DADS/DSHS EXECUTIVE FORMULARY COMMITTEE MINUTES
April 5, 2013

The Executive Formulary Committee convened on Friday, April 5, 2013 in Room 125 - ASH Building 552. The meeting was called to order by Dr. Wright, Chair at 9:50 a.m.

Mary Bowers RN, BSN	Absent	Valerie Kipfer, MSN, RN (non-voting)	Absent
Catherine Hall, Pharm.D.	√	Lilani Muthali, M.D. (non-voting)	√
Jeanna Heidel, Pharm.D. (via phone)	√	Nina Muse, M.D. (non-voting)	√
Marla Knight, Pharm.D., CGP, FASCP (via phone)	√	Jay Norwood, MSN, RN (non-voting)	Absent
Jeff Matthews, M.D.	√	Peggy Perry (non-voting)	Absent
Connie Millhollon, RN	Absent	Joe Vesowate (non-voting)	Absent
Victoria Morgan, M.D.	√	Mike Maples (non-voting)	Absent
Kenda Pittman, Pharm.D.	√	Kerry Raymond (non-voting)	Absent
Tran Quan, D.O.	√	Vacant Medical Director Position	
Ann L. Richards, Pharm.D.	√	Vacant Center Position	
Robert L. Ward, D.O.	√	Vacant Center Position	
Jennifer Wright, M.D.	√		

Guests Present:
Lisa Mican, Pharm.D., Assistant Pharmacy Director –ASH, Samantha Schulenberg, Pharmacy Intern

Introduction and Other Information

Dr. Matthews indicated that he will be moving to University of Texas Health Science Center - Tyler later this spring. As part of his workload, he will be responsible for the Rusk State Hospital patients that will be housed in Tyler. Based on his new position, it was recommended that he continue on the Executive Formulary Committee as that may help with the implementation of this new program. In a previous discussion, Ms. Peggy Perry agreed with this recommendation.

Approval of Minutes of January 25, 2013

On a motion of Dr. Ward, seconded by Dr. Matthews, the minutes of the January 25th meeting were approved as previously distributed.

Conflict of Interest Disclosure Forms

Dr. Matthews reported that some sales representatives presented food during their educational exchanges.
Adverse Drug Reaction Reports

The Executive Formulary Committee discussed two adverse drug reaction reports. Both reports were from a State

Supported Living Center.

The primary care physician was notified of a patient's rash on January 3rd. The rash was papular and was mostly on his back area. Initially, it was mildly erythematous. A week later, the rash was overtly a "drug eruption," per the primary care physician. After investigating this reaction, it was found that if a medication was responsible, then carbamazepine was the most likely offending agent. The patient had been taking carbamazepine 700 mg twice a day since May 7, 2009. The dose was increased to 800 mg twice a day on December 18, 2012. The timing and presentation of the event corresponded with the dose increase of carbamazepine. The carbamazepine dose was decreased back to 700 mg twice a day on January 8, 2013. The rash improved somewhat about a week after the dose was decreased, according to the primary care physician. The primary care physician continues to monitor the patient. The Committee wondered if the patient had been on seven of the 100 mg tablets while on the 700 mg dose but was then switched to 200 mg tablets when the patient went to the 800 mg dose. If so, then perhaps it was something in the 200 mg tablet that caused the problem. The Committee will follow up on this issue.

A patient started taking duloxetine (Cymbalta®) 30 mg twice daily on October 3rd. The dose was increased to 60 mg twice daily on November 30th. The patient started to develop ecchymosis on various locations of both lower limbs. Most recently, she developed a non-painful ecchymosis to the entire plantar side of her foot. The duloxetine dose was decreased to 90 mg/day for a week, and then back to the 60 mg/day.

Psychotropic Consent List

Dr. Richards presented the updated psychotropic consent list for the Committee's review. Besides a formatting change, the following changes were made:

- Added vilazodone (Viibryd®) as a non-formulary item under Antidepressants
- Added aripiprazole long acting injection (Abilify® Maintena™) as a non-formulary under Antipsychotics
- Added loxapine inhalant (Adasuve®) as a non-formulary under Antipsychotics

On a motion of Dr. Ward, seconded by Dr. Morgan, the recommended changes to the Psychotropic Consent list were approved. See Attachment A.

On a motion of Dr. Heidel, seconded by Dr. Ward, it was recommended that aripiprazole long acting injection be added to the Antipsychotic Tier Schedule as a Tier 3 drug. In addition, it was recommended that this drug be added to the Psychotropic Audit Criteria and Guidelines.

Quetiapine (Seroquel®, Seroquel® XR) Purchases

Dr. Richards reviewed the State Hospital purchases and returns of Seroquel® and Seroquel® XR from January through March. The State Supported Living Centers' purchases were not reviewed since these facilities receive Medicare Part D funding for the majority of their residents. The following is a summary of the State Hospitals' Seroquel® and Seroquel® XR purchases:

Facility	January	February	March	Total	# Patients for Quarter
Austin	$360.52	0	0	$360.52	1
Rio Grande	0	0	$1,121.88	$1,121.88	4
Vernon	$5,075.79	$3,383.86	$5,075.79	$13,535.44	4
Total	$5,436.31	$3,383.86	$6,197.67	$15,017.84	9

The facilities that did not purchase or return Seroquel® or Seroquel® XR are not included in the table. Currently, there are four patients on Seroquel® XR. One at Rio Grande State Center and three at North Texas State Hospital – Vernon campus. At the last meeting, the Vernon campus had four patients. The three remaining patients at Vernon were the

same ones reported in January. If the patients were placed on generic immediate release quetiapine, Rio Grande State Center could save $15,242 annually and the Vernon campus could save $40,215 annually. It was noted that the Vernon campus has not added any new patients on Seroquel® XR.

The Committee recommended that this information be shared with both Rio Grande State Center and North Texas State Hospital – Vernon campus.

Drug Deletions

The Committee did not recommend any drug deletions at the last meeting.

New Dosage Strengths

The Committee did not have any new dosage strengths to review.

Drug Formulary Sectional Review- **Antiemetics/Antivertigo**
Antihistamines
Respiratory

Dr. Hall provided the review on the agents in the Antiemetics/Antivertigo sections. See Attachment B. Dr. Hall did not recommend any changes.

In reviewing the Antihistamines section, the Committee recommended numerous changes in this section. See Attachment C. The Committee recommended the following changes:

For the Antihistamine section, keep the following:

- Cetirizine (Zyrtec®)
- Chlorpheniramine (Chlor-trimeton®, Teldrin®)
- Cyproheptadine (Periactin®)
- Fexofenadine (Allegra®)
- Hydroxyzine (Atarax®, Vistaril®)
- Loratadine (Claritin®)
- Add diphenhydramine (Benadryl®)

Remove the following from the Antihistamine section and add them to the renamed Cough, Cold, and Decongestant Preparations in the Respiratory Agents

- Brompheniramine/phenylephrine (Dimetapp® Cold and Allergy)
- Brompheniramine/pseudoephedrine (Bromfed®)
- Cetirizine/pseudoephedrine (Zyrtec® D)
- Fexofenadine/pseudoephedrine (Allegra® D)
- Loratadine/pseudoephedrine (Claritin® D)
- Triprolidine/pseudoephedrine (Actifed®)

On a motion of Dr. Matthews, seconded by Dr. Ward, the recommendation to make these changes was approved.

Dr. Hall provided a review of the Respiratory Agents section. See attachment D. In reviewing this section, Dr. Hall along with the Committee members suggested the following changes:

- Rename Bronchodilators, Combination to: Bronchodilators, Combination/Short Acting
- Rename Bronchodilators, Combination/Long Acting Beta-2 Agonists to: Bronchodilators, Combination Steroid + Long Acting Beta-2 Agonists
- Rename Cough and Cold Preparations to Cough, Cold and Decongestant Preparations (as previously mentioned)

- Delete the Antitussives section and move these products to the Cough, Cold and Decongestant Preparations.
    - Label these drugs Antitussives in this section
- Move tiotropium (Spiriva®) from the Miscellaneous Respiratory Drugs to the Bronchodilators section
- Move fluticasone/salmeterol (Advair®) to the newly named Bronchodilators, Combination Steroid + Long Acting Beta-2 Agonists section
- Delete the Decongestants sections and move these products to the newly named Cough, Cold and Decongestant Preparations
    - Add the decongestant phenylephrine to this section
    - Label these products as decongestants
- Add Mucinex® as the trade name for guaifenesin

On a motion of Dr. Ward, seconded by Dr. Morgan, it was recommended that these changes be approved.

New Drug Applications

(Please refer to <u>Attachment E</u> for the monographs and applications that were considered when determining action by the committee.)

Insulin detemir (Levemir®) - developed by Tara Howard, Pharmacy Student, presented by Dr. Mican

Insulin detemir is being considered for the Formulary due to its high use as a non-formulary agent. Insulin detemir is a long-acting insulin product. The onset of action is 3 to 4 hours and the maximum plasma level is seen 6 to 8 hours post dose. Insulin glargine (Lantus®) is longer acting than detemir. Sometimes insulin detemir needs to be administered twice a day. An advantage of detemir is that once the vial is opened, is should be discarded 42 days after initial use whether it is refrigerated or unrefrigerated. The Flex Pen should be stored at room temperature after its initial use and should be discarded after 42 days. Insulin detemir can be dosed once or twice daily. Some studies have shown lower rates of hypoglycemia and nocturnal hypoglycemia with insulin detemir than NPH or insulin glargine; however, most of the information on lower risk of hypoglycemia comes from twice daily insulin detemir dosing versus once daily insulin detemir. Insulin detemir was also found to have a higher rate of injection site reactions compared to insulin glargine. Insulin detemir does not appear to have a significant advantage over other currently available formulary options aside from a slight decrease in potential weight gain as well as possible lower risk of hypoglycemia and nocturnal hypoglycemia when dosed twice daily. The more insulin products on formulary, the increased opportunity to have medication errors with the wrong product being selected.

Following discussion, on motion of Dr. Ward, seconded by Dr. Morgan, the request to add insulin detemir (Levemir®) to the formulary was denied.

Menthol 0.44%/zinc oxide 20.6% (Calmoseptine®) - developed by Marie Therese Jackson, Pharm.D. Resident, presented by Dr. Hall

Calmoseptine® is a combination product that contains menthol and zinc oxide. Menthol may cause analgesia by desensitizing nociceptive C receptors that are responsible for sending pain signals to the brain. Zinc oxide aids in wound healing by accelerating skin re-epithelialization via unknown mechanisms. This product is being considered for Formulary due to its high non-formulary use. Calmoseptine® is indicated for use as a moisture barrier to prevent and help heal skin irritations from a variety of causes (urine, diarrhea, minor burns, wound drainage, etc.). A thin layer should be applied to reddened or irritated skin 2 to 4 times daily. The skin should first be gently cleansed with mild cleanser and then pat dry or allowed to air dry prior to application. It should be applied after each incontinent episode or diaper change.

Following discussion, on motion of Dr. Ward, seconded by Dr. Morgan, the request to add Calmoseptine® to the formulary was approved. However, it was recommended that due to price issues that the generic Risamine® should be used and not the Calmoseptine® product. The Formulary Drug Check List was completed.

Psychotropic Audit Criteria & Guidelines - Antidepressants

The Antidepressant Audit Criteria and Guidelines have not been reviewed.

Psychotropic Audit Criteria & Guidelines – Chemical Dependence Adjunct

The Chemical Dependence Adjunct Audit Criteria and Guidelines have not been developed.

Issues from the Clinical Directors' Meeting

Dr. Muse was present for this agenda item. Dr. Muse reported that the State Hospitals had four pulmonary embolism deaths in 2012; therefore this has become a focus for the Hospital Section. The main issue is assessing the risk for the development of a pulmonary embolism. Ideally, standardized guidelines would be implemented across the Hospitals.

Dr. Muse noted that drug costs continue to be monitored. She noted that in reviewing the data, San Antonio State Hospital seems to have a higher use of paliperidone palmitate (Invega® Sustenna™). The question arises as to whether or not SASH's population is different than the other State Hospitals, the MHAs served by SASH prefers this product, or that other facilities should be using this product more. Dr. Muse stated that one way to find out the answer is to look at the data. In particular, review those individuals that are re-admitted to the hospitals within a certain time frame to determine what medications these patients are receiving. This type of review may give us a better idea as to which drugs work best in our population.

FDA Drug Safety Communications

The FDA has issued the following safety communications that may have impact on our facilities.

> The FDA is warning the public that azithromycin (Zithromax® or Zmax®) can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias. The FDA has issued a Drug Safety Communication as a result of its review of a study by medical researchers as well as another study by a manufacturer of the drug that assessed the potential for azithromycin to cause abnormal changes in the electrical activity of the heart. The FDA previously released a Statement on May 17, 2012, about a study that compared the risks of cardiovascular death in patients treated with the antibacterial drugs azithromycin, amoxicillin, ciprofloxacin (Cipro®), and levofloxacin (Levaquin®), or no antibacterial drug. The study reported an increase in cardiovascular deaths and in the risk of death from any cause, in persons treated with a 5-day course of azithromycin (Zithromax®) compared to persons treated with amoxicillin, ciprofloxacin, or no drug. The risks of cardiovascular death associated with levofloxacin treatment were similar to those associated with azithromycin treatment. Health care professionals should consider the risk of torsades de pointes and fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events. The FDA notes that the potential risk of QT prolongation with azithromycin should be placed in appropriate context when choosing an antibacterial drug: Alternative drugs in the macrolide class, or non-macrolides such as the fluoroquinolones, also have the potential for QT prolongation or other significant side effects that should be considered when choosing an antibacterial drug.
>
> The FDA is evaluating unpublished new findings by a group of academic researchers that suggest an increased risk of pancreatitis and pre-cancerous cellular changes called pancreatic duct metaplasia in patients with type 2 diabetes treated with a class of drugs called incretin mimetics. These findings were based on examination of a small number of pancreatic tissue specimens taken from patients after they died from unspecified causes. The FDA has asked the researchers to provide the methodology used to collect and study these specimens and to provide the tissue samples so the Agency can further investigate potential pancreatic toxicity associated with the incretin mimetics. Drugs in the incretin mimetic class include exenatide (Byetta®, Bydureon®), liraglutide (Victoza®), sitagliptin (Januvia®, Janumet®, Janumet® XR, Juvisync®), saxagliptin (Onglyza®, Kombiglyze® XR), alogliptin (Nesina®, Kazano®, Oseni®), and linagliptin (Tradjenta®, Jentadueto®). These drugs work by mimicking the incretin hormones that the body usually produces naturally to stimulate the release of insulin in response to a meal. They are used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. The FDA has not reached any new conclusions about safety risks with incretin mimetic drugs. This early communication is intended only to inform the public and health care professionals

that the Agency intends to obtain and evaluate this new information. The FDA will participate in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and National Cancer Institute's (NCI) Workshop on Pancreatitis-Diabetes-Pancreatic Cancer in June 2013 to gather and share additional information. The FDA will communicate its final conclusions and recommendations when its review is complete or when the Agency has additional information to report. The Warnings and Precautions section of drug labels and patient Medication Guides for incretin mimetics contain warnings about the risk of acute pancreatitis. The FDA has not previously communicated about the potential risk of pre-cancerous findings of the pancreas with incretin mimetics. The FDA has not concluded these drugs may cause or contribute to the development of pancreatic cancer.

Quarterly Non-Formulary Drug Justification Report

For the second quarter of fiscal year 2013, all facilities reported use of non-formulary agents. The following were the top non-formulary agents that were prescribed:

Fiber-Stat Natural Solution Packets
Lansoprazole (Prevacid®) Solutab
Carisoprodol (Soma®)
Ondansetron (Zofran®) injection
Meloxicam (Mobic®)

The Committee suggested that meloxicam (Mobic®) be reviewed for addition to the Formulary as it is a commonly used agent in the community and is available generically.

Sectional Review for Next Meeting

The following sections will be reviewed at the next meeting:

Dermatologicals (Acne agents to Anti-infectives, Antiseptic & Germicides)

Other Issues

The following information was shared with the Committee members:

Pfizer "has announced positive topline results from a phase 4 efficacy study of the selective serotonin and norepinephrine reuptake inhibitor (SNRI) desvenlafaxine (Pristiq) extended-release tablets for the treatment of major depressive disorder (MDD) in adults." Under the multicenter, randomized controlled trial of 924 patients with MDD, those who "received for 8 weeks 50 mg/day of desvenlafaxine and those who received 100 mg/day of the medication showed a significant change from baseline on the 17-item Hamilton Rating Scale for Depression (HAM-D17) total score compared with the participants who received matching placebo." Pfizer "reports that the most common treatment-related adverse events 'were consistent with the known safety and tolerability profile of Pristiq.'"

The smaller profit margin of generic products provides fewer incentives for manufacturers to maintain high quality manufacturing standards. This, in turn, can lead to interruption of production when contamination or other quality control issues arise, according to an article in *Clinical Pharmacology* by Janet Woodcock, MD, director of the FDA Center for Drug Evaluation and Research and Marta Wosinska, Ph.D., an FDA senior economic adviser. As an example, of the 900 abbreviated new drug applications for sterile Injectables approved between 2000 and 2011 only 11 (1%) had a backup facility if manufacturing was halted. By comparison, 20% of branded sterile-injectable applications had backup facilities. Other factors relating to shortages included aging facilities**,** productions lines crowded by manufacturing a variety of products, a lack of oversight over subcontractors and the economic downturn.

The FDA officials have announced the agency will not appeal a decision that appears to limit the government's regulation of pharmaceutical manufacturers' off-label marketing ability. FDA won't ask the U.S. Supreme Court to hear the case from the Second U.S. Circuit Court of Appeals that overturned the conviction of a drug rep who had been found guilty of promoting off-label use of a company's products. The Second Court ruled that the representative and company had a right to make the claims as part of the "free speech" protections of

the Constitution. The agency said that it "does not believe that (the decision) will significantly affect the enforcement of the drug misbranding provisions of the" Food, Drug and Cosmetic Act.

According to a study published online in the British Medical Journal, "Some but not all antidepressant drugs known as SSRIs pose a very small but serious heart risk." In a Forbes blog, Larry Husten writes that, "using a pharmacovigilance approach, analyzed data from more than 38,000 patients in the Partners HealthCare system who received an ECG after receiving an antidepressant or methadone prescription." Individuals "who used citalopram, escitalopram (Lexapro) and amitriptyline, in addition to methadone, were significantly more likely to have a prolonged QT interval (QTc). By contrast, bupropion was associated with a significant decrease in QTc."

According to research published online in the Journal of Clinical Hypertension, "Elderly patients with memory problems who suddenly have visual hallucinations may need to stop taking ACE inhibitors." Investigators reported that "in four case studies, the hallucinations experienced by patients with various memory deficits disappeared after they discontinued lisinopril, an angiotensin-converting enzyme (ACE) inhibitor." While "hallucinations are '[a generally unrecognized side effect' of ACE inhibitors, this is the first published account showing an association between lisinopril and hallucinations, they wrote."

"Prenatal exposure to valproate (VPA), an antiepileptic drug (AED) that has previously been linked to major congenital malformations and lower IQ in children, has now been linked to an increased risk for autism spectrum disorders (ASD)," according to a study published online Jan. 31 in the Journal of Neurology, Neurosurgery and Psychiatry. "The study included 415 children (214 control participants and 201 children born to women with epilepsy) born between 2000 and 2004 in the northwest of England and followed until age six years." The study also revealed that "in addition to ASD, VPA was linked to an increased risk for other neurodevelopmental disorders when taken as monotherapy or in combination with other drugs."

Pfizer has been hit with a lawsuit that alleges the New York City-based pharmaceutical company's antidepressant Zoloft (sertraline) has no therapeutic benefits. Pfizer, as well American Psychiatric Association President-Elect Dr. Jeffrey Lieberman and at least three other psychiatry experts, say the suit is "without merit." However, an attorney for the plaintiff, R. Brent Wisner "argues the Food and Drug Administration shouldn't have approved Zoloft because Pfizer didn't publish some clinical studies that found the drug about as effective as a placebo." The suit "accuses Pfizer of consumer fraud and other offenses, including quietly paying prominent doctors to tout Zoloft to colleagues or to be listed as authors of positive medical journal articles the company prepared for publication," and it requests that the company reimburse the costs incurred by patients who took Zoloft despite experiencing no benefits from the medication.

The New York Times reported that medications such as Adderall (amphetamine, dextroamphetamine mixed salts) "can markedly improve the lives of children and others" with attention-deficit/hyperactivity disorder. But the "tunnel-like focus the medicines provide has led growing numbers of teenagers and young adults to fake symptoms to obtain steady prescriptions for highly addictive medications that carry serious psychological dangers." Meanwhile, some doctors "skip established diagnostic procedures, renew prescriptions reflexively and spend too little time with patients to accurately monitor side effects."

"Use of psychiatric medications is most prevalent in the southern United States and least prevalent in the West, according to a new US study" recently published online in the journal Health & Place. Even though "people living in the West are the least likely to use antipsychotics, antidepressants and stimulants, the Yale researchers found that the drugs' use is 40 percent higher in a large section of the South than in other parts of the country. The study authors attributed this discrepancy to variations in local access to health care and marketing efforts within the pharmaceutical industry."

Medscape reported that "policies restricting gifts by pharmaceutical companies to US medical schools had the lasting effect of significantly reducing prescriptions written for 2 of 3 newly approved psychotropic medications after students entered clinical practice, a difference-in-differences analysis indicates." The study was published online January 31 in the British Medical Journal. Study authors concluded that their findings provide "some early preliminary evidence that exposure to a gift restriction policy during medical school may reduce the likelihood that a physician will prescribe newly introduced medications over older alternatives within the same drug class." Medscape notes that "the American Medical Student Association has advocated for prescribing based on scientific evidence, rather than industry advertising, and since 2007 it has graded US medical schools on policies limiting interactions between students and representatives of drug and device companies."

According to a study published online Feb. 6 in JAMA Psychiatry, using the selective serotonin reuptake inhibitor antidepressant Zoloft (sertraline) together with transcranial direct current stimulation (tDCS) of the brain may benefit people suffering from moderate to severe major depressive disorder (MDD). While medication or brain stimulation both have some effect on depression, combining the two treatments for six weeks caused about two-thirds of the 120 patients in the study to feel much better. On its own, however, tDCS was about as efficacious as medication alone.

The FDA has added ofatumumab (Arzerra®), lacosamide (Vimpat®) and dalfampridine (Ampyra®) to its "watch list" for potential signals of serious risks. A drug's appearance on the list does not mean that FDA has concluded that the drug actually poses significant health risks, but it is studying whether there is a causal link.

"The amount of cannabis used does not appear to be associated with the severity of symptoms in patients with established psychosis, although the drug is linked to a small effect on psychosocial functioning," according to a study published in the Schizophrenia Bulletin. Researchers arrived at that conclusion after comparing "demographic, clinical, and substance use variables of 160 patients with established nonaffective psychosis whose substance use included cannabis with those of 167 established psychosis patients who used other substances. Clinical assessments and substance use were assessed at baseline, 12 months, and 24 months."

"Two investigational drugs for Parkinson's disease have shown promise in clinical trials for relieving specific symptoms that patients often find especially disruptive," according to research to be presented at the American Academy of Neurology's annual meeting. "An adenosine 2-alpha receptor antagonist called tozadenant reduced so-called 'off time' without promoting dyskinesias, according to C. Warren Olanow, MD, of Mt. Sinai School of Medicine in New York City, and colleagues." Meanwhile, "another group testing the norepinephrine prodrug droxidopa (Northera) reported that it provided short-term relief of lightheadedness and dizziness and reduced orthostatic hypotension, although the effect did not seem to last, reported Stuart Isaacson, MD, a neurologist in private practice in Boca Raton, Fla., and colleagues."

Investigators "analyzed the health records from more than two million people aged 40 or older with or without kidney disease who were also taking statins." The researchers found that "participants who took higher doses of statins were 34 percent more likely to be hospitalized for acute kidney injury during the first 120 days of treatment, compared to their counterparts who were taking lower doses."

"An old-line antipsychotic drug may be safer for treating Tourette syndrome than previously thought, while a novel agent could provide an entirely new approach to treating the condition, researchers said" at the American Academy of Neurology's annual meeting. "Retrospective review of 268 children and adults treated for up to 17 years with fluphenazine (Prolixin), a first-generation phenothiazine antipsychotic drug, indicated that none of them had developed tardive dyskinesia, although other movement disorders were seen in some patients, according to Subhashie Wijemanne, MD, of Baylor College of Medicine in Houston." Meanwhile, "another research group reported that an investigational dopamine D1 receptor antagonist called ecopipam, given as a

once-daily pill, effectively relieved Tourette tics in adult patients with 8 weeks of treatment - so successfully that enrollment in the open-label phase II trial was halted early."

According to a study published in Journal of the American Medical Association, the antidepressant duloxetine may help "to ease the debilitating nerve pain commonly caused by some chemotherapies."
"Most seniors with dementia who are taking an antipsychotic medication to control neuropsychiatric symptoms (NPS), such as agitation, aggression, and hallucinations, can be taken off these drugs without relapsing, according to a new literature review" published online March 28 in The Cochrane Library. "The review included nine studies with 606 participants," and the "studies used various antipsychotic drugs, either typical (first-generation) or atypical (second-generation), that were prescribed chronically, defined as treatment for at least three months, at various doses."

Results of animal studies suggest Merck's experimental sleep-aid treatment, Suvorexant (MK-4305), works without the negative side effects typically seen with other anti-insomnia treatments, such as Ambien (zolpidem) and Lunesta (eszopiclone). Suvorexant is a Dual Orexin Receptor Antagonist (DORA) whereas Ambien and Lunesta act on the gamma-aminobutyric acid (GABA) in the brain. The researchers said that the rhesus monkeys and rats given GABA-blockers during the studies were less likely to respond and recall objects than the animals given a DORA-blocker called DORA-22. The study was published in Science Translational Medicine.

Next Meeting Date

The next meeting was scheduled for July 12, 2013.

Adjourn

There being no further business, the meeting was adjourned at 12:15 p.m.

Approved: *Jennifer Wright*
Jennifer Wright, M.D., Chairman

Attachments

Attachment A – Psychotropic Consent List
Attachment B – Antiemetics/Antivertigo Sectional Review
Attachment C – Antihistamine Sectional Review
Attachment D – Respiratory Agents Sectional Review
Attachment E – New Drug Applications

Minutes Prepared by:
Ann L. Richards, Pharm.D., BCPP

Classes of Medications Frequently Used for Psychiatric Indications

Consent is required for any medication that is used in the treatment of a psychiatric diagnosis or symptom, whether or not the medication is included in this list. Refer to physician order for determination of indication for use.

The classification of psychotropic medication is fairly standard but medications can be used for treatment of illnesses that would be considered listed under a different classification. For example, some medications listed under antipsychotics maybe used as a mood stabilizer.

The Executive Formulary Committee does not endorse the use of nonformulary drugs

Antidepressants

amitriptyline (Elavil)
amoxapine (Asendin)
bupropion (Wellbutrin, Wellbutrin SR)
bupropion (Wellbutrin XL)
citalopram (Celexa)
desipramine (Norpramin)
desvenlafaxine (Pristiq) *nonformulary*
doxepin (Sinequan)
duloxetine (Cymbalta)
escitalopram (Lexapro)
fluoxetine (Prozac)
imipramine (Tofranil)
maprotiline (Ludiomil)
mirtazapine (Remeron, Remeron SolTab)
nefazodone (Serzone) *nonformulary*
nortriptyline (Pamelor, Aventyl)
paroxetine (Paxil, Paxil CR)
protriptyline (Vivactil)
sertraline (Zoloft)
trazodone (Desyrel)
trimipramine (Surmontil)
venlafaxine (Effexor, Effexor XR)
vilazodone (Viibryd) *nonformulary*

Anxiolytics/Sedatives/Hypnotics

alprazolam (Xanax, Xanax XR)
buspirone (BuSpar)
chloral hydrate (Noctec)
chlordiazepoxide (Librium)
clonazepam (Klonopin)
clorazepate (Tranxene)
diazepam (Valium)
diphenhydramine (Benadryl)
eszopiclone (Lunesta) *nonformulary*
flurazepam (Dalmane) *nonformulary*
hydroxyzine (Atarax, Vistaril)
lorazepam (Ativan)
oxazepam (Serax)
pentobarbital (Nembutal) *nonformulary*
ramelteon (Rozerem) *nonformulary*
temazepam (Restoril)
triazolam (Halcion)
zaleplon (Sonata)
zolpidem (Ambien)

Chemical Dependency Adjuncts

Antipsychotics

aripiprazole (Abilify)
Aripiprazole (Abilify Maintena) *nonformulary*
asenapine (Saphris)
chlorpromazine (Thorazine)
clozapine (Clozaril, Fazaclo) Reserve
droperidol (Inapsine) *nonformulary*
fluphenazine (Prolixin)
fluphenazine decanoate (Prolixin D)
haloperidol (Haldol)
haloperidol decanoate (Haldol D)
iloperidone (Fanapt) Reserve
loxapine (Loxitane)
loxapine inhalant (Adasuve) *nonformulary*
lurasidone (Latuda)
olanzapine (Zyprexa, Zyprexa Zydis)
olanzapine pamoate (Zyprexa Relprevv) Reserve
paliperidone (Invega)
paliperidone palmitate (Invega Sustenna)
perphenazine (Trilafon)
pimozide (Orap) *nonformulary*
quetiapine (Seroquel)
quetiapine (Seroquel XR) *nonformulary*
risperidone (Risperdal, Risperdal M-Tab)
risperidone (Risperdal Consta)
thioridazine (Mellaril)
thiothixene (Navane)
trifluoperazine (Stelazine)
ziprasidone (Geodon)

Mood Stabilizers

carbamazepine (Tegretol, Tegretol XR, Carbatrol, Equetro)
divalproex sodium (Depakote, Depakote ER)
lithium (Eskalith, Eskalith CR, Lithobid)
valproic acid (Depakene)
oxcarbazepine (Trileptal)
lamotrigine (Lamictal)

Stimulants

amphetamine/dextroamphetamine mixture (Adderall, Adderall XR)
dexmethylphenidate (Focalin) *nonformulary*
dextroamphetamine (Dexedrine)
lisdexamfetamine (Vyvanse) *nonformulary*
methamphetamine (Desoxyn) *nonformulary*
methylphenidate (Ritalin, Ritalin SR, Concerta, Metadate, Metadate CD)

Antidepressants

acamprosate (Campral) *nonformulary*
disulfiram (Antabuse)
naltrexone (ReVia, Vivitrol)
topiramate (Topamax)

Monoamine Oxidase Inhibitors

isocarboxazid (Marplan)
phenelzine (Nardil)
selegiline (Emsam) *nonformulary*
tranylcypromine (Parnate)

Other

This category must be approved prior to inclusion in this instrument

Antipsychotics

methylphenidate patch (Daytrana) *nonformulary*

Miscellaneous Drugs

atomoxetine (Strattera)
atenolol (Tenormin)
clomipramine (Anafranil)
clonidine (Catapres)
clonidine ER (Kapvay) *nonformulary*
fluvoxamine (Luvox)
gabapentin (Neurontin)
guanfacine (Tenex)
guanfacine ER (Intuniv) *nonformulary*
metoprolol (Lopressor)
nadolol (Corgard)
propranolol (Inderal)
reserpine (Serpasil) *nonformulary*
naltrexone (ReVia)
olanzapine/fluoxetine (Symbyax) *nonformulary*
pindolol (Visken) *nonformulary*

MEMORANDUM

To: Executive Formulary Committee

From: Catherine S. Hall, Pharm.D., BCPP

Through: Ann L. Richards, Pharm.D., BCPP

Subject: **Class Review, Antiemetic/Antivertigo Agents**

Date: April 5, 2013

No recommended changes

Antiemetic/Antivertigo Agents

diphenhydrAMINE (Benadryl)	$
hydrOXYzine (Atarax, Vistaril)	$ - $$
Meclizine (Antivert, Bonine)	$
Metoclopramide (Reglan)	$ - $$$
Ondansetron (Zofran, Zofran ODT)	$ - $$$
Prochlorperazine (Compazine)	
Promethazine (Phenergan)	$ - $$$$$
Trimethobenzamide (Tigan)	$$

diphenhydrAMINE (Benadryl)
Capsule: 25 mg, 50 mg
Cream, topical: 2%
Injection: 50 mg/mL
Liquid, oral: 12.5 mg/5 mL
Lotion: 1%
Tablet: 25 mg, 50 mg

hydrOXYzine (Atarax, Vistaril)
Capsule: 25 mg, 50 mg, 100 mg
Injection, as hydrochloride: 25 mg/mL, 50 mg/mL
Suspension: 25 mg/5 mL
Syrup, as hydrochloride: 10 mg/5 mL
Tablet: 10 mg, 25 mg, 50 mg, 100 mg

Meclizine (Antivert, Bonine)
Tablet: 12.5 mg, 25 mg, 50 mg

Metoclopramide (Reglan)

Injection: 5 mg/mL
Liquid, oral, sugar free: 5 mg/5 mL
Tablet: 5 mg, 10 mg

Ondansetron (Zofran, Zofran ODT)
Tablet: 4mg, 8mg
Tablet, oral disintegrating: 4mg, 8mg

Prochlorperazine (Compazine)
Injection: 5 mg/mL
Suppository, rectal: 25 mg
Tablet: 5 mg, 10 mg, 25 mg

Promethazine (Phenergan)
Injection: 25 mg/mL, 50 mg/mL
Suppository, rectal: 12.5 mg, 25 mg, 50 mg
Syrup: 6.25 mg/5 mL
Tablet: 12.5 mg, 25 mg, 50 mg

Trimethobenzamide (Tigan)
Capsule: 250 mg, 300 mg
Injection: 100 mg/mL
Suppository, rectal: 200 mg

Attachment C

MEMORANDUM

To: Executive Formulary Committee

From: Catherine S. Hall, Pharm.D., BCPP

Through: Ann L. Richards, Pharm.D., BCPP

Subject: Class Review, Antihistamines

Date: April 5, 2013

Recommendation:

Add diphenhydramine (Benadryl)

Delete the following: brompheniramine/phenylephrine (Dimetapp Cold and Allergy), brompheniramine/pseudoephedrine (Bromfed), cetirizine/pseudoephedrine (Zyrtec D), fexofenadine/pseudoephedrine (Allegra D), loratadine/pseudoephedrine (Claritin D), triprolidine/pseudoephedrine (Actifed). These agents will be moved to the Cough, Cold, and Decongestant subsection of the Respiratory Agents Section.

Antihistamines

Brompheniramine/Phenylephrine (Dimetapp Cold and Allergy)	$
Brompheniramine/Pseudoephedrine (Bromfed)	$$
Cetirizine (Zyrtec)	$
Cetirizine/Pseudoephedrine (Zyrtec D)	$
Chlorpheniramine (Chlor-Trimeton, Teldrin)	$ - $
Cyproheptadine (Periactin)	$
Fexofenadine (Allegra)	$$
Fexofenadine/Pseudoephedrine (Allegra-D)	$$
hydrOXYzine (Atarax, Vistaril)	$ - $$
Loratadine (Claritin)	$$
Loratadine/Pseudoephedrine (Claritin D)	$$ - $$
Triprolidine/Pseudoephedrine (Actifed)	$

Brompheniramine/Phenylephrine (Dimetapp Cold and Allergy)
Liquid: 1mg Brompheniramine/2.5mg Phenylephrine per 5mL

Brompheniramine/Pseudoephedrine (Bromfed)
Capsule: 12 mg Brompheniramine/120 mg Pseudoephedrine
Elixir: 4 mg Brompheniramine/30 mg Pseudoephedrine
Liquid: 15mg Brompheniramine/1mg Psuedoephedrine per 5mL, 12mg Brompheniramine/1mg Psuedoephedrine per 5mL
Syrup: 2 mg Brompheniramine/30 mg Pseudoephedrine
Tablet: 4 mg Brompheniramine/60 mg Pseudoephedrine
Tablet, sustained release: 8mg Brompheniramine/120mg Psuedoephedrine

Cetirizine (zyrTEC)
Syrup: 1 mg/ml
Tablet: 5 mg, 10 mg
Tablet, chew: 5 mg, 10 mg

Cetirizine/Pseudoephedrine (zyrTEC D)
Tablet, 12hr: 5 mg/120 mg

Chlorpheniramine (Chlor-Trimeton, Teldrin)
Capsule: 12 mg
Syrup: 2 mg/5 mL
Tablet: 4 mg, 8 mg, 12 mg
Tablet, chewable: 2 mg
Tablet, timed release: 8 mg, 12 mg

Cyproheptadine (Periactin)
Syrup: 2 mg/5 mL with 5% alcohol
Tablet: 4 mg

Fexofenadine (Allegra)
Tablet: 30 mg, 60 mg, 180 mg

Fexofenadine/Pseudoephedrine (Allegra-D)
Tablet, extended release: 60 mg Fexofenadine/120 mg Pseudoephedrine

hydrOXYzine (Atarax, Vistaril)
Capsule: 25 mg, 50 mg, 100 mg
Injection, as hydrochloride: 25 mg/mL, 50 mg/mL
Suspension: 25 mg/5 mL
Syrup, as hydrochloride: 10 mg/5 mL
Tablet: 10 mg, 25 mg, 50 mg, 100 mg

Loratadine (Claritin)
Liquid, oral: 5mg/5mL
Tablet: 10 mg

Loratadine/Pseudoephedrine (Claritin D)
Tablet, sustained release: 12hr, 24hr

Triprolidine/Pseudoephedrine (Actifed)

Capsule, extended release: Triprolidine 5 mg/Pseudoephedrine 120 mg
Syrup: Triprolidine 1.25 mg/Pseudoephedrine 30 mg per 10 mL
Tablet: Triprolidine 2.5 mg/Pseudoephedrine 60 mg

Attachment D

MEMORANDUM

To: Executive Formulary Committee

From: Catherine S. Hall, Pharm.D., BCPP

Through: Ann L. Richards, Pharm.D., BCPP

Subject: Class Review, Respiratory Agents

Date: April 5, 2013

Recommendation:

Change "Bronchodilators, Combination" to "Bronchodilators, Combination/Short Acting"

Change "Bronchodilators, Combination/Long Acting Beta-2 Agonists" to "Bronchodilators, Combination Steroid + Long Acting Beta-2 Agonists"

Remove fluticasone/salmeterol (Advair) from "Steroids" because it's already listed in "Bronchodilators, Combination Steroid + Long Acting Beta-2 Agonist".

Change "Cough and Cold Preparations" to "Cough, Cold and Decongestant Preparations"

Delete "Antitussives" and move these products to "Cough, Cold and Decongestant Preparations"
Label drugs "Antitussives" in this section

Move tiotropium (Spiriva) from "Miscellaneous Respiratory Drugs" to "Bronchodilators"

Delete "Decongestants" and move these products to "Cough, Cold and Decongestant Preparations"
Label drugs "Decongestants" in this section

Add phenylephrine to "Cough, Cold and Decongestant Preparations"

Add Mucinex as the trade name for guaifenesin

Add the following to "Cough, Cold and Decongestant Preparations": brompheniramine/phenylephrine (Dimetapp Cold and Allergy), brompheniramine/pseudoephedrine (Bromfed), cetirizine/pseudoephedrine (Zyrtec D), fexofenadine/pseudoephedrine (Allegra D), loratadine/pseudoephedrine (Claritin D), triprolidine/pseudoephedrine (Actifed).

Respiratory agents

AntitussivesBenzonatate (Tessalon perle)	$$$
Dextromethorphan	$ - $$

Bronchodilators

Albuterol (Proventil, Ventolin Vospire ER)	$ - $$$
Aminophylline	$$ - $$
Ipratropium (Atrovent Inhaler)	$$$$$$$
Salmeterol (Serevent)	$$$$$$$
Terbutaline (Brethine)	$ - $$$$$$
Theophylline (Elixophyllin)	$ - $$

Bronchodilators, Combination

Albuterol/Ipratropium (Combivent, DuoNeb)	$$ - $$$$$$$

Bronchodilators, Combination/Long Acting Beta-2 agonists

Budesonide/formoterol (Symbicort)	$$$$$$$
Fluticasone/Salmeterol (Advair)	$$$ - $$$$$

Cough and Cold Preparations

Brompheniramine/Phenylephrine (Dimetapp Cold and Allergy)	$
Brompheniramine/Pseudoephedrine (Bromfed)	$$
Chlorpheniramine (Chlor-Trimeton, Teldrin)	$ - $$
diphenhydrAMINE (Benadryl)	$
Fexofenadine (Allegra)	$ - $$
Fexofenadine/Pseudoephedrine (Allegra-D)	$$
Guaifenesin/Codeine (Robitussin AC) C-V	$$
Guaifenesin/Dextromethorphan (Robitussin DM)	$ - $$
Guaifenesin/Pseudoephedrine (MucinexD)	$$
Hydrocodone/Guaifenesin (Hycotuss, Kwelcof) C-III	$$
Loratadine (Claritin)	$$
Loratadine/Pseudoephedrine (Claritin D)	$$ - $$
Triprolidine/Pseudoephedrine (Actifed)	$

Decongestants

Pseudoephedrine (Sudafed)	$ - $$

Expectorants

Guaifenesin (Robitussin)	$ - $$
Potassium Iodide (SSKI)	$ - $

Steroids

Beclomethasone (Beconase QVAR)	$$$$$$$
Budesonide (Pulmicort)	$$$$ - $$$$$
Fluticasone (Flonase, Flovent)	$$$$$$$
Fluticasone/Salmeterol (Advair)	$$$ - $$$$$
Mometasone (Nasonex)	$$$$$$$
Triamcinolone (Azmacort, Nasacort)	$$$$$$$

Miscellaneous Respiratory Drugs

Acetylcysteine (Mucomyst)	$$$$ - $$$$$$
Cromolyn (Intal)	$$$$$$$
Montelukast (Singulair)	$$
Sodium Chloride	$ - $
Tiotropium (Spriva)	$$$$$$$
Zafirlukast (Accolate)	$$

Benzonatate (Tessalor Perle)
Capsule: 100 mg, 200 mg

Dextromethorphan
Capsule: 15 mg, 30 mg
Liquid, oral: 3.5 mg/5 mL, 7.5 mg/5 mL, 10 mg/15 mL, 15 mg/5 mL
Liquid, oral, sustained release: 30 mg/5 mL
Lozenges: 2.5 mg, 5 mg, 7.5 mg

Albuterol (Proventil, Ventolin, Vospire ER**)**
Aerosol, inhalation, chlorofluorocarbon free: 90 mcg/dose (17g) [200 doses]
Solution, inhalation: 0.083% [2.5mg/3mL], 0.5% [5 mg/mL]
Syrup: 2 mg/5 mL
Tablet: 2 mg, 4 mg
Tablet, extended release: 4 mg, 8 mg

Aminophylline (79% Theophylline)
Injection: 25 mg/mL
Suppository, rectal: 250 mg
Tablet: 200 mg

Ipratropium (Atrovent)
Inhalation: 18 mcg/actuation
Solution, nasal: 0.03%, 0.06%
Solution, nebulizing: 0.02%

Salmeterol (Serevent)
Aerosol, inhalation: 25 mcg/dose
Powder, inhalation: 50 mcg

Terbutaline (Brethine)
Aerosol, oral: 0.2 mg/actuation
Injection: 1 mg/mL
Tablet: 2.5 mg, 5 mg

Theophylline (Elixophyllin)
Capsule, timed release (12 hour): 130 mg, 260 mg
Capsule, timed release (24 hour): 100 mg, 200 mg, 300 mg
Solution, oral: 80 mg/15 mL, 150 mg/15 mL
Tablet, immediate release [Slo-phyllin]: 100 mg, 125 mg, 200 mg, 250 mg, 300 mg
Tablet, timed release:
Theolair SR (8-12 hour): 100 mg, 200 mg, 250 mg, 300 mg, 500 mg
Theo-Dur (8-24 hour): 100 mg, 200 mg, 300 mg, 450 mg
Theophylline SR (12-24 hour): 100 mg, 200 mg, 300 mg
Uniphyl (24 hour): 400 mg
Tablet, timed release (12 hour): 100 mg, 200 mg, 300 mg

Albuterol/Ipratropium (Combivent, DuoNeb)
Inhaler, oral: Albuterol 103 mcg/Ipratropium 18 mcg
Solution, inhalation: 2.5mg-0.5mg/3ml

Budesonide/Formoterol (Symbicort)
Aerosol, inhalation, oral: 160 mcg/4.5 mcg, 80 mcg/4.5 mcg

Fluticasone/Salmeterol (Advair)
Powder, inhalation: 100mcg fluticasone/50mcg salmeterol, 250mcg fluticasone/50mcg salmeterol, 500mcg fluticasone/50mcg salmeterol

Brompheniramine/Phenylephrine (Dimetapp Cold and Allergy)
Liquid: 1mg Brompheniramine/2.5mg Phenylephrine per 5mL

Brompheniramine/Pseudoephedrine (Bromfed)
Capsule: 12 mg Brompheniramine/120 mg Pseudoephedrine
Elixir: 4 mg Brompheniramine/30 mg Pseudoephedrine
Liquid: 15mg Brompheniramine/1mg Psuedoephedrine per 5mL, 12mg Brompheniramine/1mg Psuedoephedrine per 5mL
Syrup: 2 mg Brompheniramine/30 mg Pseudoephedrine
Tablet: 4 mg Brompheniramine/60 mg Pseudoephedrine
Tablet, sustained release: 8mg Brompheniramine/120mg Psuedoephedrine

Chlorpheniramine (Chlor-Trimeton, Teldrin)

Capsule: 12 mg
Syrup: 2 mg/5 mL
Tablet: 4 mg, 8 mg, 12 mg
Tablet, chewable: 2 mg
Tablet, timed release: 8 mg, 12 mg

diphenhydrAMINE (Benadryl)
Capsule: 25 mg, 50 mg
Cream, topical: 2%
Injection: 50 mg/mL
Liquid, oral: 12.5 mg/5 mL
Lotion: 1%
Tablet: 25 mg, 50 mg

Fexofenadine (Allegra)
Tablet: 30 mg, 60 mg, 180 mg

Fexofenadine/Pseudoephedrine (Allegra-D)
Tablet, extended release: 60 mg Fexofenadine/120 mg Pseudoephedrine

guaiFENesin/Codeine (Robitussin AC) C-V
Syrup: 100mg guaiFENesin/10mg codeine per 5mL

guaiFENesin/Dextromethorphan (Robitussin DM)
Liquid, oral: guaiFENesin 100 mg/Dextromethorphan 10 mg per 5 mL,
guaiFENesin 100mg/Dextromethorphan 15mg per 5mL,
guaiFENesin 66.7mg/Dextromethorphan 6.7mg per 5mL
Tablet, sustained release: guaiFENesin 300 mg/Dextromethorphan 30 mg

guaiFENesin/Pseudoephedrine (Mucinex D)
Tablet: guaiFENesin 600 mg/Pseudoephedrine 60 mg

Hydrocodone/Guaifenesin (Hycotuss,

Kwelcof) C-III
Liquid, oral: Hydrocodone 5 mg/Guaifenesin 100 mg per 5 mL

Loratadine (Claritin)
Liquid, oral: 5mg/5mL
Tablet: 10 mg

Loratadine/Pseudoephedrine (Claritin D)
Tablet, sustained release: 12hr, 24hr

Triprolidine/Pseudoephedrine (Actifed)
Capsule, extended release: Triprolidine 5 mg/Pseudoephedrine 120 mg
Syrup: Triprolidine 1.25 mg/Pseudoephedrine 30 mg per 10 mL
Tablet: Triprolidine 2.5 mg/Pseudoephedrine 60 mg

Pseudoephedrine (Sudafed)

Liquid, oral: 15 mg/5 mL, 30 mg/mL
Tablet, immediate release: 30 mg, 60 mg
Tablet, timed release: 120 mg
Tablet, extended release: 120 mg, 240 mg

guaiFENesin (Robitussin)
Caplet, sustained release: 600 mg
Liquid, oral: 100 mg/5 mL, 200 mg/5 mL
Tablet: 100 mg, 200 mg, 400mg
Tablet, sustained release: 600 mg

Potassium Iodide (SSKI)
Solution, oral: 100 mg/mL,1 g/mL

Beclomethasone, (Beconase, QVAR)
Inhaler, oral: 40mcg [100 actuations], 80mcg [100 actuations]
Spray, nasal: 0.084% (19 g) [120 metered doses]
Spray, nasal: 40mcg/actuation
Spray, nasal, aqueous: 42 mcg/inhalation (25 g) [≥200 metered doses], 84 mcg/inhalation (25 g) [≥200 metered doses]

Budesonide (Pulmicort)
Solution, inhalation: 0.25 mg, 0.5 mg, 1 mg
Fluticasone (Flonase, Flovent)
Aerosol, inhalation, oral: 44 mcg/actuation, 110 mcg/actuation, 220 mcg/actuation
Inhalation, nasal: 50 mcg/actuation

Fluticasone/Salmeterol (Advair)
Powder, inhalation: 100mcg fluticasone/50mcg salmeterol, 250mcg fluticasone/50mcg salmeterol, 500mcg fluticasone/50mcg salmeterol

Mometasone (Nasonex)
Inhalation, nasal: 50 mcg/actuation

Triamcinolone (Aristocort, Kenacort,

Azmacort, Nasacort)
Aerosol, oral, inhalation: 100 mcg/metered spray
Aerosol, topical: 0.2 mg/2 second spray
Cream, topical: 0.025%, 0.1%, 0.5%
Lotion, topical: 0.025%, 0.1%
Ointment, topical: 0.025%, 0.1%, 0.5%
Spray, intranasal: 55 mcg/actuation [100 sprays/canister]

Acetylcysteine (Mucomyst)
Solution, inhalation: 10% [100 mg/mL], 20% [200 mg/mL]

Cromolyn (Intal)
Solution, nebulizing: 10 mg/mL
Solution, nasal: 40 mg/mL
Solution, ophthalmic: 4%

Montelukast (Singulair)
Tablet, chewable: 4 mg, 5mg
Tablet: 10 mg

Sodium Chloride
Drops, nasal: 0.9%
Infusion: 0.2%, 0.45%, 0.9%, 3%, 5%, 20%, 23.4%
Injection, bacteriostatic: 0.9%
Injection, for admixtures: 50 mEq, 100 mEq, 635 mEq
Ointment, ophthalmic: 5%
Solution, irrigation: 0.45%, 0.9%
Solution, nasal: 0.4%, 0.6%, 0.65%
Solution, nebulizing: 0.9%
Solution, ophthalmic: 2%, 5%
Tablet: 650 mg, 1 g
Tablet, enteric coated: 1 g
Tablet, slow release: 600 mg

Tiotropium (Spriva)
Cap: 18mcg (with device)

Zafirlukast (Accolate)
Tablet: 10 mg, 20 mg

Appendix 1: New Drug Application Form

DSHS\DADS

(Formerly: Texas Department of Mental Health and Mental Retardation)

NEW DRUG APPLICATION
(for inclusion in the *DSHS/DADS Drug Formulary*)

** (THE NEW DRUG APPLICATION PROCESS IS DESCRIBED ON THE BACK OF THIS FORM.) **

Date: February 27, 2013

Name of practitioner submitting the application: Kenda Pittman, PharmD

Name of entity with which the practitioner is associated by employment or contract (i.e., state hospital, state supported living center, state center, or local authority (state-operated community services (SOCS) or community MHMR center)): Austin State Supported Living Center

Information regarding new drug:

Therapeutic Classification	Counterirritant/skin protectant
Generic Name	Menthol 0.44%/zinc oxide 20.625% topical
Trade Name(s)	Calmoseptine
Manufacturer(s)	Calmoseptine, Inc.
Dosage Form(s)	Topical ointment

Explain the pharmacological action or use of this drug: Counterirritant for relieving pain/itching and skin protectant for relieving skin irritation; astringent for drying oozing/weeping lesions.

Explain the advantages of this drug over those listed in the formulary: Calmoseptine provides an alternative medication for those who have failed other topical skin protectant agents. Calmoseptine ointment is an analgesic, antiseptic, antipruritic, and skin protectant combination. It works by temporarily relieving itching and pain. It also decreases moisture in the affected area.

State which drugs this new drug would replace or supplement: Supplement other topical skin protectant agents already on the formulary.

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☐ application is approved:_____
signature of chairman of facility pharmacy and therapeutics committee OR

☐ application is appropriate and complete:_____
signature of clinical/medical director or designee