

**DADS/DSHS EXECUTIVE FORMULARY COMMITTEE MINUTES  
December 5, 2008**

The Executive Formulary Committee convened on Friday, December 5, 2008 in Conference Room 295 - CO Building 2. The meeting was called to order by Dr. Matthews, Chair at 9:35 a.m.

Janet Adams, MSN, RN, CNS	Absent	Kenny Dudley (non-voting)	Absent
Emilie A. Becker, M.D.	√	Denice Geredine (non-voting)	Absent
Rosha Chadwick, R.Ph.	Absent	Mike Maples (non-voting)	Absent
Jeanna Heidel, Pharm.D.	√	Bob Burnett (non-voting)	Absent
J. Brett Hood, M.D.	√	Jay Norwood, MSN, RN (non-voting)	Absent
Jeff Matthews, M.D.	√	Julie McRae, MS, RN, CDDN (non-voting)	Absent
Lisa Mican, Pharm.D.	√	Vacant Medical Director	
Connie Millhollon, RN,	√	Vacant Center Position	
Ann L. Richards, Pharm.D.	√	Vacant Center Position	
Bill Race, M.D.	Absent	Vacant Center Position	
Lilani Muthali, M.D. (non-voting)	Absent	Vacant Center Position	
Nina Muse, M.D. (non-voting)	* √	Vacant State School Position	

\* Present for the discussion of court compelled medications

**Guest Present: Catherine Hall, Pharm.D, Clinical Pharmacologist, San Antonio State Hospital; Melissa Lewis, Pharm.D., Psychiatric Pharmacy Resident, Austin State Hospital**

**Introductions**

Dr. Catherine Hall, Clinical Pharmacologist, San Antonio State Hospital was introduced as a new member of the Committee effective at the next meeting. Dr. Lisa Mican's term is expiring after today's meeting and she will be stepping down.

**Approval of Minutes of August 22, 2008**

On a motion of Dr. Becker, seconded by Dr. Hood, the minutes of the August 22<sup>nd</sup> meeting were approved as previously distributed.

## Adverse Drug Reaction Reports

The Executive Formulary Committee received two adverse drug reaction reports. In the first case, a 25 year-old African American male was admitted to a State Hospital and was initiated on divalproex (Depakote®) ER 1,500 mg at bedtime on May 16<sup>th</sup>. On May 22<sup>nd</sup>, the dose was increased to 1,750 mg at bedtime followed by an increase to 2,000 mg at bedtime on May 29<sup>th</sup>, then increased to 2,250 mg on June 9<sup>th</sup> and then to 2,500 mg on June 17<sup>th</sup>. Olanzapine (Zyprexa®) was initiated at 10 mg three times a day on May 16<sup>th</sup>, and then increased to 35 mg/day (10 mg morning, 25 mg bedtime) May 27<sup>th</sup>, followed by an increase to 40 mg/day (10 mg morning, 30 mg bedtime) on June 3<sup>rd</sup>. The only other concomitant medication administered during this time was hydrocodone/acetaminophen (Vicodin®) 5 mg/500 mg as needed for pain and olanzapine 10 mg twice a day as needed for psychotic agitation. On admission, a CBC was not obtained. A CBC obtained on June 16<sup>th</sup> showed a WBC of 4.4 K/mm<sup>3</sup> and ANC 1.4 K/mm<sup>3</sup> and a valproic acid of 99.8 mcg/ml. On June 23<sup>rd</sup>, the CBC was 4.2 K/mm<sup>3</sup> and an ANC of 1.4 K/mm<sup>3</sup> with a valproic acid of 87.6 mcg/ml. On July 1<sup>st</sup> the patient reached his nadir for the ANC with a level of 0.8 K/mm<sup>3</sup> and a WBC of 3.9 K/mm<sup>3</sup>. The divalproex was discontinued on July 1<sup>st</sup>, lithium was initiated and the ANC rebounded with a level of 1.7 K/mm<sup>3</sup> and a WBC of 4.4 K/mm<sup>3</sup> on July 3<sup>rd</sup>. On July 7<sup>th</sup>, the CBC was 5.2 K/mm<sup>3</sup> and an ANC of 2.3 K/mm<sup>3</sup>. The patient's ANC remained above 2 during the remainder of his hospitalization.

In the second case, a 44 year-old African American female was admitted to the hospital on July 8<sup>th</sup> with a positive pregnancy test. The patient had previously been at the State Hospital from February 27<sup>th</sup> through May 2<sup>nd</sup> with a negative pregnancy test. The patient was also incarcerated in jail from June 11<sup>th</sup> to July 8<sup>th</sup>. The probable conception date ranged between May 2<sup>nd</sup> and June 10<sup>th</sup>. The patient could not recall her last menstrual period. Records from jail indicate that a sonogram was attempted at a local medical hospital but it was too early to determine an approximate gestational age. At the time of admission, the patient was prescribed prenatal vitamins and docusate calcium 240 mg twice a day. Folic acid 1 mg three times daily was initiated due to patient reporting possible first trimester exposure to divalproex (Depakote®) while an outpatient. Other outpatient medications that the patient may have been on early in her pregnancy include lithium, loxapine (Loxitane®), divalproex (Depakote®), olanzapine (Zyprexa®), clonazepam (Klonopin®), trazodone (Desyrel®) and metformin (Glucophage®). Risperidone (Risperdal®) 2 mg was prescribed on July 10<sup>th</sup> for mania with psychotic features. The dose of risperidone was subsequently increased to 3 mg at bedtime on July 21<sup>st</sup>. The patient had a high risk OB appointment on July 31<sup>st</sup> and an ultrasound dated the fetus at 7 weeks but the fetus had no active heart beat. The patient experienced a spontaneous abortion on August 5<sup>th</sup>. The patient's notable history includes two live births (2 year old and 19 year old) and four elective abortions. The patient reports receiving treatment with risperidone during her last successful pregnancy with no complications noted and requested this medication during this admission.

## New Drug Applications

**(Please refer to Attachment A for the monographs and applications that were considered when determining action by the committee.)**

### **Hepatitis A inactivated & Hepatitis B (Recombinant) Vaccine (Twinrix®) - discussed by Dr. Lewis**

Twinrix® is indicated for active immunization of persons 18 years of age or older against disease caused by hepatitis A virus and infections by all known subtypes of hepatitis B virus. Twinrix Junior® is a pediatric formulation that is available. Hepatitis viruses cause a systemic infection resulting in liver damage. Twinrix® confers immunity against both hepatitis A virus (HAV) and hepatitis B virus (HBV) by inducing specific anti-HAV antibodies and anti-HB surface antigens (HBsAg). Hepatitis A virus is predominantly transmitted person-to-person via the fecal-oral route. The incubation period for HAV averages 28 days and presentation may vary from asymptomatic to icteric hepatitis and death. Specific antibody concentrations for seroprotection are unknown. Hepatitis B virus is predominantly transmitted via sexual contact, percutaneous or mucosal exposure to infectious blood, and perinatal exposure to an infected mother. The incubation period for HBV is 30 – 180 days and may present asymptotically or symptomatically and manifestations may range from jaundice to massive hepatic necrosis and cirrhosis of the liver. Antibody concentrations  $\geq 10$  mIU/ml against HBsAg are recognized as conferring protection against HBV. Primary immunization for adults consists of 3 doses, given at 0-, 1-, and 6-month schedule. Each 1 ml dose contains 720 EIU of inactivated hepatitis A virus and 20 mcg of hepatitis B surface antigen. Alternate dosing consists of 4 doses, given at 0-, 7- and 21 to 30- days followed by a booster dose at month 12. Twinrix® should be administered by intramuscular injection.

**Following discussion, on motion of Dr. Hood, seconded by Dr. Heidel, the request to add hepatitis A inactivated and hepatitis B (recombinant) vaccine (Twinrix®) to the formulary was approved.**

### **Possible TAC Change**

At the previous meeting, a comparison between the TAC requirement for movement disorders and TIMA recommendations was completed. The TAC required evaluation every three months and TIMA followed the Mt. Sinai Conference Guidelines which required patients on second generation antipsychotics to have an evaluation completed every year, except for high risk patients where the evaluation is completed every six months. For first generation antipsychotics, it is recommended that the tardive dyskinesia evaluation be completed every six months, except for high risk patients where it is recommended that the evaluation be completed every three months. In order to change a TAC, a work group is formed to review it. This work group will address all areas of the TAC and not just the issue in question. The TAC is then distributed to the stakeholders for feedback. The entire process takes anywhere between 9 to 12 months on average. The Committee recommended pursuing this option with members of this Committee being recommended to serve on the work group. Dr. Richards will work with Ms. Perry on this project.

### **FDA Alerts**

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

The FDA notified healthcare professionals that the Agency is investigating a report from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) trial of a possible association between the use of ezetimibe/simvastatin (Vytorin®) and a potentially increased incidence of cancer. Recently, the FDA obtained preliminary results from the SEAS trial. The clinical trial tested whether lowering LDL-cholesterol with Vytorin® would reduce the risk of cardiovascular events in individuals with aortic stenosis. A lower overall cardiovascular risk was not found with Vytorin®. However, there was an additional observation that a larger percentage of subjects treated with Vytorin® were diagnosed with and died from all types of cancer combined when compared to placebo during the 5-year study. The FDA anticipates receiving a final SEAS study report in about 3 months (November/December 2008) and the Agency's review and evaluation of the clinical trial data and other relevant information should take approximately 6 months (May/June 2009).

On June 13, the FDA approved safety labeling revisions for duloxetine (Cymbalta®) to provide updated information regarding the risk of hepatotoxicity. The warning was based on sometimes fatal reports of hepatic failure that have presented as hepatitis with abdominal pain, hepatomegaly, and elevation of transaminase levels to more than 20 times the upper limit of normal with or without jaundice, reflecting a mixed or hepatocellular pattern of liver injury. Duloxetine should be discontinued in patients in whom jaundice or other evidence of clinically significant liver dysfunction develops. Treatment should not be reinstated unless another cause can be established for these symptoms. According to the FDA, cases of cholestatic jaundice with minimal elevation of transaminase levels have also been reported, and patients with chronic liver disease or cirrhosis have experienced elevated transaminases, bilirubin, and alkaline phosphatase levels. Because an interaction with alcohol may cause liver injury or aggravate preexisting disease, duloxetine is not recommended in patients with substantial alcohol use or evidence of chronic liver disease.

The December 2<sup>nd</sup> issue of Neurology reported new preliminary results that suggest that women who take valproate while pregnant increase their child's risk of developing autism spectrum disorder (ASD). The study involves 632 children – nearly half of whom were exposed to antiepileptics during gestation. Of those whose mothers took medication while pregnant, 64 were exposed to valproate, 44 to lamotrigine, 76 to carbamazepine, and 65 to other antiepileptics. The children were tested at 1, 3, and 6 years old. Two-thirds were 6 years by the end of the study. A total of 9 children have been diagnosed with ASD, and 1 has shown symptoms. The incidence of ASD was 1.6% in the total cohort. The researchers found that children whose mother were taking valproate during pregnancy were 7 times more likely to develop ASD than children whose mothers had epilepsy but did not take an epilepsy drug. The risk was not seen with other antiepileptics. None of the children

in the study had any known family history of autism.

In discussing these alerts, the question arose about the dissemination of this information to the field. It was noted that clinicians receive the “Dear Healthcare Professional” letters, that the minutes of this meeting are distributed to clinical/medical directors and if need be, a separate memo regarding the alert is distributed to the clinical/medical directors. Dr. Becker raised concern about distributing the information to the outpatient sector. She volunteered to share important information distributed via email with the Consortium of Medical Directors.

**Allele Issues with phenytoin (Dilantin®)/fosphenytoin (Cerebyx®)**

The FDA is investigating the new preliminary data regarding a potential increased risk of serious skin reactions including Stevens Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) from phenytoin therapy in Asian patients positive for human leukocyte antigen (HLA) allele, HLA-B\*1502. This allele occurs almost exclusively in patients with ancestry across broad areas of Asia, including Han Chinese, Filipinos, Malaysians, South Asian Indians, and Thais. Until the FDA evaluation is completed, healthcare providers who are considering the use of phenytoin or fosphenytoin should be aware of the risks and benefits described in the current prescribing information for this drug. Healthcare providers should consider avoiding phenytoin and fosphenytoin as alternatives for carbamazepine in patients who test positive for HLA-B\*1502.

**Survey of Child/Adolescent Dosing for Behavior Emergencies**

Previously, the “Treatment of Behavioral Emergencies Intramuscular Short-Acting Agents” for adults was approved. The Committee noted the lack of literature to support the identification of dosing of these medications for children and adolescents for behavior emergencies. As a result, a survey of the facilities regarding their dosing was completed. Dr. Richards compiled the results. The Committee reviewed the information and recommended that the following doses for children and adolescents be used as a recommendation for the treatment of behavioral emergencies with intramuscular short-acting agents in this population:

**Children (< 12 y/o)**

Drug	Maximum Single dose (mg)	Minimum Interval (hrs)	Maximum Total Dose per day (mg)
Aripiprazole	4.875 - 9.75 (older)	4 to 8	19.5
Chlorpromazine	25 – 50	6 to 8	150
Diphenhydramine	25 – 50	4 to 6	50-150
Haloperidol	2.5 – 5	4 to 6	10
Hydroxyzine	25 – 50	4 to 6	150
Lorazepam	1 – 2	4 to 8	4 -6
Olanzapine	5 – 10	4 to 6	15
Ziprasidone	10	4 to 6	20

**Children (12 y/o to < 18 y/o)**

Drug	Maximum Single dose (mg)	Minimum Interval (hrs)	Maximum Total Dose per day (mg)
Aripiprazole	9.75	4 to 8	19.5
Chlorpromazine	25 – 50	4 to 6	150
Diphenhydramine	50 – 100	4 to 6	200
Fluphenazine	2	6 to 8	10

Haloperidol	5	4 to 6	20
Hydroxyzine	50 – 100	4 to 6	200
Lorazepam	2	4 to 8	8
Olanzapine	10	4 to 6	20
Ziprasidone	10 – 20	4 to 6	40

The Committee recommended that when this information is published that it is noted that these doses were obtained from a survey of use and not from the literature.

### **MicroMedex™ vs. Lexi-Comp™**

Dr. Richards reported that the current contract for MicroMedex™ was expiring. The renewal price was significantly higher than the previous contract. Lexi-Comp™ submitted information regarding their product. Each facility was contacted regarding both products and was asked to use a free trial of Lexi-Comp™ for comparison to MicroMedex™. After the trial each facility was asked to vote on their preference. Not all facilities voted but those that did selected MicroMedex™. Central Office is currently working with MicroMedex™ for better pricing.

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

In reviewing the first quarter's non-formulary drug purchases, it was noted that guanfacine (Tenex®), cetirizine (Zyrtec®) and levalbuterol (Xopenex®) are being used frequently and it was recommended that these agents be reviewed for possible addition to the formulary. At the August meeting it was recommended that carvedilol (Coreg®) be considered for addition to the Formulary.

### **Non-Formulary Dosage Strength Additions**

In reviewing a listing of non-formulary drugs in WORx™, Dr. Richards recommended that the following dosage strengths be added to the Formulary. For these items, other dosage strengths of the drug are currently on Formulary.

- Dextromethorphan
  - Capsule: 15 mg
- Oxycodone
  - Tablet: 15 mg, 30 mg
- PrednisoLONE
  - Solution: 5 mg/5 ml
- Vitamin D
  - Capsule: 10,000 units
  - Tablet: 1,000 units

On a motion of Dr. Heidel, seconded by Dr. Becker, it was recommended that these dosage strengths be added to the Drug Formulary.

## Typical Antipsychotic Sectional Review

Dr. Mican presented the review of Typical Antipsychotics. Dr. Mican noted that the following items are no longer available:

- Chlorpromazine - Concentrate and Syrup
- Loxapine - Concentrate
- Mesoridazine – Injection, Liquid and Tablet
- Molindone – Concentrate
- Thioridazine - Concentrate

The recent TIMA Manual has different maximum doses than the Drug Formulary Book for the following medications:

- Chlorpromazine – 1,000 mg for TIMA and 2,000 mg for Drug Formulary
- Fluphenazine (oral) – 20 mg for TIMA and 60 mg for Drug Formulary
- Fluphenazine decanoate – 100 mg per 4 weeks for TIMA and 100 mg (q 1 – 4 weeks) for Drug Formulary
- Haloperidol (oral) – 20 mg for TIMA and 40 mg for Drug Formulary
- Loxapine – 150 mg for TIMA and 250 mg for Drug Formulary
- Mesoridazine – Not Listed for TIMA and 500 mg for Drug Formulary
- Thioridazine – Not Listed for TIMA and 800 mg (Absolute) for Drug Formulary
- Thiothixene – 50 mg for TIMA and 60 mg for Drug Formulary
- Trifluoperazine – 40 mg for TIMA and 80 mg for Drug Formulary

The Committee discussed the source of the dosing recommendations for TIMA. The Committee will follow up with the individuals that were involved in the development of the recent manual.

Dr. Mican made the following recommendations to the Committee:

1. Consider adjusting antipsychotic maximum dosing to be more in line with current maximum doses and TIMA maximum doses, particularly with regard to chlorpromazine, fluphenazine oral and decanoate, and trifluoperazine
2. Remove chlorpromazine concentrate and syrup; the concentrate is not available and the syrup is not available through McKesson
3. Remove loxapine concentrate as it is not available
4. Remove mesoridazine from the formulary, reserve drug list, and maximum dosing table as all formulations of mesoridazine are no longer available through McKesson
5. Remove molindone concentrate and molindone 100 mg tablets as these products are no longer available through McKesson
6. Remove thioridazine concentrate and thioridazine 15 mg, 150 mg, and 200 mg tablets as these products are no longer available through McKesson

The Committee was concerned about changing the recommended maximum daily dosing without further information as to the source of TIMA's recommendation. The Committee will investigate this issue.

Dr. Mican reviewed the audit criteria and made the following recommendations:

- Antipsychotics (chlorpromazine, fluphenazine, haloperidol, loxapine, molindone, perphenazine, thiothixene, trifluoperazine)
  - Under Precautions to Consider (Relative Contraindication) - Add: Tardive Dyskinesia
  - Under Precautions – Delete: hepatic function impairment, breast cancer, history of neuroleptic malignant syndrome, Parkinson's disease
  - Under Precautions – Add: myasthenia gravis (chlorpromazine), dementia-related psychosis
  - Under Pregnancy and Breast-Feeding – Change: “Most antipsychotics are FDA Pregnancy Category C” to “FDA Pregnancy Category C”
  - Under Drug Interactions of Major Significance – Add the following under See Table A: “Chlorpromazine

- (major substrate 2D6, major inhibitor 2D6), Fluphenazine (major substrate 2D6), Haloperidol (major substrate 2D6 and 3A4, moderate inhibitor 2D6 and 3A4), Loxapine (unknown), Molindone (unknown), Perphenazine (major substrate 2D6), Thiothixene (major substrate 1A2), Trifluoperazine (major substrate 1A2)”
- Under Side Effects Which Require Medical Attention – Move “Akathisia” under item #2 and delete “or other late-onset EPS” from the Tardive Dyskinesia listing
  - Under Patient Monitoring Parameter – Add “within 30 days of initiation if none in last 2 years”
- Antipsychotics (thioridazine, mesoridazine)
    - Delete mesoridazine (Serentil®) from list as it is no longer available
    - Under Precautions to Consider (Absolute Contraindication) – Add: Drugs that significantly inhibit thioridazine metabolism or clearance (fluvoxamine, propranolol, pindolol, fluoxetine, paroxetine, or any drug known to significantly inhibit 2D6); History of cardiac arrhythmias or QTc interval prolongation; Patients with reduced CYP2D6 enzyme activity
    - Under Precautions to Consider (Relative Contraindication) - Add: Tardive Dyskinesia
    - Under Precautions – Delete: hepatic function impairment, arrhythmias, breast cancer, glaucoma, history of neuroleptic malignant syndrome, prostatic hypertrophy, Parkinson’s disease
    - Under Precautions – Add: myasthenia gravis, dementia-related psychosis
    - Under Pregnancy and Breast-Feeding – Change: “Most antipsychotics are FDA Pregnancy Category C” to “FDA Pregnancy Category C”
    - Under Drug Interactions of Major Significance – Add: Specifically contraindicated with fluvoxamine, propranolol, pindolol, fluoxetine, paroxetine, or any drug known to significantly inhibit 2D6 or prolong the QTc interval
    - Under Drug Interactions of Major Significance – Add the following under See Table A: “Thioridazine (major substrate 2D6, moderate inhibitor 2D6)
    - Under Side Effects Which Require Medical Attention – Delete “or other late-onset EPS” from the Tardive Dyskinesia listing
    - Under Patient Monitoring Parameter – Add “within 30 days of initiation if none in last 2 years” and “EKG at baseline, 7-14 days after dose increase or medication change impairing the metabolism of thioridazine and every 6 months thereafter”
  - Decanoates (fluphenazine decanoate, haloperidol decanoate)
    - Under Precautions to Consider (Relative Contraindication) - Add: Tardive Dyskinesia
    - Under Precautions – Delete: hepatic function impairment, breast cancer, history of neuroleptic malignant syndrome, Parkinson’s disease
    - Under Precautions – Add: dementia-related psychosis
    - Under Drug Interactions of Major Significance – Add the following under See Table A: “Fluphenazine (major substrate 2D6), Haloperidol (major substrate 2D6 and 3A4, moderate inhibitor 2D6 and 3A4)”
    - Under Side Effects Which Require Medical Attention – Move “Akathisia” to item #1 and add dystonia, pseudo-Parkinsonism to item #1 and delete “or other late-onset EPS” from the Tardive Dyskinesia listing
    - Under Patient Monitoring Parameter – Add “within 30 days of initiation if none in last 2 years”

Following discussion, on motion of Dr. Heidel, seconded by Dr. Becker, all the recommendations made were approved with the exception of the changes in the maximum doses. The Committee will follow up on this issue.

#### **Drug Formulary Sectional Review-**

#### **Cardiovascular Agents**

Dr. Tramonte was not available to provide the Cardiovascular Agent Review.

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

The cardiovascular agents will be reviewed at the next meeting.

## **DSHS/DADS Drug Formulary 2009**

The 2009 version of the drug formulary was presented for approval. The book includes changes that have been made this calendar year. Prior to publishing the book, the changes that were made as the result of today's meeting will be included. The Committee made recommendations for changes to the Drug Formulary. On a motion of Dr. Becker, seconded by Ms. Millhollon the 2009 Drug Formulary was approved as modified.

### **Court Compelled Medications**

Dr. Becker raised an issue that had been brought to her attention. In one area, a judge has raised an issue with using medication for an indication that is outside their classification system for consent. For example, atypical antipsychotics are listed under the antipsychotic category for consenting purposes. However, many atypical antipsychotics have an indication in bipolar disorder so it could be used as a mood stabilizer as well. The judge raises concern about having a patient court compelled for an antipsychotic that is being used as a mood stabilizer as the antipsychotic is not listed in the mood stabilizer group. The Committee discussed that many of the psychiatric agents can be used for different indications and without the clinical expertise, it would be difficult to know how to apply this information to the specific clinical case. The Committee recommended that the Consent List contain a statement that indicates that the classification of psychotropic medication is fairly standard but medications can be used for treatment of illnesses in other classes.

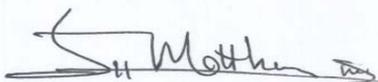
### **Next Meeting Date**

The next meeting was scheduled for March 27, 2009.

### **Adjourn**

There being no further business, the meeting was adjourned at 1:00 p.m.

Approved:



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Jeffery Matthews, M.D., Chair  
Executive Formulary Committee

### **Attachments**

- Attachment A – New Drug Application
- Attachment B – Typical (First Generation) Antipsychotic Sectional Review

Minutes Prepared by:

Ann L. Richards, Pharm.D., BCPP

TEXAS DEPARTMENT OF STATE HEALTH SERVICES AND THE  
DEPARTMENT OF AGING AND DISABILITIES SERVICES

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: December 5, 2008

Name of practitioner submitting the application: Ann Richards, Pharm.D.

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)): San Antonio State Hospital

Information regarding new drug:

<b>Therapeutic Classification</b>	Vaccine
<b>Generic Name</b>	Hepatitis A Inactivated & Hepatitis B (Recombinant) Vaccine
<b>Trade Name(s)</b>	Twinrix®
<b>Manufacturer(s)</b>	GlaxoSmithKline
<b>Dosage Form(s)</b>	1 ml & 20 mcg

Explain the pharmacological action or use of this drug:

**Active immunization for Hepatitis A virus (HAV) & Hepatitis B virus (HBV)**

Explain the advantages of this drug over those listed in the formulary:

**Combination project for ease of administration**

State which drugs this new drug would replace or supplement:

None

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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

### Typical (First Generation) Antipsychotic Sectional Review

Medication	Formulation	Adult Max Dose/Day*	Max Cost/Day	Formulary Status
chlorproMAZINE (Thorazine)	Concentrate	2,000	Not Avail	F
	Injection	400	\$27.28	
	Syrup	2,000	Not Avail	
	Tablet	2,000	\$3.60	
Fluphenazine (Prolixin)	Concentrate	60	\$5.70	F
	Elixir	60	\$21.60	
	Injection (Hcl)	20	\$44.78	
	Tablet	60	\$1.14	
Fluphenazine Decanoate (Prolixin)	Injection (decanoate)	100 (q 1 - 4 weeks)	\$0.41	F
Haloperidol (Haldol)	Concentrate	40	\$17.45	F
	Injection (lactate)	40	\$9.11	
	Tablet	40	\$3.66	
Haloperidol Decanoate (Haldol)	Injection (decanoate)	450 mg per month	\$0.78	F
Loxapine (Loxitane)	Capsule	250	\$5.00	F
	Concentrate	250	Not Avail	
Mesoridazine (Serentil)	Injection	N/A	None Avail	F
	Liquid	500		
	Tablet	500		
Molindone (Moban)	Concentrate	225	Not Avail	F
	Tablet	225	\$15.45	
Perphenazine (Trilafon)	Tablet	64	\$1.28	F
Thioridazine (Mellaril)	Concentrate	800	Not Avail	F
	Tablet	800	\$2.21	
Thiothixene (Navane)	Capsule	60	\$6.79	F
Trifluoperazine (Stelazine)	Tablet	80	\$2.83	F

F= Formulary, NF= Non-Formulary, \*= Maximum from DSHS EFC Max Dose/Day

## Antipsychotics

Differences between TIMA maximum doses and EFC maximum doses noted in **BOLD** type

Drug	Suggested Maximum Dose (mg/day)*			
	TIMA	Adult	Child (< 12 y/o)	Adolescent (12 y/o to < 18 y/o)
chlorproMAZINE (Thorazine)	<b>1,000</b>	2,000		
Fluphenazine <sup>1</sup> (oral) (Prolixin)	<b>20</b>	60		
Fluphenazine Decanoate <sup>1</sup> (Prolixin)	<b>100 per 4 weeks</b>	100 (q 1 - 4 weeks)		
Haloperidol <sup>2</sup> (oral) (Haldol)	<b>20</b>	40	5	10
Haloperidol Decanoate <sup>2</sup> (Haldol)	450 per 4 weeks	450 mg per month		
Loxapine (Loxitane)	<b>150</b>	250		
Mesoridazine (Serentil) <sup>3</sup> - RESERVE USE	<b>NOT LISTED</b>	500		
Molindone (Moban)	225	225		
Perphenazine (Trilafon)	64	64		32
Thioridazine (Mellaril) <sup>3</sup> - RESERVE USE	<b>NOT LISTED</b>	(ABSOLUTE ) 800		
Thiothixene (Navane)	<b>50</b>	60		
Trifluoperazine (Stelazine)	<b>40</b>	80		

\*except where noted

<sup>1</sup> Fluphenazine Therapeutic Concentration = 1 - 3 ng/mL

<sup>2</sup> Haloperidol Therapeutic Concentration = 3 - 15 ng/mL

<sup>3</sup> A boxed warning has been added to advise clinicians of prolongation of the QTc interval

## Treatment of Behavioral Emergencies Intramuscular Short-Acting Agents

MEDICATION	MAX SINGLE DOSE (MG)	MINIMUM INTERVAL (HRS)	MAX TOTAL DOSE PER DAY (MG)
IM Chlorpromazine <sup>2</sup>	100*	2	400
IM Fluphenazine <sup>4-5</sup>	10	1	20
IM Haloperidol <sup>2</sup>	10	1	40

\*Initial dose is not recommended to be greater than 50mg if tolerability is unknown

## Current DSHS Typical (First Generation) Antipsychotic Formulary List

### **chlorproMAZINE (Thorazine)**

Concentrate, oral: 30 mg/mL, 100 mg/mL

Injection: 25 mg/mL

Syrup: 10 mg/5 mL

Tablet: 10 mg, 25 mg, 50 mg, 100 mg, 200 mg

### **Fluphenazine (Prolixin)**

Concentrate: 5 mg/mL with 14% alcohol

Elixir: 2.5 mg/5 mL with 14% alcohol

Injection, as decanoate: 25 mg/mL

Injection, as hydrochloride: 2.5 mg/mL

Tablet: 1 mg, 2.5 mg, 5 mg, 10 mg

### **Haloperidol (Haldol)**

Concentrate, oral: 2 mg/mL

Injection, as decanoate: 50 mg/mL, 100 mg/mL

Injection, as lactate: 5 mg/mL

Tablet: 0.5 mg, 1 mg, 2 mg, 5 mg, 10 mg, 20 mg

### **Loxapine (Loxitane)**

Capsule: 5 mg, 10 mg, 25 mg, 50 mg

Concentrate, oral: 25 mg/mL

### **Mesoridazine (Serentil) - RESERVE USE**

Injection: 25 mg/mL

Liquid, oral: 25 mg/mL

Tablet: 10 mg, 25 mg, 50 mg, 100 mg

### **Molindone (Moban)**

Concentrate, oral: 20 mg/mL

Tablet: 5 mg, 10 mg, 25 mg, 50 mg, 100 mg

### **Perphenazine (Trilafon)**

Tablet: 2 mg, 4 mg, 8 mg, 16 mg

### **Thioridazine (Mellaril) - RESERVE USE**

Concentrate, oral: 30 mg/mL, 100 mg/mL

Tablet: 10 mg, 15 mg, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg

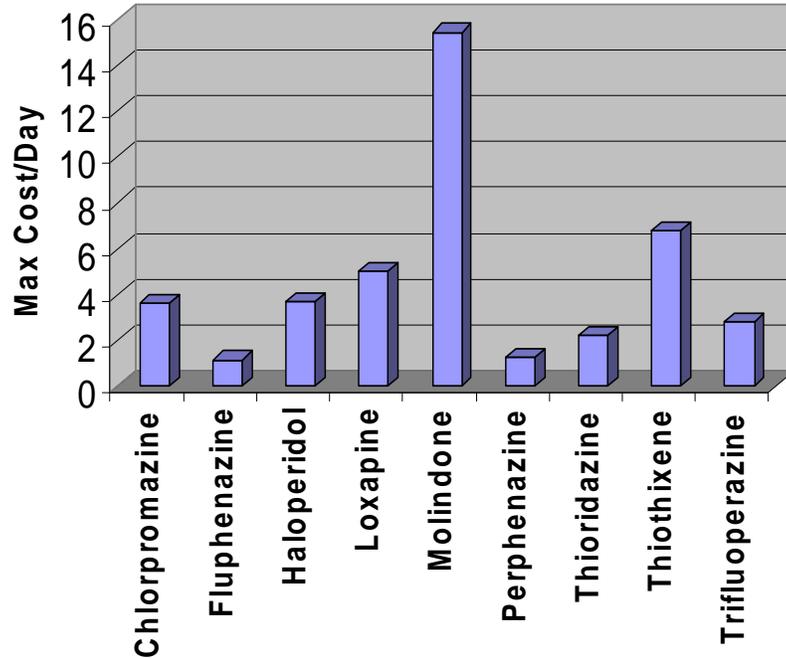
### **Thiothixene (Navane)**

Capsule: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg

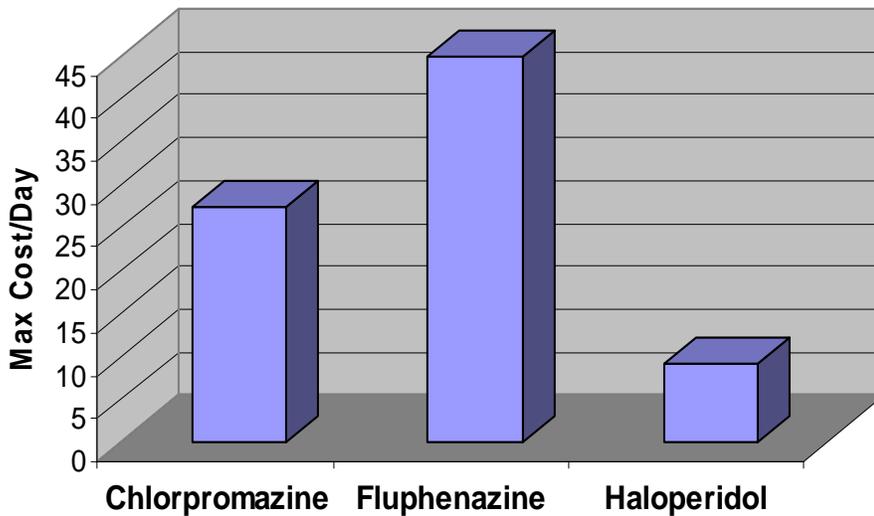
### **Trifluoperazine (Stelazine)**

Tablet: 1 mg, 2 mg, 5 mg, 10 mg

### Typical Antipsychotics: Oral Capsule or Tablet Formulations



### Short-Acting Injectable Typical Antipsychotics



## Formulary Recommendations

1. Consider adjusting antipsychotic maximum dosing to be more in line with current maximum doses and TIMA maximum doses, particularly with regard to chlorproMAZINE, fluphenazine oral and decanoate, and trifluoperazine.
2. Remove chlorproMAZINE concentrate and syrup; the concentrate is not available and the syrup is not available through McKesson.
3. Remove loxapine concentrate as it is not available.
4. Remove mesoridazine from the formulary, reserve drug list, and maximum dosing table as all formulations of mesoridazine are no longer available through McKesson.
5. Remove molindone concentrate and molindone 100 mg tablets as these products are no longer available through McKesson.
6. Remove thioridazine concentrate and thioridazine 15 mg, 150 mg, and 200 mg tablets as these products are no longer available through McKesson.