

**DADS/DSHS EXECUTIVE FORMULARY COMMITTEE MINUTES  
July 12, 2013**

The Executive Formulary Committee convened on Friday, July 12, 2013 in Room 125 - ASH Building 552. The meeting was called to order by Dr. Wright, Chair at 9:30 a.m.

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

**Guests Present:** Angela Campbell, Pharm.D., Clinical Pharmacist –ASH, Kasey Leggette, Pharm.D., Pharmacy Resident

**Introduction and Other Information**

Dr. Balfanz was introduced as the newest member of the Executive Formulary Committee. Dr. Balfanz is filling one of the vacant center position..

**Approval of Minutes of April 5, 2013**

On a motion of Ms. Millhollon, seconded by Dr. Hall, the minutes of the April 5<sup>th</sup> meeting were approved as previously distributed.

**Conflict of Interest Disclosure Forms**

Dr. Matthews reported that food at a going away party was provided by a drug company.

## **ASH (Austin State Hospital) Benztropine DUE (Drug Utilization Evaluation)**

Dr. Campbell presented information on the benztropine DUE completed at ASH. Dr. Campbell noted that benztropine use seemed high, so the hospital completed an audit of all patients on benztropine. In completing this review, it was noted that only 31% of patients were prescribed benztropine for an appropriate use or indication. Most commonly, patients were prescribed benztropine for prophylaxis/prevention of antipsychotic-induced extrapyramidal side effects (EPS) when no EPS had occurred and without documented history of the patient having a past episode of EPS on the same or similar medication. Evidence/literature does not support routine prophylaxis for EPS with benztropine or long-term use of benztropine, as this may be harmful to the patient. As a result of this audit, ASH developed guidelines for the use of benztropine. The following are indications that ASH considered to be appropriate for the use of benztropine:

- Treatment of acute dystonia (muscle spasm/stiffness)
- Treatment of Pseudoparkinsonism (Akinesia/bradykinesia, cogwheel rigidity, Pill-rolling resting tremor
  - Rule-out tremor secondary to other medications: divalproex/valproic acid – coarse positional tremor; lithium – usually a fine, rapid, intentional tremor, etc.
- Prophylaxis of dystonia or Pseudoparkinsonism in high risk patients. High risk defined as patients with a documented history of having a past episode of EPS on the same or similar medication (i.e., past severe dystonia with haloperidol, newly starting fluphenazine; both are high-potency first generation antipsychotic medications). Prophylaxis should be time-limited, not continued indefinitely
- Antipsychotic-induced hypersalivation
- Parkinson's disease as adjunctive therapy

In addition, ASH developed guideline/recommendations for appropriate benztropine use and Medication Audit Criteria and Guidelines Drug Audit Checklist (See Attachment A). After reviewing this information, on a motion of Ms. Millhollon, seconded by Dr. Wright, it was recommended that ASH's Medication Audit Criteria and Guidelines, including the Drug Audit Checklist be included in the minutes and posted on the website for other facilities to use.

## **Adverse Drug Reaction Reports**

The Executive Formulary Committee discussed several adverse drug reaction reports.

In the first case, on March 20<sup>th</sup>, a 52 year old female was prescribed cefadroxil (Duricef®) 500 mg twice a day for seven days as an adjunct for otitis external. On April 8<sup>th</sup>, the patient reportedly developed desquamation of the dorsum and palms of both hands only (no mouth ulcers, or blisters/rash/desquamation of other areas). Nursing and staff stated there wasn't an overt rash as a precursor to the skin shedding. The event was abated with time and diphenhydramine (Benadryl®) 25 mg every 8 hours was prescribed for 3 days. The patient had previously had amoxicillin recorded as an allergy between November 1999 and November 2000. However, no additional information was noted regarding the amoxicillin rash. The patient also had clindamycin (rash) added to her allergy profile in December 2003.

A 30 year old African-American female had been on clozapine (Clozaril®) for approximately seven years. Routine CBC monitoring showed a gradual decline in absolute neutrophil count (ANC). The decline became actionable starting February 5<sup>th</sup> with an ANC of 1.6 K/mm<sup>3</sup> with required twice per week CBC monitoring. At next CBC on February 7<sup>th</sup>, the ANC fell to 1.2 K/mm<sup>3</sup>, which required holding the dose and daily CBC monitoring. After that, the ANC remained at 2.0 K/mm<sup>3</sup> or lower that required twice per week CBC, until March 5<sup>th</sup> when the ANC fell again to 1.3 K/mm<sup>3</sup>, and then to 1.2 K/mm<sup>3</sup> on March 19<sup>th</sup>. Both instances required repeated holds of clozapine and daily CBC. The dose was never restarted after March 19<sup>th</sup> due to the ANC remaining around the 1.0 K/mm<sup>3</sup> mark. Finally, the ANC fell to 0.9 K/mm<sup>3</sup> on March 24<sup>th</sup>, which caused clozapine to be permanently discontinued with no possibility of rechallenge. All decisions to increase CBC frequency, hold doses, and discontinue clozapine were based on the official guidelines.

A 46 year old white male was transferred to the psychiatric hospital from an acute care psychiatric facility on 10/25/12 with symptoms of confusion, agitation and hallucinations. Medications on admission include; multivitamin one a day, baby aspirin 81 mg daily, omeprazole (Prilosec®) 20 mg twice daily, olmesartan (Benicar®) 40 mg daily, risperidone (Risperdal®) 2 mg at bedtime, benztropine (Cogentin®) 1 mg twice a day, divalproex extended release (Depakote®) ER 1500 mg at bedtime, hydroxyzine (Vistaril®) 25 mg three times a day, propranolol (Inderal®) 40 mg twice daily, and trazodone (Desyrel®) 150 mg at bedtime. Labs obtained on 10/26/12 include: CMP within normal limits, sodium 145 mEq/L, potassium 4.4 mEq/L, AST 35 U/L, ALT 47 U/L, random blood glucose 86 mg/dl, BUN 17 mg/dl, creatinine 1.2 mg/dl, ammonia 59 mcg/dl. The divalproex was discontinued. On the morning of 10/27/12, the patient was alert and

oriented to person, not in any acute distress, but mumbled incoherently, cognition fluctuated, and slightly unsteady gait. The patient was given lactulose 30 ml three times a day for 2 days to lower ammonia level. On 10/28/12, the patient's cognition improved and on 10/29/12, the ammonia was 38 mcg/dl. The patient's sensorium had cleared significantly. The lactulose was discontinued. On 10/30/12, the patient was sedated with slow/confused thinking, slurred speech, flat affect, and unsteady/slow gait. The wife stated these symptoms were not present prior to admission. The patient was diagnosed with probable drug induced delirium. All psychiatric medications were discontinued, however, fluoxetine was restarted to avoid SSRI withdrawal and clonazepam (Klonopin®) was prescribed instead of alprazolam (Xanax®). On 10/31/12, the patient had improved and was alert and oriented with no further problems.

A 40 year-old Hispanic male with diagnoses of schizoaffective disorder was unable to eat or drink on January 14<sup>th</sup>. In addition, the patient was observed to be picking at his clothes in a delirium like manner, and developed symptoms of increasing lethargy, becoming unresponsive to verbal commands and unable to stand. The patient has history of seizures with two occurring during the previous week, but no seizures were observed on this day. The patient was transported to the ER. The only recent medication change was an increase in the dose of divalproex from 1,000 mg to 1,500 mg. The last valproic acid level was 95 mcg/ml. He was admitted to the medical hospital. At the hospital, the risperidone (Risperdal®) dose was decreased from 6 mg to 3 mg; divalproex extended release (Depakote® ER), trazodone (Desyrel®), zolpidem (Ambien®), pregabalin (Lyrica®) were held. In addition, IV fluids given. Lactulose was ordered for ammonia level around 120 mcg/dl. The patient returned to the State Hospital much improved. On January 18<sup>th</sup>, the ammonia was down to about 25 mcg/dl.

A 56 year old Korean female was admitted to a State Hospital on 3/19/12 with a diagnosis of schizophrenia, paranoid type with possible dementia which was recently added. In the weeks preceding the adverse event date, a haloperidol serum level was found to be supra-therapeutic (30.6 ng/ml on 3/28/13). Haloperidol oral dose was subsequently tapered down and discontinued over the course of a week (4/3/13 - 4/10/13). Medications ordered as of 4/20/13 included: fluvoxamine (Luvox®) 150 mg daily (same dose since 7/13/12), donepezil (Aricept®) 5 mg daily (started 4/18/13) and haloperidol (Haldol®) decanoate 200 mg injection every 4 weeks. On 4/20/13, the patient appeared pale, displayed malaise, and reported one episode of emesis. She remained afebrile, temperature never above 98.0 degrees. On April 21<sup>st</sup>, she was reported to be noticeably changed in behavior, withdrawn with a more blunted affect. Nursing staff noted a decreased appetite, drooling, and stiff/slow movements. Based on a physician assessment, a stat CPK (level 1,413 U/L) was ordered and she was transferred to a local medical hospital. Vitals on April 21<sup>st</sup> at 9:30am; Temp 99.2 degrees, pulse 106 beats/min, blood pressure 134/84 mm Hg, respiration 18 breaths/min. Another temperature was recorded at 9:50 am 101 degrees with a pulse 106 beats/min. Outside hospital records showed CPK 1,452 U/L upon admission. In addition, on April 21<sup>st</sup> she was also noted to have tachycardia and blood pressure was elevated at 149/89 mm Hg. NMS was suspected and she was placed on IV fluids, bromocriptine (Parlodel®) 2.5 mg every 8 hours for 48 hours for rigidity, benztropine (Cogentin®) 0.5 mg daily, and dantrolene (Dantrium®) 50 mg IV. On April 22<sup>nd</sup>, dantrolene was discontinued as NMS symptoms were improved although rhabdomyolysis continued with elevated CPK of 907 U/L with downward trend. It was noted to be difficult to check for rigidity due to her unwillingness to have her arms moved. On April 26<sup>th</sup>, she was noted to be more alert, responding to questions, with a CPK level of 383 U/L. Upon return to the State Hospital on April 26<sup>th</sup>, her physical exam noted no drooling, rigidity or cog wheeling. Vitals on April 26<sup>th</sup> at 2:25 pm: temperature 97.1 degrees, pulse 100 beats/min, blood pressure 132/89 mm Hg. Medications at readmission included: benztropine 0.5 mg daily, donepezil 5 mg daily, fluvoxamine 150 mg daily, with lorazepam (Ativan®) and diphenhydramine (Benadryl®) both as needed for anxiety. Haloperidol decanoate use was not resumed. Benztropine was discontinued on May 1<sup>st</sup> as it was no longer needed since rigidity and cog wheeling were no longer present.

Although the haloperidol serum level from March 28<sup>th</sup> of 30.6 ng/ml was noted to be supra-therapeutic (therapeutic range 2-15 ng/ml), the haloperidol oral dose was subsequently tapered down from 4/3-4/10/13. A possible explanation for the elevated haloperidol level may be a drug-drug pharmacokinetic interaction with fluvoxamine. No follow-up haloperidol level was obtained prior to the NMS event and no adjustment was made to the haloperidol decanoate dose. Her most recent haloperidol decanoate injection was on 4/18/13, just 3 days prior to this event. It may be reasonable to conclude that NMS was precipitated by the increased serum haloperidol level; however, consideration must be given to other possible drug therapy contributors as haloperidol and fluvoxamine had been prescribed for quite some time at the same dose aside from recent decrease and subsequent discontinuation of oral haloperidol.

There have been reports of cholinesterase inhibitors such as donepezil causing NMS. One case report documented development of NMS like syndrome in 2 patients started on donepezil. Within 5-8 days of initiating donepezil both patients displayed lethargy, rigidity, diaphoresis, fluctuating blood pressure, and elevated creatinine kinase (Int J Geriatr Psychiatry 2006); 21:192-4). Another case report described development of NMS in a patient on olanzapine and donepezil. This patient had been treated with olanzapine for 10 years without adverse effects. Fatigue, progressive weakness, confusion, lethargy, and severe muscle stiffness was noted one week after initiation of donepezil (Nature Clinical Practice Neurology 2008; 4 (3) :170-4). Another report detailed a case in which olanzapine was added to rivastigmine therapy that was followed by NMS presentation. However, after the last increase of olanzapine, the rivastigmine was also increased shortly thereafter. Therefore, it seems difficult to determine if NMS was caused by olanzapine, rivastigmine, or by the combination of the two agents. One theory regarding donepezil precipitating NMS when added to an antipsychotic suggests that the combination of antipsychotics and cholinesterase inhibitors causes an acetylcholine/dopamine imbalance; dopamine receptor blockade with increased acetylcholine.

In this case, the patient had been prescribed haloperidol for quite some time as well as fluvoxamine at stable doses aside from taper of oral haloperidol in the weeks prior to the reaction after the elevated haloperidol level was discovered. The only recent addition to the regimen was donepezil. Around this time the patient was also noted to be experiencing nausea, vomiting and had poor oral intake so it is possible that dehydration may have also increased the risk of NMS. Cholinesterase inhibitors such as donepezil are well known for contributing to GI side effects. Interestingly, the NMS symptoms resolved despite the continuation of donepezil monotherapy so it is most likely the pharmacodynamics interaction with haloperidol along with possible dehydration that contributed to the adverse event.

A 32 year old female was noted to have irregularly heavy menstrual bleeding on March 28<sup>th</sup>. Levofloxacin (Levaquin®) was prescribed on March 30<sup>th</sup> for possible UTI/URI. On April 3<sup>rd</sup>, she was sent to the ER for seizure activity that did not respond to diazepam (Diasat®). During hospitalization, the levofloxacin was discontinued on April 3<sup>rd</sup> and cefepime (Maxipime®) was started. She had her PEG tube replaced on April 4<sup>th</sup>. During recovery from this procedure, she began having seizures and went into respiratory distress. She was admitted to the ICU, and oxygen and vancomycin (Vancocin®) were given in addition to the cefepime. On April 5<sup>th</sup>, her hemoglobin was 6.7 g/dl, hematocrit 22%, noted to be likely due to vaginal bleeding. A blood transfusion was performed. Infectious Disease and Neurology consults were performed on April 11<sup>th</sup>. Palliative care was recommended. The Neurologist felt she was in an encephalopathic state, and EEG showed diffuse slowing. Her PT and INR were elevated on April 12<sup>th</sup> (31.2 seconds; 2.95, respectively). The cause of the coagulopathy with elevated AST was uncertain. Labs on April 13<sup>th</sup> revealed hemoglobin less than 7 g/dl, total bilirubin 2.9 mg/dl, AST 8,493 U/L, LDH 7,907 U/L, PT 54.3 seconds, INR 5.16, sodium 128 mEq/L, platelets 85,000 K/mm<sup>3</sup>. The possibility of an intracranial bleed was noted, as well as liver failure of unknown etiology. GI specialist suggested this type of reaction was likely consistent with an idiosyncratic reaction to medications. Comfort care was continued and she was re-admitted to the facility on April 17<sup>th</sup>. On April 30<sup>th</sup>, the clinical presentation changed and she was more responsive than before. She was sent back to the hospital on May 1<sup>st</sup> for full support. Lab work on May 10<sup>th</sup> was remarkably normal. LFTs and PT/INR had decreased substantially (LFTs were within normal limits, PT/INR 12.2 seconds/1.14). Feedings and medications were slowly re-introduced.

A 58 year old African American female with diagnosis of schizophrenia, diabetes, seizure disorder, congested heart failure, obesity, hypertension, chronic constipation, hyperlipidemia, and GERD was admitted to a State Hospital. She has been in and out of the of the hospital system since age 18 years. She has a history of violence and poor medication compliance with frequent refusal of all oral medications. Olanzapine pamoate (Zyprexa® Relprevv™) 300 mg every 2 weeks was initiated on 1/17/12 and resulted in improvement in psychiatric condition including agitation and aggression. On 8/14/12, approximately 15 minutes after her injection, she seemed over sedated; 1-2 hours later she continued to have slurred speech, confusion, sedation, and disorientation. Patient was transported to the ER where she was admitted for observation and supportive treatment for approximately 60 hours. She was discharged with diagnosis of post-injection delirium/sedation syndrome. Olanzapine pamoate was changed to 150 mg daily for 2 days every 2 weeks. She was sent to ER on 9/27/12 with excessive sedation, but no delirium; diagnosis was dehydration so she was given 1 liter of normal saline. She was not eating and drinking consistently and one 150 mg dose of olanzapine pamoate was held. She was sent to ER again on 10/2/13 with low blood pressure (80/58 mm Hg) and lethargy. She only received 150 mg of olanzapine pamoate on the last injection, was very agitated and aggressive, and had not been eating or drinking. At the ER, she was again diagnosed with dehydration. The olanzapine pamoate dose was decreased to 105 mg daily for 2 days every 2 weeks and sedatives as well as blood pressure medications will be held prior to next olanzapine pamoate injection to avoid hypotension and excessive sedation. On 10/15/12, the patient was readmitted to hospital due to severe constipation, excessive sedation and dehydration. She had not been eating or drinking and received one dose of

lorazepam (Ativan®) for agitation. She received 2 liters of normal saline and was returned to psychiatric hospital. Psychiatrically she decompensated over the previous month and became very psychotic with tactile hallucinations and severe delusions. The olanzapine pamoate was discontinued and fluphenazine ordered.

**Quetiapine (Seroquel®, Seroquel® XR) Purchases**

Dr. Richards reviewed the State Hospital purchases and returns of Seroquel® and Seroquel® XR from April through June. 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	April	May	June	Total	# Patients for Quarter
Austin	0	0	\$1,121.88	\$1,121.88	1
Rio Grande	\$2,561.54	\$2,561.54	\$1,121.88	\$6,244.96	5
Terrell	0	0	\$1,439.66	\$1,439.66	2
Vernon	\$3,383.86	\$3,383.86	\$1,691.93	\$8,459.65	4
Total	\$5,945.40	\$5,945.40	\$5,375.35	\$17,266.15	12

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 Austin State Hospital that was initially tried on generic but insisted that they are allergic to generic, thus placed on the XR version. One at Rio Grande State Center that was initially placed on immediate release but then changed to extended release. Two are currently at the Vernon campus, both have been in a state hospital continuously since 2007.

The Committee recommended to continue to monitor this information.

**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.

**NorthSTAR Formulary**

The Committee reviewed NorthSTAR’S proposed Drug Formulary for the next contract year. The NorthSTAR Formulary was compared to the DSHS/DADS Drug Formulary. The following is a summary of the findings:

- On NorthSTAR’s formulary but not on DSHS/DADS – flurazepam (Dalmane®), mesoridazine (Serentil®), molindone (Moban®), nefazodone (Serzone®), quetiapine (Seroquel®) XR. Flurazepam, mesoridazine and nefazodone are not on the DSHS/DADS Formulary due to safety issues. Molindone is not commercially available at this time.
- The NorthSTAR Formulary does not include all of the psychotropic drugs listed in the DSHS/DADS Formulary.
- Some of the maximum doses listed in the NorthSTAR Formulary do not match the DSHS/DADS Formulary maximum doses
- NorthSTAR has drugs listed by indication. DSHS uses the Psychotropic Audit Criteria and Guidelines as a reference for the use of drugs in specific indications. For example, the NorthSTAR Formulary has gabapentin (Neurontin®) listed as being used as a mood stabilizer, however, DSHS does not recognize this as there is lack of evidence to support gabapentin’s use in this indication.

The Committee recommends the following changes to the NorthSTAR Formulary:

- Include all drugs and maximum doses as listed in the DSHS/DADS Formulary
- Continue with NorthSTAR's tiered system as appropriate
- Consider using the Psychotropic Audit Criteria and Guidelines in the prior authorization process
- Since the DSHS/DADS Formulary is updated quarterly, review the EFC website page for changes

Due to time constraints regarding the completion of these minutes, Dr. Muse will provide feedback to NorthSTAR.

### **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.

### **Antipsychotic Tier Schedule**

Dr. Richards presented an updated version of the Antipsychotic Tier Schedule. The updated version is based on current pricing and dosing. The proposed tiers are as follows:

#### Tier 1 (no prior approval)

Aripiprazole (Abilify®)	Lurasidone (Latuda®)
Asenapine (Saphris®)	Olanzapine (Zyprexa®)
Chlorpromazine (Thorazine®)	Perphenazine (Trilafon®)
Fluphenazine (Prolixin®)	Quetiapine (Seroquel®)
Fluphenazine (Prolixin®) decanoate LAI	Risperidone (Risperdal®)
Haloperidol (Haldol®)	Thiothixene (Navane®)
Haloperidol (Haldol®) decanoate LAI	Trifluoperazine (Stelazine®)

#### Tier 2 (requires documentation for reason for use instead of Tier 1 option)

Clozapine (Clozaril®, Fazaclo®)	Paliperidone palmitate LAI (Invega® Sustenna™)
Iloperidone (Fanapt®)	Risperidone microspheres LAI (Risperdal® Consta™)
Paliperidone (Invega®)	Ziprasidone (Geodon®)
An combination of two antipsychotics for hospitals	

#### Tier 3 (requires prospective review by clinical director or designee)

Aripiprazole (Abilify®) LAI	Quetiapine (Seroquel® XR) extended release
Olanzapine pamoate LAI (Zyprexa® Relprevv™)	Thioridazine (Mellaril®)
Any combination of three or more antipsychotics	

During the discussion on adding aripiprazole LAI to the formulary, it was recommended that aripiprazole LAI be placed in the Tier 2 category. On a motion of Dr. Matthews, seconded by Dr. Ward, the Antipsychotic Tier Schedule was approved as modified.

Dr. Hall provided the review on the agents in the Dermatologicals (Acne Agents to Anti-infectives; Antiseptic & Germicides) sections. See Attachment B. Dr. Hall made the following recommendations:

Delete the following:

- Sulfur/resorcinol (Sulforcin®, Rezamid®)
- Dibucaine (Nupercainal®)
- Calcium undecylenate (Caldesene®)
- Zinc undecylenate (Desenex®)
- Methotrexate
- Benzalkonium chloride (Zephiran®)

Make the following change:

- Remove ciclopirox (Loprox®, Penlac®) from the Antibiotics section. It will continue to be listed in the Antifungal section

On a motion of Ms. Millhollon, seconded by Dr. Morgan, the recommendations for changes to the Dermatologicals – Part One were approved.

### **New Drug Applications**

**(Please refer to Attachment C for the monograph and application that were considered when determining action by the committee.)**

#### **Aripiprazole Long-acting Injection (Abilify® Maintena™) - developed by Dr. Saklad, presented by Dr. Richards**

Aripiprazole long-acting injection (LAI) is given once a month and should only be prescribed after tolerability and efficacy to oral aripiprazole has been established. The recommended starting and maintenance dose is 400 mg administered monthly ( $\geq 26$  days) as a single injection. Aripiprazole absorption from the intramuscular injection into the systemic circulation is slow and prolonged following the intramuscular injection due to low solubility of aripiprazole and the crystal structure of aripiprazole monohydrate. Oral antipsychotic overlap for 14 consecutive days at the same dose is needed when starting aripiprazole LAI. Some patients may benefit from a reduction to a 300 mg maintenance dose to improve tolerability. Dosage adjustments are required for the following:

**Situation**

Adverse effects

Concomitant use with strong CYP2D6 or CYP3A4 inhibitors for more than 14 days

**Note (1):** No dose adjustment is necessary if concomitant use is less than 14 days

Concomitant use with a combination of inhibitors of CYP2D6 and CYP3A4 for more than 14 days

**Note (1):** No dose adjustment is necessary if concomitant use is less than 14 days

Missed dose - second or third scheduled dose: if more than 4 weeks and less than 5 weeks have elapsed since last dose

Missed dose - second or third scheduled dose: if more than 5 weeks have elapsed

Missed dose - fourth or subsequently scheduled doses: if more than 4 weeks and less than 6 weeks have elapsed since last dose

Missed dose - fourth or subsequently scheduled doses: if more than 6 weeks have elapsed

Poor metabolizers of CYP2D6

Poor metabolizers of CYP2D6 taking concomitant CYP3A4 inhibitor for more than 14 day

**Note (1):** No dose adjustment is necessary if concomitant use is less than 14 days

**Action to take**

Consider dose reduction to 300 mg IM

1) For patients receiving 400 mg IM once monthly, reduce aripiprazole dose to 300 mg IM once monthly

2) For patients receiving 300 mg IM once monthly, reduce aripiprazole dose to 200 mg IM once monthly

**Note (2):** Aripiprazole dose increase may be necessary upon withdrawal of the CYP2D6 or CYP3A4 inhibitor

1) For patients receiving aripiprazole 400 mg IM once monthly, reduce aripiprazole dose to 200 mg IM once monthly

2) For patients receiving 300 mg IM once monthly, reduce aripiprazole dose to 160 mg IM once monthly

**Note (2):** Aripiprazole dose increase may be necessary upon withdrawal of the inhibitor of CYP2D6 or CYP3A4

Administer dose as soon as possible

Restart concomitant oral aripiprazole for 14 days with the next injection

Administer dose as soon as possible

Restart concomitant oral aripiprazole for 14 days with the next injection

Reduce aripiprazole dose to 300 mg IM once monthly

Reduce aripiprazole dose to 200 mg IM once monthly

**Note (2):** Dose increase may be necessary upon withdrawal of the CYP3A4 inhibitor

**Following discussion, on motion of Ms. Millhollon, seconded by Dr. Balfanz, the request to add aripiprazole LAI (Abilify® Maintena™) to the formulary was approved.** It was recommended that aripiprazole LAI be placed in the Tier 2 category for the Antipsychotic Tier Schedule.

Meloxicam (Mobic®) will be discussed at the next meeting.

**Benztropine Injection Recall**

Dr. Richards reported that Fresenius Kabi USA issued a voluntary nationwide recall for four lots of benzotropine mesylate injection 2 mg/2 ml due to the potential presence of glass particles (glass delamination) in the vials. The information was distributed to all of the pharmacy directors.

**Issues from the Clinical Directors' Meeting**

Dr. Muse reported that Dr. Jim Baker has been hired as the Medical Director for Behavioral Health effective July 15<sup>th</sup>. She noted that this position is now 75% DSHS and 25% MSHSA.

**FDA Drug Safety Communications**

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

The FDA is advising health care professionals and women that the anti-seizure medication valproate sodium and related products, valproic acid and divalproex sodium, are contraindicated and should not be taken by pregnant women for the prevention of migraine headaches. Based on information from a recent study, there is evidence that these medications can cause decreased IQ scores in children whose mothers took them while pregnant. Stronger warnings about use during pregnancy will be added to the drug labels, and valproate's pregnancy category for migraine use will be changed from "D" (the potential benefit of the drug in pregnant women may be acceptable despite its potential risks) to "X" (the risk of use in pregnant women clearly outweighs any possible benefit of the drug). Valproate products will remain in pregnancy category D for treating epilepsy and manic episodes associated with bipolar disorder. This alert is based on the final results of the Neurodevelopmental Effects of Antiepileptic Drugs (NEAD) study showing that children exposed to valproate products while their mothers were pregnant had decreased IQs at age 6 compared to children exposed to other anti-epileptic drugs. Valproate products should not be used in pregnant women for prevention of migraine headaches and should be used in pregnant women with epilepsy or bipolar disorder only if other treatments have failed to provide adequate symptom control or are otherwise unacceptable.

In an update, the FDA is notifying the public that FDA has approved label changes specifying new dosing recommendations for zolpidem products (Ambien®, Ambien® CR, and Edluar®), which are widely prescribed sleep medications. FDA has approved these changes because of the known risk of next-morning impairment with these drugs. FDA urges health care professionals to caution all patients (men and women) who use these products about the risks of next-morning impairment for activities that require complete mental alertness, including driving.

- The recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien®, Edluar®, and Zolpimist®) and from 12.5 mg to 6.25 mg for extended-release products (Ambien® CR).
- For zolpidem and other insomnia drugs, prescribe the lowest dose that treats the patient's symptoms.
- Inform patients that impairment from sleep drugs can be present despite feeling fully awake.
- The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo®'s approval in November 2011, the label already recommended a lower dosage for women than for men.

The FDA is investigating two unexplained deaths in patients who received an intramuscular injection of the antipsychotic drug Zyprexa® Relprevv™ (olanzapine pamoate). The patients died 3-4 days after receiving an appropriate dose of the drug, well after the 3-hour post-injection monitoring period required under the Zyprexa® Relprevv™ Risk Evaluation and Mitigation Strategy (REMS). Both patients were found to have very high olanzapine blood levels after death. Under the REMS, patients are required to receive the olanzapine pamoate injection at a REMS-certified health care facility, to be continuously monitored at the facility for at least 3 hours following an injection, and to be accompanied home from the facility. The olanzapine pamoate label contains warnings about the risk of post-injection delirium sedation syndrome (PDSS), a serious condition in which the drug enters the blood too fast following an intramuscular injection, causing greatly elevated blood levels with marked sedation (possibly including coma) and/or delirium. The FDA is providing this information to health care professionals while it continues its investigation. If therapy with olanzapine pamoate is started or continued in patients, health care professionals should follow the REMS requirements and drug label recommendations.

### **Quarterly Non-Formulary Drug Justification Report**

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

Levalbuterol (Xopenex®)  
Guanfacine ER (Intuniv® ER)  
Lansoprazole (Prevacid®) Solutab  
Meloxicam (Mobic®)

Carisoprodol (Soma®)

The Committee noted that meloxicam (Mobic®) is scheduled for review for addition to the Formulary in the near future.

### **Sectional Review for Next Meeting**

The following sections will be reviewed at the next meeting:

Dermatologicals (Scabicides to Wound agents)  
Irrigation  
Immunological

### **Other Issues**

The following information was shared with the Committee members:

Lundbeck announced that the investigational anti-depressant Brintellix (vortioxetine), which it developed with its Osaka, Japan-based partner Takeda, was significantly more effective than Servier's Valdoxan (agomelatine) during a four-week treatment protocol. In 2012, the companies submitted applications for approval of Brintellix as a treatment for adults with major depressive disorder to regulatory bodies in the EU and to the US Food and Drug Administration. In this latest study, Lundbeck's Research and Development Leader Anders Gersel Pedersen said Brintellix was effective as therapy for patients who do not respond well to selective serotonin reuptake inhibitors (SSRIs) or to serotonin and noradrenaline reuptake inhibitors (SNRIs).

Regardless of whether mothers took selective serotonin reuptake inhibitors or were depressed and unmedicated during pregnancy, their offspring at 12 months weighed the same as control children, according to study in the American Journal of Psychiatry. In addition, there were no between-group differences in length or head circumference. In Journal Watch Psychiatry, Joel Yager says that while the findings "may offer some reassurance ... we need more detailed information about the children's physical and neurocognitive development over time to fully assess the impact of antenatal depression on offspring development, regardless of whether the mothers were medicated".

The Time "Healthland" blog reports, "Doctors often first learn of new drugs during sales meetings with pharmaceutical sales representatives, during which the representatives educate physicians about their latest offerings, provide free samples, and, according to the law, inform doctors of potential side effects associated with the medications." Now, however, a new study published online April 10 "in the Journal of General Internal Medicine found that an important part of these drug pitch meetings is often missing: discussions about harmful side effects." What's more, "the omissions included drugs with the most serious, black box warnings of potential adverse effects."

Alkermes announced Wednesday that in the mid-stage trial, ALKS 5461 "significantly reduced depressive symptoms across a range of standard measures, including the study's primary outcome measures, which include the Hamilton Depression Rating Scale (P = .026), the Montgomery-Åsberg Depression Rating Scale (P = .004), and the Clinical Global Impression–Severity Scale (P = .035)."

The New York Times "Motherlode" blog reported, "A cautiously worded study based on data collected in Sweden has found that 'in utero exposure to both selective serotonin reuptake inhibitors (SSRIs) and nonselective monoamine reuptake inhibitors (tricyclic antidepressants) was associated with an increased risk of autism spectrum disorders [ASDs], particularly without intellectual disability.'" The blog added, "The Swedish medical birth register (which contains data on current drug use reported by mothers early in their pregnancies), along with a system of publicly funded screenings for autism spectrum disorders and extensive national and regional registers of various health issues, make a detailed, population-based case-control study possible - one

that controls for other variables like family income, parent educational level, maternal and paternal age and even maternal region of birth (all factors the authors note have been previously associated with autism)." The study appeared April 19 in the BMJ.

The Wall Street Journal reported that researchers are now testing experimental medications that may treat depression quickly, within just a few days or hours. Current medicines may require weeks to work, and not everyone benefits from them. The Journal quotes antidepressant researchers Carlos A. Zarate, MD, of the National Institutes of Mental Health, as saying, "You can control seizures and control hypertension within minutes and hours." He added, "That is what we should aim for" in the treatment of depression. The Journal points out that some research involves using already existing medications, such as the animal anesthetic ketamine or scopolamine, commonly used as a treatment for motion sickness. Work is in preliminary stages, so it will be years before the Food and Drug Administration approves any of these medications for the treatment of depression. The Journal also notes that these experimental treatments target glutamate instead of serotonin.

According to a study published in the April 24 issue of the Journal of the American Medical Association, "Children born to mothers who took the anti-seizure drug valproate were five times more likely to be born with autism than those whose mothers didn't take the medication." The medication "was also tied to a three-fold increase of autism spectrum disorder, which includes Asperger syndrome and other developmental disorders," the study found.

According to research presented at the 14th International Congress on Schizophrenia Research "The prosocial peptide oxytocin may improve social functioning in people with schizophrenia." Findings from "a small randomized controlled trial showed that oxytocin, delivered as an intranasal spray, significantly improved the ability of patients with schizophrenia to tell when people were being sarcastic or lying." Additionally, oxytocin "improved the ability to discern moods, and it enhanced patients' ability to smell the floral aldehyde odorant lily, a scent that individuals with schizophrenia have trouble detecting."

According to research published in JAMA Internal Medicine, the use of selective serotonin reuptake inhibitors (SSRIs) "around the time of surgery may increase risks associated with the procedure, including bleeding, the need for a blood transfusion, hospital readmission and even death." Investigators looked at data on "more than half a million people who had surgery at 375 U.S. hospitals between 2006 and 2008."

According to a report the Substance Abuse and Mental Health Services Administration, the "number of emergency room visits involving adverse reactions to the sleep drug zolpidem - the active ingredient in Ambien and other sleep medications - jumped nearly 220% from 2005 to 2010," The SAMHSA report indicates "19,487 emergency visits were related to zolpidem in 2010, up from 6,111 in 2005." Moreover, it notes that in 2010, nearly "three-quarters (74%) of the patients showing up in ERs with problems in 2010 were age 45 or older, and 68% were women," and that overall, there were "4.9 million drug-related visits" to emergency departments in the US.

"Depression is relatively common in patients who undergo heart bypass surgery, and a new study" published in the Annals of Thoracic Surgery "finds that short-term use of antidepressants may aid patients' recovery." Investigators "looked at 182 patients who started taking a selective serotonin reuptake inhibitor (SSRI) antidepressant two to three weeks before undergoing coronary artery bypass graft surgery and continued taking it for six months after the procedure." The researchers also followed a similar number of patients who were given a placebo. The investigators found that "during the six months after the surgery, the patients who took the antidepressant reported less depression and better quality of life than those who took the placebo."

Medwire reported that research published in the April issue of the European Archives of Psychiatry and Clinical Neuroscience "failed to find an improvement in cognitive performance in patients with schizophrenia who use or have used cannabis - findings that refute those of several other studies." For the study, investigators examined "the relationship between lifetime use of cannabis, assessed over a 10-year period, and cognitive

performance in 42 patients with schizophrenia, 35 of their unaffected siblings, and 42 mentally healthy individuals." The study "found that cannabis use in the previous 10 years and lifetime cannabis use significantly increased positive symptoms, while longitudinal cannabis use over the past 10 years, current use, and lifetime cannabis use increased negative symptoms."

According to a study published May 7 in the journal BMC Medicine, "Certain types of antidepressants may put people at an increased risk for developing a deadly superbug infection." "Researchers from the University of Michigan revealed that individuals who suffer from depression and those taking antidepressants such as mirtazapine and fluoxetine had a much higher chance of contracting Clostridium difficile infection (CDI) - a life threatening infection that can cause severe diarrhea and inflammation of the colon."

Teva Pharmaceuticals USA, Inc. and Alexza Pharmaceuticals, Inc. released a joint statement, announcing they have signed an exclusive US license and supply agreement for Alexza's Adasuve (loxapine) to treat acute agitation associated with schizophrenia or bipolar I disorder in adults. Under the terms of the agreement, Teva will manage the commercial and clinical actions for the treatment, which includes conducting post-approval trials for new indications, in the US; and Alexza will have the responsibility of producing and supplying Adasuve to Teva. According to the New York Times, "the generic drug maker Ranbaxy pleaded guilty to federal drug safety violations and will pay \$500 million in fines to resolve claims that it sold subpar drugs and made false statements to the Food and Drug Administration about its manufacturing practices at two factories in India, the company and federal prosecutors announced." According to the Times, "the settlement is the largest in history involving a generic manufacturer and drug safety, the Justice Department said" in a news release.

"The hallucinogen ketamine relieved symptoms of hard-to-treat depression within a day of treatment, in the largest study yet of the popular club drug's use in psychiatry." In the study of "72 people whose depression hadn't responded to at least two antidepressants, patients taking ketamine were twice as likely to report improvement than those on a placebo." The researchers from Baylor College of Medicine in Houston and Mount Sinai School of Medicine in New York "presented their findings at American Psychiatric Association meeting."

According to the results of a study presented at the American Psychiatric Association's annual meeting, "A stimulant drug, lisdexamfetamine dimesylate (Vyvanse), nearly abolished eating binges in adult patients who had experienced such episodes four times a week." "In a randomized, placebo-controlled trial, 11 weeks of treatment with the drug, which is currently approved for attention-deficit/hyperactivity disorder (AD/HD), cut the mean rate of days with binge eating to as little as 0.1 week, said Susan McElroy, MD, of Lindner Center of HOPE in Mason, Ohio." In contrast, "patients assigned to placebo in the 270-patient trial had a mean bingeing rate of 1.1 days/week at the end of treatment, McElroy reported."

H. Lundbeck A/S and partner Takeda Pharmaceutical Company released a joint statement, announcing that in a Phase III clinical trial, their investigational antidepressant Brintellix (vortioxetine) "significantly improved symptoms in the 20-milligram dose, with patients' scores on the Montgomery-Asberg Depression Rating Scale falling by 15.57 after 8 weeks of treatment, compared with 16.90 for patients taking 60 milligrams" of Eli Lilly's Cymbalta (duloxetine). However, the companies noted that the lower dose (15-mg) of Brintellix that was tested in the late-stage trial "didn't meet statistical significance."

The Wall Street Journal reports study data on 2,000 patients confirms Merck's insomnia treatment candidate, Suvorexant (orexin receptor antagonist), is effective, but the safety of the therapy when administered at higher doses is concerning, according to Food and Drug Administration personnel. The FDA later rejected the application because the FDA "concluded that safety data presented by Merck did not support approval" of suvorexant in the higher doses and "recommended that most patients start on a 10-milligram dose, which the company had not proposed selling."

According to the results of a 183-patient study presented at the American Psychiatric Association's annual meeting, patients with schizophrenia "switching from regular daily antipsychotic medications to a long-acting form of aripiprazole (Abilify Maintena) had markedly fewer hospitalizations." "Hospitalization rates were

slashed by two-thirds among all patients undergoing the open-label medication switch (rate ratio 0.34,  $P < 0.0001$ ), reported John M. Kane, MD, of Zucker Hillside Hospital in Glen Oaks, NY.” And, “the reduction was even greater among patients who remained on the long-acting drug for at least three months, with a rate ratio of 0.24 ( $P < 0.0001$ ), he reported.”

According to research published in *BJU International*, benzodiazepines and certain antidepressants may be associated with a higher likelihood of erectile dysfunction (ED). Investigators surveyed more than 2,300 men. The investigators found that tricyclic antidepressants were associated with a three-fold higher risk of developing ED, while benzodiazepines were associated with a more than two-fold higher risk of developing the condition.

According to a 377-patient study presented at the American Psychiatric Association’s annual meeting, “Antidepressant use in patients hospitalized with bipolar depression (BD) is ineffective at best, and at worst may be harmful to some patients.” Researchers “found there was no difference in hospital readmission rates among patients who received antidepressants and those who did not. Furthermore, they found that in patients with BD, when controlling for comorbid anxiety, one antidepressant – venlafaxine – was associated with a three-fold higher rate of hospital readmission.”

France will prohibit the use of electronic cigarettes in public, making the product subject to the same rules that were implemented in 2007 to curb tobacco use. Media advertising and sale of e-cigarettes to minors will be banned in the country as part of the concern over the implications of e-cigarettes on public health. E-cigarettes were first invented in China in 2003, as many nations began imposing bans on smoking, and are aimed at giving the user a similar sensation to smoking a cigarette. They were thought to be much healthier than normal smoking because they do not contain the tobacco and other carcinogens found in cigarettes. Many experts have since expressed concerns about certain chemicals contained in the liquid, notably the propylene glycol.

A small study (63 patients) with major depression has identified a pattern of brain activity that appears distinct in those who responded to escitalopram (Lexapro), compared with those who improved with psychotherapy. The study, published in *JAMA Psychiatry*, showed that a the brain scan using positron emission technology (PET) discovered that the area of the brain known as the insula demonstrated distinct changes in patients receiving the medication compared to those who responded to psychotherapy, suggesting that the imaging technique could potentially be helpful in determining who should get which treatment.

According to a meta-analysis published in the June issue of the *American Journal of Psychiatry*, “Adults aged 60 years and older with long-standing moderate to severe depression are most likely to derive clinically meaningful benefit from antidepressant therapy.” However, “antidepressants do not appear to be effective for older patients with late-onset illness.” Researchers arrived at these conclusions after examining data from seven studies encompassing 2,283 patients.

According to the results of a study presented at the 10th International Conference on Bipolar Disorders Latuda (lurasidone) an antipsychotic approved in 2010 by the US Food and Drug Administration as a “monotherapy for acute episodes of schizophrenia in adults, is safe and effective adjunctive medication for treatment-resistant outpatients with bipolar disorder of any type.” The 49 patients involved in the study were “treatment-refractory adult outpatients who had failed multiple standard and off-label bipolar disorder medications” and “were treated for a minimum of two months.”

According to a 28-participant study published online June 14 in the *Journal of Cognitive Neuroscience*, “A popular anti-insomnia medication, zolpidem (Ambien, Sanofi-Aventis US), increases the ability to remember images, but only those that have negative or highly arousing content.” Researchers arrived at this conclusion after using “two hypnotic medications, zolpidem and sodium oxybate (Xyrem, Jazz Pharmaceuticals, Inc.), to pharmacologically manipulate sleep spindle density, which they defined as the number of spindles in stage 2 divided by the minutes of stage 2.” Because the effect of benzodiazepines on sleep is similar to that of zolpidem, the study’s lead author “said that future research should investigate whether benzodiazepine-like drugs increase retention of negative and arousing memories, especially in patients with PTSD.”

According to the results of a 73-patient study recently published online in the *American Journal of Psychiatry*, a publication of the American Psychiatric Association, “A combination of antidepressant therapy and counseling is an effective way to treat anxiety in older adults.” Each of the patients, aged 60 and older, suffered from generalized anxiety disorder. After a three-month period of taking the antidepressant Lexapro (escitalopram),

patients were randomized either to just continue taking the medication for 16 more weeks or to taking the antidepressant plus undergoing cognitive behavioral therapy (CBT). Over time, “taking the antidepressant lowered anxiety levels, but the improvement was much greater in patients who also received” CBT, the study found.

According to a review published online June 27 in the BMJ, “Lithium helps prevent suicide and is associated with a lower risk for all-cause mortality in patients with mood disorders.” After “analyzing 48 randomized controlled trials involving 6674 participants,” researchers wrote, “Lithium was associated with a reduced risk of suicide when compared with placebo, and also a reduced risk of deliberate self-harm compared with carbamazepine.”

The FDA approved Brisdelle (paroxetine), the first nonhormonal therapy for treating moderate-to-severe hot flashes that occur for some women during menopause. Hisamitsu Pharmaceutical’s US subsidiary, Noven Pharmaceuticals, will market Brisdelle, which is essentially a low-dose formulation of the antidepressant Paxil (paroxetine). Brisdelle® is available in 7.5 mg capsules.

Sunovion Pharmaceuticals announced that the FDA approved two new indications for the use of Latuda® (lurasidone HCl) as 1) monotherapy and 2) adjunctive therapy with either lithium or valproate, both to treat adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression).

The FDA approved Novartis’ application to expand the use of its transdermal film Exelon® (rivastigmine) to “treat symptoms of severe” Alzheimer’s disease. The Basel, Switzerland-based pharmaceutical company, “introduced Exelon® in 2000 as a capsule to patients with mild to moderate Alzheimer’s and Parkinson’s diseases;” and the FDA approved the patch form of Exelon®, which “works by temporarily preventing the breakdown of the brain’s neurotransmitters,” in 2007 to treat both the mild and the moderate “forms of both diseases.”

“Game developers hope that one day they might supplement therapy and support groups by putting mental health care into patients’ homes or pockets.” However, “most of the games have yet to go through rigorous testing to see whether they work – or might inadvertently harm patients – and the makers aren’t yet allowed to make health claims for their products.” The piece adds that the FDA “plans to require approval for only a ‘small subset’ of Web or mobile medical apps ‘that may present potential harm to consumers,’ a spokeswoman for the federal agency said in an e-mail.” The spokeswoman indicated some games claiming to diagnose or treat mental health disorders may be subject to review by the FDA.

A growing body of evidence is finding that stimulants used to treat attention-deficit/hyperactivity disorder (AD/HD), including Ritalin® (methylphenidate) and Adderall® (amphetamine, dextroamphetamine mixed salts), may not improve the academic outcomes of the students who take them. Researchers are studying how the medications can improve a person’s focus and attention, but not grades and test scores. The Federal MTA study that looked at the effects of long-term AD/HD treatment, which found that the medicines’ benefits wore off by the third year of treatment and that an eight-year follow-up found no difference between any of the study groups’ academic achievements.

US regulators are now questioning “sloppy data and irregularities” coming from large clinical trials in China. The article notes Bristol-Myers Squibb and Pfizer’s “blood thinner Eliquis® [apixaban], approved in December, was stalled for nine months because of misconduct, errors and an alleged cover-up attempt at a Chinese trial site overseen by Bristol-Myers, according to documents posted by the US Food and Drug Administration.” This delay eventually led to a “lengthy reanalysis of the data and spurred a debate within the agency on what the drug’s label should say about its effectiveness.” Thomas Marciniak, an FDA medical team leader not involved in the Eliquis® application, explained drug makers will continue to have problems “with sloppy data and misconduct as long as they keep doing trials in places like China without providing better oversight.”

“Stimulant medications appear to lower the risk for substance abuse disorders in adolescents with attention-deficit/hyperactivity disorder (AD/HD),” according to a study published online July 11 in the British Journal of Psychiatry. “In a large, prospective, longitudinal study investigating the effect of stimulant medication on the development of substance use disorder (SUD) in AD/HD, investigators from the State University of New York Upstate Medical University in Syracuse found that adolescents with AD/HD who were not treated with a stimulant medication for their disorder had a two-fold increased risk of developing an SUD, compared with

their counterparts who were treated.” In addition, untreated teens “with AD/HD had a 2.6-fold increased risk of developing an SUD compared with a healthy, age-matched control group.”

**Next Meeting Date**

The next meeting was scheduled for October 18, 2013.

**Adjourn**

There being no further business, the meeting was adjourned at 1:30 p.m.

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

**Attachments:**

- Attachment A – Medication Audit Criteria and Guideline for Benztropine
- Attachment B – Dermatologicals Part One Sectional Review
- Attachment C – New Drug Application

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

**Medication Audit Criteria and Guidelines**  
**Drug Audit Checklist**

<b>Reviewer:</b>	<b>Date:</b>
<b>Class: Anticholinergic</b>	
<b>Drug: Benztropine mesylate (Cogentin) tablets</b>	

Audit#	Male		Appropriate Use/Monit.	
	Female			
Ordering Physician			Yes	No

<b>INDICATIONS</b>	1. Parkinson's Disease as adjunctive therapy			
	2. Treatment of EPS (NOT tardive dyskinesia) due to neuroleptic drugs, specify EPS type if noted (i.e. dystonia, parkinsonism, akathisia)			
	3. Prophylaxis of EPS ONLY if developed EPS in the past on the same or similar medication (i.e. dystonia in the past with high potency FGA haloperidol and rx fluphenazine which is also a high potency FGA)			
	4. Other Non FDA-approved indication			

<b>CONTRAINDICATIONS</b>	<b>Absolute</b>	1. Hypersensitivity to benztropine			
		2. Pediatric patients < 3 years of age			
	<b>Relative</b>	1. Narrow angle glaucoma			
		2. BPH			
		3. Pregnancy			
		4. Renal impairment			
		5. Hepatic impairment			
		6. Elderly ( $\geq$ 65 years of age)			
		7. Tardive dyskinesia			
		8. Tachycardia (HR > 100 bpm)			

<b>PATIENT MONITORING</b>	<b>Patient Monitoring Parameters</b>	1. Pulse (Baseline and periodically during therapy)			
		2. Symptoms of EPS or Parkinson's disease (After initiation and periodically during therapy to assess continued need, i.e. reassess continued need for therapy 1-2 weeks after initiation for dystonia)			
		3. Anticholinergic Side Effects			
<b>Dosing</b>		ADULT: max 6 mg in single or divided doses PEDIATRIC, children > 3 years: max 0.05mg/kg/dose in single or divided doses			

Additional Comments:


**Presence of Clinically Significant Drug Interactions**

Other Anticholinergic Medications (Anticholinergic burden rating; Mild, Moderate, High)\*

Use provided references to assist in ranking

Anticholinergic Drug	Mild	Moderate	High

**Other Drug Interactions:**

Medication	Yes	No	Comments
Cholinesterase inhibitors			
Potassium Chloride			
Topiramate			

**Any side effects related to Benztropine Therapy?**

<b>Side Effects</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Tachycardia			
Dry mouth			
Constipation			
Delirium/Mental Confusion			
Blurred vision			
Rash			
Urinary retention			
Other			

## MEMORANDUM

**To:** Executive Formulary Committee  
**From:** Catherine S. Hall, Pharm.D., BCPP  
**Through:** Ann L. Richards, Pharm.D., BCPP  
**Subject:** Class Review, Dermatologicals  
**Date:** July 12, 2013

**Recommendation:** Delete sulfur/resorcinol (Sulforcin, Rezamid), dibucaine (Nupercainal), calcium undecylenate (Caldesene), zinc undecylenate (Desenex), methotrexate, benzalkonium chloride (Zephiran)

**Remove Ciclopirox (Loprox, Penlac) from the Antibiotics section. It will continue to be listed in Antifungals.**

## Dermatologicals

## Acne Agents

Adapalene (Differin)	\$\$\$\$\$\$\$
Benzoyl Peroxide	\$ - \$\$
Benzoyl Peroxide/Clindamycin (BenzaClin)	\$\$\$\$\$\$\$
Clindamycin (Cleocin T)	\$\$\$ - \$\$\$\$\$
Erythromycin/Benzoyl Peroxide (Benzamycin)	\$\$\$\$\$\$\$
Metronidazole (Noritate, MetroGel)	\$\$\$\$\$\$\$
Salicylic Acid/Sulfur	\$-\$\$\$\$
Sulfacetamide Sodium (Sebizon)	\$\$\$\$\$\$\$
Sulfur/Resorcinol (Sulforcin, Rezamid)	\$\$\$\$
Tazarotene (Tazorac, Avage)	\$\$\$\$\$\$\$
Tretinoin Gel (Retin-A)	\$\$\$\$\$\$\$ - \$\$\$\$\$\$

**Anesthetics, Local**

Benzocaine (Lanacaine)	\$\$ - \$\$\$
Dibucaine (Nupercainal)	\$\$ - \$\$\$\$
Ethyl Chloride	\$\$\$\$\$\$\$
Lidocaine (Xylocaine)	\$\$ - \$\$\$\$\$\$
Lidocaine/Prilocaine (EMLA, Lidoderm)	\$\$\$ - \$\$\$\$
Pramoxine (Tronothane)	\$\$\$ - \$\$\$\$\$\$\$\$

**Anti-Histamine Agents**

Calamine/Zinc Oxide/Glycerin (Calamine Lotion)	\$
Calamine/Pramoxine (Caladryl)	\$\$\$
diphenhydrAMINE (Benadryl)	\$
Doxepin (Zonalon)	\$\$\$\$\$\$\$
Pramoxine/Zinc (Caladryl Clear)	\$\$

**Anti-Infectives****jAntibiotics**

Bacitracin (Baciguent)	\$
Bacitracin/Polymyxin B (Polysporin)	\$\$\$ - \$\$\$\$
Ciclopirox (Loprox, Penlac)	\$\$\$\$-\$\$\$\$\$\$\$
Clindamycin (Cleocin T)	\$\$\$ - \$\$\$\$\$\$
Gentamicin (Garamycin)	\$\$\$
Metronidazole (Noritate, MetroGel)	\$\$\$\$\$\$\$
Mupirocin (Bactroban)	\$\$\$\$\$\$\$
Neomycin/Polymyxin B/Bacitracin (Triple Antibiotic Ointment)	\$
Polymyxin B/Neomycin (Neosporin)	\$\$ - \$\$\$\$\$\$\$\$

**Antiviral**

Acyclovir (Zovirax)	\$\$\$\$\$\$\$
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**Antifungals**

Calcium Undecylenate (Caldesene)	\$\$
Ciclopirox (Loprox)	\$\$\$\$-\$\$\$\$\$\$\$
Clotrimazole (Lotrimin, Fungoid)	\$\$\$\$\$
Ketoconazole (Nizoral)	\$\$\$\$\$\$\$ - \$\$\$\$\$\$\$\$
Miconazole (Monistat)	\$\$\$ - \$\$\$\$\$\$
Nystatin (Mycostatin)	\$\$ - \$\$\$\$\$
Terbinafine (Lamisil)	\$\$\$\$\$\$\$
Tolnaftate (Tinactin)	\$\$ - \$\$\$
Zinc Undecylenate (Desenex)	\$\$\$ - \$\$\$\$

**Antipsoriatics**

Calcipotriene (Dovonex)	\$\$\$\$\$\$\$\$
Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)	\$\$\$
Methotrexate	\$\$\$\$
Selenium Sulfide (Selsun)	\$\$ - \$\$\$\$
Tazarotene (Tazorac, Avage)	\$\$\$\$\$\$\$\$

**Antiseborrheic Agents**

Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)	\$\$\$
Salicylic Acid/Sulfur	\$-\$\$\$\$
Selenium Sulfide (Selsun)	\$\$ - \$\$\$\$
Sulfacetamide Sodium (Sebizon)	\$\$\$\$\$\$\$\$

**Antiseptics & Germicides**

Benzalkonium Chloride (Zephiran)	\$\$ - \$\$\$\$
Chlorhexidine (Hibiclens, Bactoshield)	\$\$ - \$\$\$
Hexachlorophene (pHisoHex)	\$\$\$ - \$\$\$\$\$\$\$
Povidone-Iodine (Betadine)	\$ - \$\$\$\$\$

**Adapalene (Differin)**

Cream: 0.1%  
Gel, topical: 0.1%

**Benzoyl Peroxide**

Bar: 5%  
Cream, topical: 10%  
Gel, topical: 2.5%, 5%, 10%  
Liquid, topical: 5%, 10%  
Lotion: 10%  
Pads: 9%  
Wash, topical: 2.5%, 4%, 5%, 10%

**Benzoyl Peroxide/Clindamycin (BenzaClin)**

Gel, topical: Benzoyl Peroxide 5%/Clindamycin 1%

**Clindamycin (Cleocin, Cleocin T)**

Capsule: 75 mg, 150 mg, 300 mg  
Gel, topical: 1% [10 mg/g]  
Granules for oral solution: 75 mg/5 mL  
Injection: 150 mg/mL  
Lotion: 1% [10 mg/mL]  
Solution, topical: 1% [10 mg/mL]

**Erythromycin/Benzoyl Peroxide (Benzamycin)**

Gel, topical: Erythromycin 30 mg/Benzoyl Peroxide 50 mg per gram (with 16% alcohol)

**metroNIDAZOLE (Flagyl, Noritate, MetroGel)**

Capsule: 375 mg

Cream, topical: 0.75%, 1%

Gel, topical: 0.75% [7.5 mg/mL]

Gel, vaginal: 0.75%

Injection: 5 mg/mL

Powder for injection: 500 mg

Tablet: 250 mg, 500 mg

**Salicylic Acid/Sulfur**

Bar:

Cleanser

Cream

Gel

Lotion

Shampoo:

**Sulfacetamide Sodium (Sulamyd, Sebizon)**

Gel: 10%

Lotion: 10%

Ointment, ophthalmic: 10%

Solution, ophthalmic: 10%

**Sulfur/Resorcinol (Sulforcin, Rezamid)**

Lotion: Sulfur 5%/Resorcinol 2% [with up to 28% alcohol]

**Tazarotene (Tazorac, Avage)**

Cream, topical: 0.05%, 0.1%

Gel, topical: 0.05%, 0.1%

**Tretinoin Gel (Retin-A)**

Cream, topical: 0.025%, 0.05%, 0.1%

Gel, topical: 0.01%, 0.025%, 0.1%

Liquid, topical: 0.05%

**Benzocaine (Lanacaine, Cepacol, Oragel)**

Topical, for mucous membranes:

Gel: 6%, 20%

Liquid: 20%

Topical, dermatologic:

Cream, topical: 5%, 6%

Ointment: 5%

Spray: 5%, 20%

Mouth/Throat preparations:

Gel: 6.3%, 7.5%, 10%, 15%, 20%

Liquid: 5%, 6.3%, 10%, 20%

**Dibucaine (Nupercainal)**

Ointment, topical: 1%

**Ethyl Chloride**

Spray: 100 g, 105 mL, 120 mL, 270 mL

**Lidocaine (Lidoderm, Xylocaine)**

Injection: 0.4%, 1%, 2%, 4%, 10%

Gel, topical: 2%, 2.5%

Liquid, topical: 2.5%, 4%

Liquid, viscous: 2%

Ointment, topical: 2.5%, 5%

Patch: 5%

Solution, topical: 2%, 4%

**Lidocaine/Prilocaine (EMLA)**

Cream: Lidocaine 2.5%/Prilocaine 2.5%

**Pramoxine (Tronothane)**

Cream, topical: 1%

Gel, topical: 1%

Lotion: 1%

Ointment, topical: 1%

Spray: 1%

**Calamine/Zinc Oxide/Glycerin (Calamine Lotion)**

Lotion, topical: 120 mL, 240 mL, 480 mL

**Calamine/Pramoxine (Caladryl)**

Lotion, topical: 180 mL

**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

**Doxepin (SINEquan, Zonalon)**

Capsule: 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg  
Concentrate, oral: 10 mg/mL  
Cream: 5%

**Pramoxine/Zinc (Caladryl Clear)**

Lotion, topical: 1% pramoxine/0.1% zinc acetate

**Bacitracin (Baciguent)**

Injection: 50,000 units  
Ointment, ophthalmic: 500 units/g  
Ointment, topical: 500 units/g

**Bacitracin/Polymyxin B (Polysporin)**

Ointment, ophthalmic: Bacitracin 500 units/Polymyxin B 10,000 units/g  
Ointment, topical: Bacitracin 500 units/Polymyxin B 10,000 units/g  
Powder, topical: Bacitracin 500 units/Polymyxin B 10,000 units/g

**Ciclopirox (Loprox, Penlac)**

Shampoo: 1%  
Solution, Topical: 8%

**Clindamycin (Cleocin, Cleocin T)**

Capsule: 75 mg, 150 mg, 300 mg  
Gel, topical: 1% [10 mg/g]  
Granules for oral solution: 75 mg/5 mL  
Injection: 150 mg/mL  
Lotion: 1% [10 mg/mL]  
Solution, topical: 1% [10 mg/mL]

**Gentamicin (Garamycin)**

Cream, topical: 0.1%  
Infusion, premixed in D5W: 60 mg, 80 mg, 100 mg  
Infusion, premixed in NS: 40 mg, 60 mg, 80 mg, 90 mg, 100 mg, 120 mg  
Injection: 10 mg/mL, 40 mg/mL  
Injection, intrathecal (preservative free): 2 mg/mL  
Ointment, ophthalmic: 0.3% [3 mg/g]  
Ointment, topical: 0.1%  
Solution, ophthalmic: 0.3% [3 mg/mL]

**metroNIDAZOLE (Flagyl, Noritate, MetroGel)**

Capsule: 375 mg  
Cream, topical: 0.75%, 1%  
Gel, topical: 0.75% [7.5 mg/mL]  
Gel, vaginal: 0.75%  
Injection: 5 mg/mL  
Powder for injection: 500 mg  
Tablet: 250 mg, 500 mg

**Mupirocin (Bactroban)**

Cream, topical: 2%  
Ointment, intranasal: 2%  
Ointment, topical: 2%

**Neomycin/Polymyxin B/Bacitracin (Triple Antibiotic Ointment)**

Ointment, topical: Neomycin 3.5 mg/Polymyxin B 5000 units/Bacitracin 400 units

**Polymyxin B/Neomycin (Neosporin)**

Cream: Polymyxin B 10,000 units/Neomycin 3.5 mg

**Acyclovir (Zovirax)**

Capsule: 200 mg  
Cream: 0.5%  
Powder for injection: 500 mg, 1000 mg  
Ointment, topical 5% [50 mg/g]: 3 gm, 15 gm  
Suspension, oral: 200 mg/5 mL  
Tablet: 400 mg, 800 mg

**Calcium Undecylenate (Caldesene)**

Powder, topical: 10%

**Ciclopirox (Loprox, Penlac)**

Shampoo: 1%  
Solution, Topical: 8%

**Clotrimazole (Lotrimin, Mycelex, Gyne-Lotrimin, Fungoid)**

Cream, topical: 1%  
Cream, vaginal: 1%, 2%  
Lotion: 1%  
Solution, topical: 1%  
Suppository, vaginal: 100 mg, 200 mg  
Tablet, vaginal: 100 mg, 500 mg  
Troche: 10 mg

**Ketoconazole (Nizoral)**

Cream, topical: 2%  
Shampoo: 2%  
Tablet: 200 mg

**Miconazole (Monistat)**

Cream, topical: 2%  
Cream, vaginal: 2%  
Injection: 10 mg/mL  
Lotion: 2%  
Powder, topical: 2%  
Spray, topical: 2%  
Suppository, vaginal: 100 mg, 200 mg

**Nystatin (Mycostatin)**

Cream, topical: 100,000 units/g  
Ointment, topical: 100,000 units/g  
Powder for oral suspension: 50 million units, 1 billion units, 2 billion units, 5 billion units  
Powder, topical: 100,000 units/g  
Suspension, oral: 100,000 units/mL  
Tablet, oral: 500,000 units  
Troche: 200,000 units

**Terbinafine (Lamisil)**

Cream, topical: 1%  
Tablet: 250 mg

**Tolnaftate (Tinactin)**

Aerosol, topical, liquid: 1%  
Aerosol, topical, powder: 1%  
Cream, topical: 1%  
Powder, topical: 1%  
Solution, topical: 1%

**Zinc Undecylenate (Desenex)**

Cream, topical: 20%  
Foam, topical: 10% [with 35.2% alcohol]  
Ointment, topical: 30 gm  
Powder, topical: 19%

**Calcipotriene (Dovonex)**

Cream, topical: 0.005%  
Ointment, topical: 0.005%  
Solution, topical: 0.005%

**Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)**

Cream, topical: 2%  
Liquid, topical: 30%  
Shampoo: 1%, 2%, 2.5%, 5%  
Solution, topical: 120 mL, 480 mL

**Methotrexate**

Injection: 2.5 mg/mL, 25 mg/mL

Injection, preservative free: 25 mg/mL

Powder for injection: 20 mg, 25 mg, 50 mg, 100 mg, 250 mg, 1 g

Tablet: 2.5 mg

**Selenium Sulfide (Selsun)**

Shampoo: 1%, 2.5%

**Tazarotene (Tazorac, Avage)**

Cream, topical: 0.05%, 0.1%

Gel, topical: 0.05%, 0.1%

**Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)**

Cream, topical: 2%

Liquid, topical: 30%

Shampoo: 1%, 2%, 2.5%, 5%

Solution, topical: 120 mL, 480 mL

**Salicylic Acid/Sulfur**

Bar:

Cleanser

Cream

Gel

Lotion

Shampoo:

**Selenium Sulfide (Selsun)**

Shampoo: 1%, 2.5%

**Sulfacetamide Sodium (Sulamyd, Sebizon)**

Gel: 10%

Lotion: 10%

Ointment, ophthalmic: 10%

Solution, ophthalmic: 10%

**Benzalkonium Chloride (Zephiran)**

Concentrate, topical: 17%

Solution, topical, aqueous: 1:750

Spray, topical: 1:750

**Chlorhexidine (Peridex, Hibiclens, Bactoshield )**

Liquid, topical, with 4% isopropyl alcohol: 4%

Rinse, oral, with 12% alcohol: 0.12%

**Hexachlorophene (pHisoHex)**

Liquid, topical: 3%

**Povidone-Iodine (Betadine)**

Cleanser, topical: 60 mL, 240 mL

Ointment, topical: 10%

Solution, prep: 30 mL, 60 mL, 240 mL, 473 mL, 1000 mL, 4000 mL

Solution, topical: 10%

## MEMORANDUM

**To:** Executive Formulary Committee  
**From:** Catherine S. Hall, Pharm.D., BCPP  
**Through:** Ann L. Richards, Pharm.D., BCPP  
**Subject:** Class Review, Dermatologicals  
**Date:** July 12, 2013

**Recommendation:** Delete sulfur/resorcinol (Sulforcin, Rezamid), dibucaine (Nupercainal), calcium undecylenate (Caldesene), zinc undecylenate (Desenex), methotrexate, benzalkonium chloride (Zephiran)

**Remove Ciclopirox (Loprox, Penlac) from the Antibiotics section. It will continue to be listed in Antifungals.**

**Dermatologicals****Acne Agents**

Adapalene (Differin)	\$\$\$\$\$\$\$\$
Benzoyl Peroxide	\$ - \$\$
Benzoyl Peroxide/Clindamycin (BenzaClin)	\$\$\$\$\$\$\$\$
Clindamycin (Cleocin T)	\$\$\$ - \$\$\$\$\$\$
Erythromycin/Benzoyl Peroxide (Benzamycin)	\$\$\$\$\$\$\$\$
Metronidazole (Noritate, MetroGel)	\$\$\$\$\$\$\$\$
Salicylic Acid/Sulfur	\$-\$\$\$\$
Sulfacetamide Sodium (Sebizon)	\$\$\$\$\$\$\$\$
Sulfur/Resorcinol (Sulforcin, Rezamid)	\$\$\$\$
Tazarotene (Tazorac, Avage)	\$\$\$\$\$\$\$\$
Tretinoin Gel (Retin-A)	\$\$\$\$\$\$\$ - \$\$\$\$\$\$\$\$

**Anesthetics, Local**

Benzocaine (Lanacaine)	\$\$ - \$\$\$
Dibucaine (Nupercainal)	\$\$ - \$\$\$\$
Ethyl Chloride	\$\$\$\$\$\$\$
Lidocaine (Xylocaine)	\$\$ - \$\$\$\$\$\$
Lidocaine/Prilocaine (EMLA, Lidoderm)	\$\$\$ - \$\$\$\$
Pramoxine (Tronothane)	\$\$\$ - \$\$\$\$\$\$\$\$

**Anti-Histamine Agents**

Calamine/Zinc Oxide/Glycerin (Calamine Lotion)	\$
Calamine/Pramoxine (Caladryl)	\$\$\$
diphenhydrAMINE (Benadryl)	\$
Doxepin (Zonalon)	\$\$\$\$\$\$\$
Pramoxine/Zinc (Caladryl Clear)	\$\$

**Anti-Infectives**

**Antibiotics**

Bacitracin (Baciguent)	\$
Bacitracin/Polymyxin B (Polysporin)	\$\$\$ - \$\$\$\$
Ciclopirox (Loprox, Penlac)	\$\$\$\$-\$\$\$\$\$\$\$
Clindamycin (Cleocin T)	\$\$\$ - \$\$\$\$\$\$
Gentamicin (Garamycin)	\$\$\$
Metronidazole (Noritate, MetroGel)	\$\$\$\$\$\$\$
Mupirocin (Bactroban)	\$\$\$\$\$\$\$
Neomycin/Polymyxin B/Bacitracin (Triple Antibiotic Ointment)	\$
Polymyxin B/Neomycin (Neosporin)	\$\$ - \$\$\$\$\$\$\$\$

**Antiviral**

Acyclovir (Zovirax)	\$\$\$\$\$\$\$
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**Antifungals**

Calcium Undecylenate (Caldesene)	\$\$
Ciclopirox (Loprox)	\$\$\$\$-\$\$\$\$\$\$\$
Clotrimazole (Lotrimin, Fungoid)	\$\$\$\$\$
Ketoconazole (Nizoral)	\$\$\$\$\$ - \$\$\$\$\$\$
Miconazole (Monistat)	\$\$\$ - \$\$\$\$\$\$
Nystatin (Mycostatin)	\$\$ - \$\$\$\$\$\$
Terbinafine (Lamisil)	\$\$\$\$\$\$\$
Tolnaftate (Tinactin)	\$\$ - \$\$\$
Zinc Undecylenate (Desenex)	\$\$\$ - \$\$\$\$

### Antipsoriatics

Calcipotriene (Dovonex)	\$\$\$\$\$\$\$
Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)	\$\$\$
Methotrexate	\$\$\$\$
Selenium Sulfide (Selsun)	\$\$ - \$\$\$\$
Tazarotene (Tazorac, Avage)	\$\$\$\$\$\$\$

### Antiseborrheic Agents

Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)	\$\$\$
Salicylic Acid/Sulfur	\$-\$\$\$\$
Selenium Sulfide (Selsun)	\$\$ - \$\$\$\$
Sulfacetamide Sodium (Sebizon)	\$\$\$\$\$\$\$

### Antiseptics & Germicides

Benzalkonium Chloride (Zephiran)	\$\$ - \$\$\$\$
Chlorhexidine (Hibiclens, Bactoshield)	\$\$ - \$\$\$
Hexachlorophene (pHisoHex)	\$\$\$ - \$\$\$\$\$\$\$\$
Povidone-Iodine (Betadine)	\$ - \$\$\$\$\$

#### **Adapalene (Differin)**

Cream: 0.1%  
Gel, topical: 0.1%

#### **Benzoyl Peroxide**

Bar: 5%  
Cream, topical: 10%  
Gel, topical: 2.5%, 5%, 10%  
Liquid, topical: 5%, 10%  
Lotion: 10%  
Pads: 9%  
Wash, topical: 2.5%, 4%, 5%, 10%

#### **Benzoyl Peroxide/Clindamycin (BenzaClin)**

Gel, topical: Benzoyl Peroxide 5%/Clindamycin 1%

#### **Clindamycin (Cleocin, Cleocin T)**

Capsule: 75 mg, 150 mg, 300 mg  
Gel, topical: 1% [10 mg/g]  
Granules for oral solution: 75 mg/5 mL  
Injection: 150 mg/mL  
Lotion: 1% [10 mg/mL]  
Solution, topical: 1% [10 mg/mL]

**Erythromycin/Benzoyl Peroxide (Benzamycin)**

Gel, topical: Erythromycin 30 mg/Benzoyl Peroxide 50 mg per gram (with 16% alcohol)

**metronIDAZOLE (Flagyl, Noritate, MetroGel)**

Capsule: 375 mg

Cream, topical: 0.75%, 1%

Gel, topical: 0.75% [7.5 mg/mL]

Gel, vaginal: 0.75%

Injection: 5 mg/mL

Powder for injection: 500 mg

Tablet: 250 mg, 500 mg

**Salicyclic Acid/Sulfur**

Bar:

Cleanser

Cream

Gel

Lotion

Shampoo:

**Sulfacetamide Sodium (Sulamyd, Sebizon)**

Gel: 10%

Lotion: 10%

Ointment, ophthalmic: 10%

Solution, ophthalmic: 10%

**Sulfur/Resorcinol (Sulforcin, Rezamid)**

Lotion: Sulfur 5%/Resorcinol 2% [with up to 28% alcohol]

**Tazarotene (Tazorac, Avage)**

Cream, topical: 0.05%, 0.1%

Gel, topical: 0.05%, 0.1%

**Tretinoin Gel (Retin-A)**

Cream, topical: 0.025%, 0.05%, 0.1%

Gel, topical: 0.01%, 0.025%, 0.1%

Liquid, topical: 0.05%

**Benzocaine (Lanacaine, Cepacol, Oragel)**

Topical, for mucous membranes:

Gel: 6%, 20%

Liquid: 20%

Topical, dermatologic:

Cream, topical: 5%, 6%

Ointment: 5%

Spray: 5%, 20%

Mouth/Throat preparations:

Gel: 6.3%, 7.5%, 10%, 15%, 20%

Liquid: 5%, 6.3%, 10%, 20%

**Dibucaine (Nupercainal)**

Ointment, topical: 1%

**Ethyl Chloride**

Spray: 100 g, 105 mL, 120 mL, 270 mL

**Lidocaine (Lidoderm, Xylocaine)**

Injection: 0.4%, 1%, 2%, 4%, 10%

Gel, topical: 2%, 2.5%

Liquid, topical: 2.5%, 4%

Liquid, viscous: 2%

Ointment, topical: 2.5%, 5%

Patch: 5%

Solution, topical: 2%, 4%

**Lidocaine/Prilocaine (EMLA)**

Cream: Lidocaine 2.5%/Prilocaine 2.5%

**Pramoxine (Tronothane)**

Cream, topical: 1%

Gel, topical: 1%

Lotion: 1%

Ointment, topical: 1%

Spray: 1%

**Calamine/Zinc Oxide/Glycerin (Calamine Lotion)**

Lotion, topical: 120 mL, 240 mL, 480 mL

**Calamine/Pramoxine (Caladryl)**

Lotion, topical: 180 mL

**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

**Doxepin (SINEquan, Zonalon)**

Capsule: 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg  
Concentrate, oral: 10 mg/mL  
Cream: 5%

**Pramoxine/Zinc (Caladryl Clear)**

Lotion, topical: 1% pramoxine/0.1% zinc acetate

**Bacitracin (Baciguent)**

Injection: 50,000 units  
Ointment, ophthalmic: 500 units/g  
Ointment, topical: 500 units/g

**Bacitracin/Polymyxin B (Polysporin)**

Ointment, ophthalmic: Bacitracin 500 units/Polymyxin B 10,000 units/g  
Ointment, topical: Bacitracin 500 units/Polymyxin B 10,000 units/g  
Powder, topical: Bacitracin 500 units/Polymyxin B 10,000 units/g

**Ciclopirox (Loprox, Penlac)**

Shampoo: 1%  
Solution, Topical: 8%

**Clindamycin (Cleocin, Cleocin T)**

Capsule: 75 mg, 150 mg, 300 mg  
Gel, topical: 1% [10 mg/g]  
Granules for oral solution: 75 mg/5 mL  
Injection: 150 mg/mL  
Lotion: 1% [10 mg/mL]  
Solution, topical: 1% [10 mg/mL]

**Gentamicin (Garamycin)**

Cream, topical: 0.1%  
Infusion, premixed in D5W: 60 mg, 80 mg, 100 mg  
Infusion, premixed in NS: 40 mg, 60 mg, 80 mg, 90 mg, 100 mg, 120 mg  
Injection: 10 mg/mL, 40 mg/mL  
Injection, intrathecal (preservative free): 2 mg/mL  
Ointment, ophthalmic: 0.3% [3 mg/g]  
Ointment, topical: 0.1%  
Solution, ophthalmic: 0.3% [3 mg/mL]

**metronIDAZOLE (Flagyl, Noritate, MetroGel)**

Capsule: 375 mg  
Cream, topical: 0.75%, 1%  
Gel, topical: 0.75% [7.5 mg/mL]  
Gel, vaginal: 0.75%  
Injection: 5 mg/mL  
Powder for injection: 500 mg  
Tablet: 250 mg, 500 mg

**Mupirocin (Bactroban)**

Cream, topical: 2%  
Ointment, intranasal: 2%  
Ointment, topical: 2%

**Neomycin/Polymyxin B/Bacitracin (Triple Antibiotic Ointment)**

Ointment, topical: Neomycin 3.5 mg/Polymyxin B 5000 units/Bacitracin 400 units

**Polymyxin B/Neomycin (Neosporin)**

Cream: Polymyxin B 10,000 units/Neomycin 3.5 mg

**Acyclovir (Zovirax)**

Capsule: 200 mg  
Cream: 0.5%  
Powder for injection: 500 mg, 1000 mg  
Ointment, topical 5% [50 mg/g]: 3 gm, 15 gm  
Suspension, oral: 200 mg/5 mL  
Tablet: 400 mg, 800 mg

**Calcium Undecylenate (Caldesene)**

Powder, topical: 10%

**Ciclopirox (Loprox, Penlac)**

Shampoo: 1%  
Solution, Topical: 8%

**Clotrimazole (Lotrimin, Mycelex, Gyne-Lotrimin, Fungoid)**

Cream, topical: 1%  
Cream, vaginal: 1%, 2%  
Lotion: 1%  
Solution, topical: 1%  
Suppository, vaginal: 100 mg, 200 mg  
Tablet, vaginal: 100 mg, 500 mg  
Troche: 10 mg

**Ketoconazole (Nizoral)**

Cream, topical: 2%  
Shampoo: 2%  
Tablet: 200 mg

**Miconazole (Monistat)**

Cream, topical: 2%  
Cream, vaginal: 2%  
Injection: 10 mg/mL  
Lotion: 2%  
Powder, topical: 2%  
Spray, topical: 2%  
Suppository, vaginal: 100 mg, 200 mg

**Nystatin (Mycostatin)**

Cream, topical: 100,000 units/g  
Ointment, topical: 100,000 units/g  
Powder for oral suspension: 50 million units, 1 billion units, 2 billion units, 5 billion units  
Powder, topical: 100,000 units/g  
Suspension, oral: 100,000 units/mL  
Tablet, oral: 500,000 units  
Troche: 200,000 units

**Terbinafine (Lamisil)**

Cream, topical: 1%  
Tablet: 250 mg

**Tolnaftate (Tinactin)**

Aerosol, topical, liquid: 1%  
Aerosol, topical, powder: 1%  
Cream, topical: 1%  
Powder, topical: 1%  
Solution, topical: 1%

**Zinc Undecylenate (Desenex)**

Cream, topical: 20%  
Foam, topical: 10% [with 35.2% alcohol]  
Ointment, topical: 30 gm  
Powder, topical: 19%

**Calcipotriene (Dovonex)**

Cream, topical: 0.005%  
Ointment, topical: 0.005%  
Solution, topical: 0.005%

**Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)**

Cream, topical: 2%  
Liquid, topical: 30%  
Shampoo: 1%, 2%, 2.5%, 5%  
Solution, topical: 120 mL, 480 mL

**Methotrexate**

Injection: 2.5 mg/mL, 25 mg/mL  
Injection, preservative free: 25 mg/mL  
Powder for injection: 20 mg, 25 mg, 50 mg, 100 mg, 250 mg, 1 g  
Tablet: 2.5 mg

**Selenium Sulfide (Selsun)**

Shampoo: 1%, 2.5%

**Tazarotene (Tazorac, Avage)**

Cream, topical: 0.05%, 0.1%  
Gel, topical: 0.05%, 0.1%

**Coal Tar (Ionil-T, Tegrin, Pentrax, Polytar)**

Cream, topical: 2%  
Liquid, topical: 30%  
Shampoo: 1%, 2%, 2.5%, 5%  
Solution, topical: 120 mL, 480 mL

**Salicyclic Acid/Sulfur**

Bar:  
Cleanser  
Cream  
Gel  
Lotion  
Shampoo:

**Selenium Sulfide (Selsun)**

Shampoo: 1%, 2.5%

**Sulfacetamide Sodium (Sulamyd, Sebizon)**

Gel: 10%  
Lotion: 10%  
Ointment, ophthalmic: 10%  
Solution, ophthalmic: 10%

**Benzalkonium Chloride (Zephiran)**

Concentrate, topical: 17%  
Solution, topical, aqueous: 1:750  
Spray, topical: 1:750

**Chlorhexidine (Peridex, Hibiclens, Bactoshield )**

Liquid, topical, with 4% isopropyl alcohol: 4%  
Rinse, oral, with 12% alcohol: 0.12%

**Hexachlorophene (pHisoHex)**

Liquid, topical: 3%

**Povidone-Iodine (Betadine)**

Cleanser, topical: 60 mL, 240 mL  
Ointment, topical: 10%  
Solution, prep: 30 mL, 60 mL, 240 mL, 473 mL, 1000 mL, 4000 mL  
Solution, topical: 10%

**APPENDIX 1: NEW DRUG APPLICATION FORM**

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: 6/26/13

Name of practitioner submitting the application: QUYNH NGUYEN, MD

Name of entity with which the practitioner is associated by employment or contract (i.e., state hospital, state school, state center, or local authority (state-operated community services (SOCS) or community MHMR center)):

Information regarding new drug:

Therapeutic Classification	Antipsychotic (Atypical)
Generic Name	Aripiprazole
Trade Name(s)	Abilify Maintena
Manufacturer(s)	Otsuka
Dosage Form(s)	300mg + 400mg vial of lyophilized powder for reconstitution

Explain the pharmacological action or use of this drug: Schizophrenia treatment.

Explain the advantages of this drug over those listed in the formulary: improving pt ~~comp~~ adherence. once a month injection, slow release medication.

State which drugs this new drug would replace or supplement: Supplement oral Atypical Antipsychotic treatment

\*\*\*\*\*

application is approved

\_\_\_\_\_  
signature of chairman of facility pharmacy and therapeutics committee

OR

application is appropriate and complete

Quynh Nguyen  
signature of clinical/medical director or designee