cox Approve Approve as amended Disapprove No action
Commissioner

H. Recommendation: No brand antimuscarinic 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

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

Kathy Spill Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Cox Approve Approve as amended Disapprove No action
Commissioner

I. Recommendation: No brand beta-3 adrenergic agonist 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

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

Ruthy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A. Approve Approve as amended Disapprove No action
Commissioner

J. Recommendation: No brand disease-modifying antirheumatic 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. P. Rowe, MD Approve Approve as amended Disapprove No action
Medical Director

Ruthy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A. Approve Approve as amended Disapprove No action
Commissioner

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

Amendment: None

Vote: Unanimous to approve as recommended

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

Kathy Hall Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie D. Approve Approve as amended Disapprove No action
Commissioner

Respectfully submitted,

Thomas Pomfret

11/04/2020

Thomas C. Pomfret, PharmD, MPH, BCPS

Date

Rachel Bacon

11/04/2020

Rachel Bacon, PharmD

Date