Medication
Audit Criteria and Guidelines

-- INDEX –

The audit criteria and guidelines are developed for use in the treatment of psychiatric conditions and not medical conditions.

Criteria and Drug Audit Form Number CURRENT #	Description
22.	DECANOATES fluphenazine decanoate (Prolixin® Decanoate), haloperidol decanoate (Haldol® Decanoate)
23.	RISPERIDONE (RISPERDAL®), OLANZAPINE (ZYPREXA®), QUETIAPINE (SEROQUEL®), ZIPRASIDONE (GEODON®)
24.	SEDATING ANTIHISTAMINES diphenhydramine HCL (Benadryl®), hydroxyzine HCL (Atarax®)
25.	ZALEPLON (SONATA®)
26.	ZOLPIDEM (AMBIEN®)
27.	BETA-BLOCKERS propranolol (Inderal®), atenolol (Tenormin®), metoprolol (Lopressor®), nadolol (Corgard®)
28.	CLOMIPRAMINE (ANAFRANIL®)
29.	GABAPENTIN (NEURONTIN®)
30.	NALTREXONE (REVIA®)
31.	STIMULANTS methylphenidate (Ritalin®, Concerta™), dextroamphetamine (Dexedrine®), dextroamphetamine/amphetamine mixture (Adderall®)
32.	DULOXETINE (CYMBALTA®)

Medication Audit Criteria and Guidelines

Purpose of Laboratory Monitoring

This document was developed based on the premise that the laboratory tests needed for prescribing psychotropic medications are apart from the laboratory tests obtained for the evaluation of the patient's general health status. The required laboratory tests listed are specific for risk factors associated with that particular psychotropic medication. The required psychotropic medication laboratory screening does not substitute for a good history and physical and subsequent healthcare screening needed for the provision of good general medical care for the person who has become a psychiatric patient.

The specific laboratory tests required for the use of psychotropic medication can be obtained from other treatment settings provided:

- The laboratory tests were obtained within 90 days prior to initiation of treatment.

- The actual values of the tests are documented in the chart. Other documentation shall include the date the lab work was obtained and the name of the laboratory.

- There are no intervening illnesses within those 90 days which would necessitate repeating the lab work.

The laboratory tests listed in this document are minimum requirements. The clinician is encouraged to obtain any necessary lab work which he/she feels is clinically justified.

CARBAMAZEPINE (TEGRETOL®)

INDICATIONS

1) Cyclic mood disorders
2) Aggressive behavior secondary to a psychiatric disorder
3) Chronic Pain
4) Acute mania

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to carbamazepine or tricyclic antidepressants

Relative:

1) History of blood dyscrasias
2) Myoclonic seizure, atonic seizures
3) AV heart block
4) History of bone marrow -suppression
5) Pregnancy/nursing mothers
6) Concomitant use of clozapine (Clozaril®)

Precautions

1) Diabetes Mellitus
2) SIADH
3) Glaucoma or urinary retention
4) Concomitant use of monoamine oxidase (MAO) inhibitors
5) Coronary artery disease
6) Hyponatremia, dilutional
7) Renal function impairment

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Anticoagulants, coumadin
2) Anticonvulsants, hydantoin, succinimide, primidone, felbamate
3) Barbiturates
4) Benzodiazepines metabolized via hepatic microsomal enzymes, especially clonazepam
5) Valproic acid
6) Antidepressants, tricyclic
7) Cimetidine
8) Clarithromycin, erythromycin or troleandomycin
9) Contraceptives, estrogen-containing, oral
10) Estrogens, including estramustine
11) Quinidine
12) Corticosteroids
13) Calcium channel blockers (especially diltiazem and verapamil)
14) Isoniazid
15) Monoamine oxidase (MAO) inhibitors, including furazolidone and procarbazine
16) Propoxyphene
17) Antipsychotics (especially haloperidol and risperidone)
18) Nefazodone

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

CARBAMAZEPINE (TEGRETOL®) - continued

PRECAUTIONS TO CONSIDER (continued)

Age-Specific considerations

None

Side Effects Which Require Medical Attention

1) Blurred or double vision
2) Rash
3) Sore throat or fever
4) Worsening confusion or disorientation
5) Nausea, vomiting diarrhea or abdominal discomfort
6) Drowsiness, lethargy
7) Headache
8) Bone or joint pain

PATIENT MONITORING

Patient Monitoring Parameters

1) CBC with platelets – baseline and 1 to 2 weeks after each dose increase and as clinically indicated
2) Hepatic function panel and electrolytes; baseline and as clinically indicated.
3) Pregnancy Test – as clinically indicated
4) Carbamazepine Levels – 3-4 weeks after dose adjustment, then as clinically indicated

Usual therapeutic levels 4-12 mcg/ml
Therapeutic ranges for the lab used should be listed on the report.

Dosing

Take with food to avoid stomach upset

See TDMHMR Formulary for dosage guidelines.

LAMOTRIGINE (LAMICTAL®)

INDICATIONS

1) Cyclic mood disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed

Relative:

1) Pregnancy/nursing mothers
2) Age less than 16 years of age

Precautions

1) Combined use with Valproic acid
2) Photosensitivity
3) Renal or hepatic impairment

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Valproic acid
2) Acetaminophen
3) Carbamazepine, phenytoin, phenobarbital

Age-Specific Considerations

1) Safety and efficacy in children<16 has not been established

Side Effects Which Require Medical Attention

1) Rash
2) Headache
3) Diplopia
4) Rhinitis
5) Nausea, vomiting, diarrhea or abdominal discomfort
6) Drowsiness, lethargy, dizziness

PATIENT MONITORING

Patient Monitoring Parameters

1) Renal Function Test - baseline and as clinically indicated
2) Hepatic Function Test - baseline, yearly and as clinically indicated
3) Pregnancy Test - as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

LITHIUM (ESKALITH®, LITHOBID®, ESKALITH CR®, etc.)

INDICATIONS

1) Cyclic mood disorders
2) Augmentation of antidepressant therapy
3) Aggressive behavior secondary to a psychiatric disorder
4) Acute mania

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed

Relative:

1) Cardiovascular disease
2) Severe dehydration
3) Goiter or hypothyroidism
4) Psoriasis
5) Pregnancy/nursing mothers
6) Renal insufficiency
7) Hyperparathyroidism
8) Concomitant use of diuretics

Precautions

1) Diagnosis of a seizure disorder
2) Parkinson's disease
3) Dehydration
4) Severe infections
5) Dementia, brain injuries
6) Urinary retention
7) Thyroid disorders
8) Psoriasis
9) Severe acne

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category D.

Drug Interactions of Major Significance

1) Concomitant use of diuretics
2) Concomitant use of non-steroidal anti-inflammatory drugs
3) Iodine containing substances
4) Antipsychotics

Age-Specific Considerations

Monitoring of skeletal development in children if chronic lithium therapy is advised. Geriatric patients usually require lower doses and more frequent monitoring.

LITHIUM (ESKALITH®, LITHOBID®, ESKALITH CR®, etc.) - continued

PRECAUTIONS TO CONSIDER

Side Effects Which Require Medical Attention

1) Weight gain
2) Edema
3) Hypothyroidism
4) Slurred speech
5) Drowsiness, lethargy
6) Nausea, vomiting, diarrhea
7) Ataxia
8) Trembling
9) Polydipsia
10) Polyuria
11) Headache

PATIENT MONITORING

Patient Monitoring Parameters

1) EKG (mandatory for everyone – baseline, yearly and as clinically indicated)
2) CBC – baseline, yearly and as clinically indicated
3) Thyroid studies – baseline; then TSH every 6 months and as clinically indicated
4) BUN, creatinine, glucose and electrolytes; baseline and as clinically indicated.
5) UA - baseline and as clinically indicated
6) Pregnancy Test - as clinically indicated
7) Lithium Levels – one week after initiation or dosage change and as clinically indicated
8) Calcium and phosphate, in children under 12, prior to initiation and as clinically indicated

Usual therapeutic Level: 0.6-1.5 meq/L (12 hour post dose)
Therapeutic ranges for the lab used should be listed on the report.

Dosing

Take with food to avoid stomach upset
See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

OXCARBAZEPINE (TRILEPTAL®)

INDICATIONS

1) Cyclic mood disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to carbamazepine or oxcarbazepine

Relative:

1) Hyponatremia

Precautions

1) Renal insufficiency

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Oral contraceptives
2) Phenytoin

Age-Specific considerations

None

Side Effects Which Require Medical Attention

1) Psychomotor retardation
2) Concentration difficulties
3) Somnolence and fatigue
4) Ataxia, gait disturbances
5) Nausea, vomiting
6) Signs and symptoms of hyponatremia

PATIENT MONITORING

Patient Monitoring Parameters

1) Electrolytes – baseline and as clinically indicated
2) Pregnancy Test – as clinically indicated

Dosing

See TDMHMR Formulary for dosage guidelines.

TOPIRAMATE (TOPAMAX®)

INDICATIONS

1) Cyclic mood disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed

Relative:

1) Pregnancy/nursing mothers

Precautions

1) Kidney stones
2) Parasthesias
3) Renal or hepatic impairment

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) oral contraceptives
2) carbonic anhydrase inhibitors
3) valproic acid, carbamazepine, phenytoin

Age-Specific Considerations

1) Safety and efficacy in children have not been established

Side Effects Which May Require Medical Attention

1) Psychomotor slowing
2) Headache
3) Diplopia
4) Dizziness
5) Nausea, vomiting, anorexia
6) Nervousness
7) Drowsiness, lethargy, somnolence
8) Depression
9) Weight loss

PATIENT MONITORING

Patient Monitoring Parameters

1) Metabolic studies including renal function, hepatic function and serum bicarbonate - baseline, and as clinically indicated
2) Pregnancy Test - as clinically indicated

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

VALPROIC ACID (DEPAKENE®), DIVALPROEX SODIUM (DEPAKOTE®)

INDICATIONS

1) Cyclic mood disorders
2) Aggressive behavior secondary to a psychiatric disorder
3) Chronic Pain
4) Acute mania

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed

Relative

1) Hepatic disease/impairment
2) Blood dyscrasias, clotting disorders or concomitant drugs that alter clotting function (aspirin, non-steroidal anti-inflammatory drugs, warfarin, heparin, low molecular weight heparins, clopidogrel etc.)
3) Pregnancy/nursing mothers

Precautions

1) Hypoalbuminemia
2) Renal impairment

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category D.

Drug Interactions of Major Significance

1) Concomitant CNS depressants
2) Anticoagulants
3) Carbamazepine
4) Felbamate
5) Concomitant hepatotoxic medications
6) Mefloquine
7) Phenytoin
8 Lamotrigine
9) Non-steroidal anti-inflammatory drugs
10) Aspirin
11) Phenobarbital
12) Diazepam

Age-specific Considerations

Age younger than 10 years old due to high risk of hepatic toxicity
Geriatric patients have increased amounts of free drug (use lower total plasma concentration or get free VPA plasma concentration)

Side Effects Which Require Medical Attention

1) Worsening confusion or disorientation
2) Nausea, vomiting, diarrhea, abdominal discomfort or anorexia
3) Bruising or bleeding
4) Clinically significant weight gain
5) Tremors

VALPROIC ACID (DEPAKENE®), DIVALPROEX SODIUM (DEPAKOTE®) - continued

PATIENT MONITORING

Patient Monitoring Parameters

1) CBC - with differential and platelet count - baseline then one (1) to two (2) weeks after each dosage increase, and as clinically indicated
2) Hepatic function panel- baseline and as clinically indicated
3) Pregnancy Test – baseline and as clinically indicated
4) Valproic acid level – 1-2 weeks after initiation and dosage change, then as clinically indicated.
5) Serum creatinine and BUN at baseline and as clinically indicated

Usual therapeutic levels 50-150 mcg/ml
Therapeutic ranges for the lab used should be listed on the report.

Dosing

Take with food to avoid stomach upset
See TDMHMR Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

VERAPAMIL (CALAN®, ISOPTIN®)

INDICATIONS

1) Cyclic mood disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed
2) Severe left ventricular dysfunction
3) Hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock
4) Sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker)
5) Second or third AV block (except in patients with a functioning artificial ventricular pacemaker)
6) Patients with atrial flutter or atrial fibrillation and an accessory bypass tract (Wolff-Parkinson-White)

Relative:

1) Hepatic function impairment
2) Renal impairment
3) Cardiac conduction disturbances not outlined in absolute contraindications

Precautions

Pregnancy/nursing mothers

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Carbamazepine
2) Lithium

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

Safety and efficacy not established for those under 18 years old.

Side Effects Which Require Medical Attention

1) Hypotension
2) Constipation
3) Nausea
4) Headache, chronic or recurrent
5) Dizziness or lightheadedness
6) Bradycardia

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated
2) Renal and Liver Function Test - baseline and as clinically indicated
3) Vital signs with initial dosing and with any dosage change.
4) EKG within one year prior to initiation of drug.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

BENZODIAZEPINES

alprazolam (Xanax®), chlordiazepoxide (Librium®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), Oxazepam (Serax®), temazepam (Restoril®), triazolam (Halcion®), Clonazepam (Klonopin®)

INDICATIONS

1) Anxiety disorders
2) Panic disorder
3) Anxiety associated with depression
4) Short term use for the treatment of insomnia
5) Sedative hypnotic withdrawal
6) Akathisia
7) Acute intervention for agitation/violent behavior
8) Bipolar disorder, mania - adjunctive or second line therapy
9) Alcohol/substance abuse withdrawal

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed

Relative:

1) Pregnancy/nursing mothers
2) Myasthenia gravis
3) Severe COPD

Precautions

1) Hepatic impairment
2) Porphyria
3) History of alcohol and drug abuse
4) Sleep apnea
5) Sedative hypnotic intoxication/dependence
6) Discontinuation or rapid dose reduction
7) Attention Deficit Hyperactivity Disorder (ADHD)
8) Dementias/delirium

Pregnancy and Breast-Feeding

See relative contraindications. Most benzodiazopines are FDA Pregnancy Category D or X.

Drug Interactions of Major Significance

1) Alcohol or CNS depressants
2) Clozapine (excessive sedation or respiratory depression)
3) Other drugs with respiratory depression

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

1) Lower doses should be used in children and elderly
2) Avoid long half-life drugs in elderly (causes falls)
3) May cause excitability in children, elderly and persons with developmental disabilities

Side Effects Which Require Medical Attention

1) Worsening agitation, disinhibition or aggression
2) Obtundation
3) Ataxia
4) Redness, swelling or pain at injection site

BENZODIAZEPINES - continued

alprazolam (Xanax®), chlordiazepoxide (Librium®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), Oxazepam (Serax®), temazepam (Restoril®), triazolam (Halcion®), Clonazepam (Klonopin®)

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.

Exceptions to maximum dosage must be justified as per medication rule.

BUSPIRONE (BUSPAR®)

INDICATIONS

1) Anxiety Disorder
2) Aggressive behavior
3) Self injurious behavior
4) Augmentation for resistant depression

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed

Relative:

1) Hepatic function impairment
2) Renal impairment

Precautions

1) Pregnancy/nursing mothers
2) Doses > 45 mg. day in patients with developmental disabilities

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category B.

Drug Interactions of Major Significance

1) Concomitant monoamine oxidase (MAO) inhibitors
2) Erythromycin
3) Itraconazole
4) Nefazodone

Age-Specific Considerations

Safety and efficacy not established for those under 18 years old.

Side Effects Which Require Medical Attention

1) Worsening confusion or agitation
2) Restlessness (akathisia)
3) Nausea
4) Headache, chronic or recurrent
5) Dizziness or lightheadedness

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated

Dosing

See TDMHMR Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

AMOXAPINE (ASENDIN®)

INDICATIONS

1) Depression with psychotic features

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Recovery phase of myocardial infarction

Relative:

1) Pregnancy/nursing mothers
2) History of neuroleptic malignant syndrome

Precautions

Alcohol intoxication, bipolar disorder in the absence of a mood stabilizer, recent or current blood dyscrasias, cardiovascular disorders including arrhythmia, heart block and failure, patients at risk for paralytic ileus, glaucoma, hepatic function impairment, hyperthyroidism, prostatic hypertrophy, renal failure, diagnosis of a seizure disorder, urinary retention, Parkinson's disease, tardive dyskinesia or history of EPS.

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

None

Age-Specific Considerations

1) Not indicated in children under age 16

Side Effects Which Require Medical Attention

1) Anticholinergic effects
2) Sexual function impairment
3) Seizures
4) Dizziness, lightheadedness or fainting
5) EPS
6) Akathisia
7) Tardive dyskinesia
8) Symptoms of prolactin elevation (galactorrhea, amenorrhea, gynecomastia)
9) Signs and symptoms of neuroleptic malignant syndrome

PATIENT MONITORING

Patient Monitoring Parameters

1) EKG – baseline and as clinically indicated.
2) Pregnancy test - as clinically indicated.
3) Screening for abnormal involuntary movements using a standardized test-prior to initiation, six months, annually and as clinically indicated.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

BUPROPION (WELLBUTRIN® and WELLBUTRIN® SR)

INDICATIONS

1) Depressive Disorders
2) Attention deficit hyperactivity disorder
3) Nicotine Dependence

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Anorexia nervosa and bulimia
3) Diagnosis of a seizure disorder

Relative:

None

Precautions

Bipolar disorder in the absence of a mood stabilizer, hepatic function impairment, renal failure, CNS tumor, head trauma or history of seizures, pregnancy/nursing mothers.

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category B.

Drug Interactions of Major Significance

1) Concomitant monoamine oxidase inhibitors (furazolidone, procarbazine, selegiline, tranylcypromine, phenelzine, isoniazid)
2) Concomitant use of CNS depressants
3) Cimetidine
4) Concomitant use of medications with anticholinergic effects
5) Noradrenergic anti-hypertensive agents (clonidine, guanabenz, guanadrel, guanethidine)
6) Concomitant use of drugs that lower seizure threshold

Age-Specific Considerations

None

Side Effects Which Require Medical Attention

1) Delirium or cognitive dysfunction
2) Seizure
3) Headache, severe
4) Restlessness

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test - as clinically indicated.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

MIRTAZAPINE (REMERON®)

INDICATIONS

1) Depressive Disorders
2) Insomnia

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed

Relative:

1) Pregnancy/nursing mothers

Precautions

Bipolar disorder in the absence of mood stabilizer, recovery phase of myocardial infarction, hepatic function impairment, renal failure, diagnosis of a seizure disorder

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

Concomitant monoamine oxidase inhibitors (or within 14 days of an MAOI)

Age-Specific Considerations

No data available in individuals under the age of 18

Side Effects Which Require Medical Attention

1) Agranulocytosis (or signs of infection: sore throat, fever, etc.)
2) Elevated cholesterol
3) Dizziness, unsteadiness, lightheadedness or fainting
4) Increased weight gain/appetite
5) Elevation in liver enzymes (ALT)
6) Orthostatic hypotension

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

MONOAMINE OXIDASE INHIBITORS
phenelzine (Nardil®), tranylcypromine (Parnate®)

INDICATIONS

1) Depressive Disorders
2) Panic Disorders
3) Anxiety Disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Pheochromocytoma
3) Congestive heart failure
4) Concomitant use of another monoamine oxidase inhibitor
5) Concomitant use with meperidine
6) Concomitant use with SSRI's, buspirone or venlafaxine
7) Concomitant use of pressor amines (e.g. ephedrine, phenylpropanolamine, pseudoephedrine)
8) Stimulants

Relative:

1) Impaired renal function
2) Severe hepatic disease
3) Pregnancy/nursing mothers
4) Hyperthyroidism
5) Concomitant use of tricyclic antidepressant, methyldopa, dopamine, levodopa, selegiline, dextromethorphan

Precautions

Bipolar disorder in the absence of a mood stabilizer, hepatic function impairment, renal function impairment, hypertension or history of hypertension, diagnosis of a seizure disorder or history of seizures, recent cardiac disease including myocardial infarction, concomitant use of antihypertensives.

Pregnancy and Breast-Feeding

See relative contraindications. Phenelzine and tranylcypromine are FDA Pregnancy Category C.

Age-Specific Considerations

No data available in individuals under the age of 18.

Side Effects Which Require Medical Attention

1) Headache
2) Sexual dysfunction
3) Blood pressure alteration, especially hypertension
4) Delirium
5) Dizziness, lightheadedness or fainting (orthostatic hypotension)
6) Clinically significant weight gain

MONOAMINE OXIDASE INHIBITORS - continued
phenelzine (Nardil®), tranylcypromine (Parnate®)

PRECAUTIONS TO CONSIDER (continued)

Drug Interactions of Major Significance

See absolute and relative contraindications

FOODS CONTAINING TYRAMINE

****High Amounts of Tyramine***
Smoked, aged or pickled meat or fish
Sauerkraut
Aged Cheeses such as Swiss and Cheddar
Yeast extracts
Fava beans

*****Moderate Amounts of Tyramine***
Beer
Avocados
Meat extracts
Red wines such as Chianti

******Low Amounts of Tyramine***
Caffeine-containing beverages
Distilled spirits
Chocolate
Soy sauce
Cottage and cream cheeses
Yogurt and sour cream

*May not consume
**May consume in moderation
***May consume

Adapted from Shulman KI, et al. Dietary restriction, tyramine, and the use of monoamine oxidase inhibitors. J. Clin. Psychopharmacol. 1989; 9: 397.

PATIENT MONITORING

Patient Monitoring Parameters

1) Blood chemistries with emphasis on hepatic and renal functions; baseline, yearly and as clinically indicated during prolonged or high dose therapy.
2) Pregnancy test – as clinically indicated.
3) Blood pressure at baseline and during dosage adjustments and as clinically indicated. Therapeutic ranges for the lab used should be listed on the report.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

NEFAZODONE (SERZONE®)

INDICATIONS

1) Depressive Disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed or trazodone.
2) Patients who were withdrawn from nefazodone because of evidence of liver injury.

Relative:

1) Pregnancy/nursing mothers

Precautions

1) Bipolar disorder in the absence of a mood stabilizer, recovery phase of myocardial infarction, hepatic function impairment, renal failure, diagnosis of a seizure disorder.
2) Active liver disease, elevated baseline serum transaminases.

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Concomitant monoamine oxidase inhibitors (or within 14 days of an MAOI)
2) Alprazolam, triazolam
3) Carbamazepine
4) Pimozide

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

No data available in individuals under the age of 18.

Side Effects Which Require Medical Attention

1) Priapism
2) Dizziness, unsteadiness, lightheadedness or fainting
3) Visual changes
4) Rash
5) Tinnitus
6) Bradycardia less than 50 beats/min.
7) Elevated liver function tests
8) Dark urine, anorexia, malaise and GI symptoms

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test – as clinically indicated.
2) ALT and AST – baseline, at 1, 2, 4, 6 and 12 months, then annually and as clinically indicated. Stop drug if AST or ALT levels are 3 times (or greater) the upper limit of normal.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

SSRIs: CITALORPAM (CELEXA®), FLUOXETINE (PROZAC®), SERTRALINE (ZOLOFT®), PAROXETINE (PAXIL®), FLUVOXAMINE (LUVOX®)

INDICATIONS

1) Depressive Disorders
2) Obsessive-compulsive disorder
3) Panic disorder
4) Eating disorders
5) Self injurious behavior
6) Late Luteal Phase Disorder
7) Anxiety Disorders
8) Social Phobia

PRECAUTIONS TO CONSIDER

Contraindications

Absolute

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Concurrent administration of MAOI (or within 14 days of receiving citalopram, sertraline, paroxetine or fluvoxamine; or within 35 days of receiving fluoxetine)

Relative

1) Severe hepatic function impairment
2) Severe renal function impairment
3) Seizure disorder or history of seizure disorder

Precautions

Bipolar disorder in the absence of a mood stabilizer, hepatic function impairment, renal failure, diagnosis of a seizure disorder, diabetes mellitus, pregnancy/nursing mothers.

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category C, except for paroxetine which is Category D

Drug Interactions of Major Significance

1) See contraindications
2) Alcohol
3) Concomitant use of CNS depressants
4) Phenytoin
5) Valproic acid, divalproex sodium
6) Tolbutamide
7) Carbamazepine

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

None

Side Effects Which Require Medical Attention

1) Chills or fever
2) Joint or muscle pain
3) Skin rash
4) Hives or itching
5) Trouble breathing
6) Sexual function impairment
7) Severe GI distress
8) Akathisia
9) Hyponatremia
10) Hypothyroidism

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test - as clinically indicated.

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

TRAZODONE (DESYREL®)

INDICATIONS

1) Depressive Disorders
2) Insomnia

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed or nefazodone
2) Recovery phase of myocardial infarction

Relative:

1) Pregnancy/nursing mothers

Precautions

Alcohol intoxication, bipolar disorder in the absence of a mood stabilizer, cardiovascular disorders including arrhythmia, heart block and failure, hepatic function impairment, renal failure, diagnosis of a seizure disorder, hypotension and history of priapism.

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

None

Age-Specific Considerations

Has not been studied in persons younger than 18.

Side Effects Which Require Medical Attention

1) Priapism
2) Dizziness, lightheadedness or fainting

PATIENT MONITORING

Patient Monitoring Parameters

1) EKG - as clinically indicated.
2) Pregnancy test - as clinically indicated.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

TRICYCLIC ANTIDEPRESSANTS

amitriptyline (Elavil®), desipramine (Norpramin®, Pertofrane®), doxepin (Sinequan®), imipramine (Tofranil®), maprotiline (Ludiomil®), nortriptyline (Pamelor®, Aventyl®), protriptyline (Vivactil®), trimipramine (Surmontil®)

INDICATIONS

1) Depressive Disorders
2) Panic disorder
3) Bulimia nervosa
4) Attention deficit hyperactivity disorder
5) Functional enuresis
6) Anxiety disorders
7) Chronic Pain
8) Insomnia
9) Obsessive-Compulsive Disorder

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Recovery phase of myocardial infarction
3) Pheochromocytoma

Relative:

1) Pregnancy/nursing mothers

Precautions

Alcohol intoxication, bipolar disorder in the absence of a mood stabilizer, recent or current blood dyscrasias, cardiovascular disorders including arrhythmia, diseases states where increased anticholinergic activity may complicate disease course (narrow-angle glaucoma, benign prostatic hypertrophy), heart block and failure, lower respiratory tract symptoms (asthma), , hepatic function impairment, hyperthyroidism, renal failure, diagnosis of a seizure disorder.

Pregnancy and Breast-Feeding

See relative contraindications. Most tricyclic antidepressants are FDA Pregnancy Category C or D.

Drug Interactions of Major Significance

1) Concomitant monoamine oxidase inhibitors (furazolidone, procarbazine, selegiline, tranylcypromine, phenelzine, isoniazid)
2) Concomitant use of CNS depressants
3) Cimetidine
4) Concomitant use of medications with anticholinergic effects
5) Noradrenergic anti-hypertensive agents (clonidine, guanabenz, guanadrel, guanethidine)
6) SSRI

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

Most agents are not recommended for use in children; if used, conservative dosing, EKG prior to dosage increase and plasma concentration monitoring are advised.

TRICYCLIC ANTIDEPRESSANTS - continued

amitriptyline (Elavil®), desipramine (Norpramin®, Pertofrane®), doxepin (Sinequan®), imipramine (Tofranil®), maprotiline (Ludiomil®), nortriptyline (Pamelor®, Aventyl®), protriptyline (Vivactil®), trimipramine (Surmontil®)

PRECAUTIONS TO CONSIDER (continued)

Side Effects Which Require Medical Attention

1) Anticholinergic effects
2) Sexual function impairment
3) Seizures
4) Dizziness, lightheadedness or fainting (orthostatic hypotension)
5) Tachycardia greater than 100 beats/min
6) Jaundice
7) QTc >500 msec

PATIENT MONITORING

Patient Monitoring Parameters

1) EKG – baseline and as clinically indicated.
2) Pregnancy test - as clinically indicated.
3) Blood levels as clinically indicated. Therapeutic ranges for the lab used should be listed on the report. See Antidepressant Table in current TDMHMR Drug Formulary Book.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

VENLAFAXINE (EFFEXOR® and EFFEXOR® ER)

INDICATIONS

1) Depressive Disorders
2) Attention deficit hyperactivity disorder
3) Anxiety disorders
4) Chronic Pain

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Pheochromocytoma
3) Concomitant use of monoamine oxidase inhibitor

Relative:

1) Impaired renal function
2) Severe hepatic disease
3) Pregnancy/nursing mothers
4) Hyperthyroidism
5) Hypertension or history of hypertension

Precautions

Bipolar disorder in the absence of a mood stabilizer, hepatic function impairment, renal function impairment, diagnosis of a seizure disorder or history of seizures.

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Concurrent administration of MAOI, or within 14 days of MAOI
2) SSRIs or other serotonergic drugs

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-specific Considerations

No data available in individuals under the age of 18.

Side Effects Which Require Medical Attention

1) Headache
2) Sexual dysfunction
3) Blood pressure alteration, especially hypertension
4) Delirium
5) Visual disturbances

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test – as clinically indicated.
2) Blood pressure during dosage titration and as clinically necessary.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

ANTIPSYCHOTICS

chlorpromazine (Thorazine®), fluphenazine (Prolixin®), haloperidol (Haldol®), loxapine (Loxitane®), molindone (Moban®), perphenazine (Trilafon®), thiothixene (Navane®), trifluoperazine (Stelazine®)

INDICATIONS

1) Disorders with psychotic symptoms (schizophrenia, schizoaffective disorder, manic disorders, depression with psychotic features, drug-induced psychosis, psychosis associated with other organic conditions)
2) Tourette's disorder (haloperidol only)
3) Personality disorders – schizotypal, paranoid and borderline
4) Acute and/or short term use for management of aggressive or violent behavior
5) Stereotypes

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed or structurally related medication
2) Severe CNS depression

Relative:

1) Pregnancy/nursing mothers
2) History of drug-induced agranulocytosis or leukopenia
3) Breast cancer
4) History of neuroleptic malignant syndrome
5) Narrow angle glaucoma (for chlorpromazine)
6) Impaired hepatic function
7) Prostatic hypertrophy (for chlorporamazine)
8) Parkinson's disease
9) Severe cardiovascular diseases, including certain conduction disturbances

Precautions

Alcoholism (active), recent or current blood dyscrasias, hepatic function impairment, angina, hypotension, congestive heart failure, arrhythmias, breast cancer, glaucoma, history of neuroleptic malignant syndrome, benign prostatic hypertrophy, Parkinson's disease, poorly controlled seizure disorder, urinary retention, patients at risk for paralytic ileus.

Pregnancy and Breast-Feeding

See relative contraindications. Most antipsychotics are FDA Pregnancy Category C.

ANTIPSYCHOTICS - continued

chlorpromazine (Thorazine®), fluphenazine (Prolixin®), haloperidol (Haldol®), loxapine (Loxitane®), molindone (Moban®), perphenazine (Trilafon®), thiothixene (Navane®), trifluoperazine (Stelazine®)

PRECAUTIONS TO CONSIDER (continued)

Drug Interactions of Major Significance

1) Concomitant use of CNS depressants
2) Antithyroid agents
3) Concomitant use of agents that cause EPS (including droperidol metoclopramide, amoxapine, metyrosine, pimozide, reserpine)
4) Concomitant use of hypotension producing agents
5) Levodopa
6) Concomitant anticholinergic drugs (for chlorpromazine)

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

1) Conservative dosing and careful monitoring are advised in children and the elderly

Side Effects Which Require Medical Attention

1) Anticholinergic effects (for chlorpromazine)
2) Acute extrapyramidal side effects (dystonia, pseudo-Parkinsonism)
3) Akathisia
4) Hypotension
5) Rashes, photosensitivity and altered pigmentation
6) Tardive dyskinesia or other late-onset EPS
7) Visual changes
8) Early symptoms of agranulocytosis effects (fever, sore throat, weakness)
9) Fluctuating vital signs
10) Altered consciousness
11) Galactorrhea
12) Amenorrhea
13) Gynecomastia
14) Poikilothermia
15) Signs and symptoms of neuroleptic malignant syndrome

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test – as clinically indicated
2) BMI measurement – when a new antipsychotic is initiated, at every visit (monthly for inpatients) for 6 months after the new antipsychotic is initiated, and quarterly when the antipsychotic dose is stable.
3) Fasting plasma glucose level or hemoglobin A_{1c} – before initiating a new antipsychotic, then yearly.

   If a patient has significant risk factors for diabetes and for those that are gaining weight – before initiating a new antipsychotic, 4 months after starting an antipsychotic, and then yearly.
4) Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides] – Every 2 years or more often if lipid levels are in the normal range, every 6 months if the LDL level is > 130 mg/dl

ANTIPSYCHOTICS - continued
chlorpromazine (Thorazine®), fluphenazine (Prolixin®), haloperidol (Haldol®), loxapine (Loxitane®), molindone (Moban®), perphenazine (Trilafon®), thiothixene (Navane®), trifluoperazine (Stelazine®)

5) Sexual function inquiry – inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbance yearly.

   If a patient is receiving an antipsychotic known to be associated with prolactin elevation, then at each visit (quarterly for inpatients) for the first 12 months after starting an antipsychotic or until the medication dose is stable and then yearly.
6) Prolactin level – if there is evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory yearly.
7) EPS Evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase
8) Tardive dyskinesia evaluation – every 6 months.

   For high risk patients (including the elderly), every 3 months.
9) Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision – yearly
10) Ocular evaluations – yearly for patients older than age 40 years; every 2 years for younger patients.

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

ANTIPSYCHOTICS

mesoridazine (Serentil®), thioridazine (Mellaril®)

INDICATIONS

1) Schizophrenia, refractory (failed other classes of antipsychotics)

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed or structurally related medication
2) Severe CNS depression
3) QTc > 450 msec
4) Hypomagnesemia
5) Hypokalemia
6) Retinitis Pigmentosa
7) Concomitant use of other drugs known to prolong QTc interval
8) Known heart disease
9) Personal history of syncope
10) Family history of sudden death at an early age (under age of 40 years)
11) Congenital long QT syndrome

Relative:

1) Pregnancy/nursing mothers
2) History of drug induced agranulocytosis or leukopenia
3) Breast cancer
4) History of neuroleptic malignant syndrome
5) Narrow angle glaucoma
6) Impaired hepatic function
7) Prostatic hypertrophy
8) Parkinson's disease

Precautions

Alcoholism (active), recent or current blood dyscrasias, hepatic function impairment, angina, hypotension, congestive heart failure, arrhythmias, breast cancer, glaucoma, history of neuroleptic malignant syndrome, prostatic hypertrophy, Parkinson's disease, poorly controlled seizure disorder, urinary retention, patients at risk for paralytic ileus.

Pregnancy and Breast-Feeding

See relative contraindications. Most antipsychotics are FDA Pregnancy Category C.

ANTIPSYCHOTICS - continued
mesoridazine (Serentil®), thioridazine (Mellaril®)

PRECAUTIONS TO CONSIDER (continued)

Drug Interactions of Major Significance

1) Concomitant use of CNS depressants
2) Antithyroid agents
3) Concomitant use of agents that cause EPS (including droperidol metoclopramide, amoxapine, metyrosine, pimozide, reserpine)
4) Concomitant use of hypotension producing agents
5) Levodopa
6) Concomitant anticholinergic drugs

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

1) Conservative dosing and careful monitoring are advised in children and the elderly

Side Effects Which Require Medical Attention

1) Anticholinergic effects
2) Acute extrapyramidal side effects (akathisia, dystonia, pseudo-Parkinsonism)
3) Hypotension
4) Rashes, photosensitivity and altered pigmentation
5) Tardive dyskinesia or other late-onset EPS
6) Visual changes
7) Early symptoms of agranulocytosis effects (fever, sore throat, weakness)
8) Fluctuating vital signs
9) Altered consciousness
10) Galactorrhea
11) Amenorrhea
12) Gynecomastia

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test – as clinically indicated
2) BMI measurement – when a new antipsychotic is initiated, at every visit (monthly for inpatients) for 6 months after the new antipsychotic is initiated and quarterly when the antipsychotic dose is stable.
3) Fasting plasma glucose level or hemoglobin A_{1c} – before initiating a new antipsychotic, then yearly.

   If a patient has significant risk factors for diabetes and for those that are gaining weight – before initiating a new antipsychotic, 4 months after starting an antipsychotic, and then yearly.
4) Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides] – Every 2 years or more often if lipid levels are in the normal range, every 6 months if the LDL level is > 130 mg/dl

ANTIPSYCHOTICS - continued

mesoridazine (Serentil®), thioridazine (Mellaril®)

Patient Monitoring Parameters

5) Sexual function inquiry – inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbance yearly.

   If a patient is receiving an antipsychotic known to be associated with prolactin elevation, then at each visit (quarterly for inpatients) for the first 12 months after starting an antipsychotic or until the medication dose is stable and then yearly
6) Prolactin level – if there is evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory yearly.
7) EPS Evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase
8) Tardive dyskinesia evaluation – every 6 months.

   For high risk patients (including the elderly), every 3 months.
9) Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision – yearly
10) Ocular evaluations – yearly for patients older than age 40 years; every 2 years for younger patients
11) Serum potassium level – baseline, every six months and as clinically indicated
12) Serum magnesium level – baseline and as clinically indicated (especially if potassium level is low)

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

CLOZAPINE (CLOZARIL®, FAZACLO®)

INDICATIONS

1) For use in patients with refractory schizophrenia or schizoaffective disorder, defined as failure on two antipsychotics from two different chemical families given for sufficient time (6-12 weeks) at a sufficient dose (1000 mg/day of chlorpromazine equivalents).
2) For use in schizophrenic or schizoaffective patients who cannot tolerate other antipsychotics.
3) Psychosis associated with other organic conditions, (who have failed two antipsychotics, or who cannot tolerate other antipsychotics)
4) Manic disorders with psychosis (in patients who have failed two antipsychotics)
5) Reduction in the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Myeloproliferative disorders
3) History of clozapine-induced agranulocytosis or severe granulocytopenia
4) Uncontrolled epilepsy
5) Severe CNS depression
6) Paralytic ileus
7) Concomitant use of agents that may cause bone marrow suppression, including carbamazepine (Tegretol®, Carbatrol®, Equetro®))

Relative:

1) History of drug induced agranulocytosis or leukopenia
2) Breast cancer
3) History of neuroleptic malignant syndrome
4) Narrow angle glaucoma
5) Impaired hepatic function
6) Prostatic hypertrophy
7) Parkinson's disease
8) Severe cardiovascular diseases
9) History of seizure
10) Diabetes Mellitus

Precautions

Alcoholism (active), recent or current blood dyscrasias, hepatic function impairment, angina, hypotension, congestive heart failure, arrhythmias, breast cancer, glaucoma, prostatic hypertrophy, obesity, Parkinson’s disease, urinary retention, patients at risk for paralytic ileus, pregnancy/nursing mothers.

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category B.

CLOZAPINE (CLOZARIL®, FAZACLO®) *- continued*

PRECAUTIONS TO CONSIDER

Drug Interactions of Major Significance

1) Concomitant use of CNS depressants
2) Antithyroid agents
3) Concomitant use of agents that cause EPS (including droperidol, metoclopramide, amoxapine metyrosine, pimozide, reserpine)
4) Concomitant use of hypotension producing agents
5) Levodopa
6) Concomitant use of agents that cause bone marrow suppression

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

Safety and efficiency have not been established in children under the age of 16. Geriatric patients may be more susceptible to orthostatic and anticholinergic effects.

Side Effects Which Require Medical Attention

1) Anticholinergic effects
2) Hypotension
3) Rashes, photosensitivity and altered pigmentation
4) Tardive dyskinesia or other late-onset EPS
5) Visual changes
6) Early symptoms of agranulocytosis (fever, sore throat, weakness)
7) Fluctuating vital signs
8) Altered consciousness
9) Fever
10) Drooling
11) Hyperglycemia
12) Clinically significant weight gain
13) Seizure
14) Hypercholesterolemia or hypertriglyceridemia

CLOZAPINE (CLOZARIL®, FAZACLO®) *- continued*

PATIENT MONITORING

Patient Monitoring Parameters

1) CBC as indicated by guidelines established by the manufacturer
2) Pregnancy test – as clinically indicated
3) BMI measurement – when a new antipsychotic is initiated, at every visit (monthly for inpatients) for 6 months after the new antipsychotic is initiated, and quarterly when the antipsychotic dose is stable.
4) Fasting plasma glucose level or hemoglobin A_{1c} – before initiating a new antipsychotic, then yearly.

   If a patient has significant risk factors for diabetes and for those that are gaining weight – before initiating a new antipsychotic, 4 months after starting an antipsychotic, and then yearly.
5) Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides] – Every 2 years or more often if lipid levels are in the normal range, every 6 months if the LDL level is > 130 mg/dl
6) Sexual function inquiry – inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbance yearly

   If a patient is receiving an antipsychotic known to be associated with prolactin elevation, then at each visit (quarterly for inpatients) for the first 12 months after starting an antipsychotic or until the medication dose is stable and then yearly.
7) Prolactin level – if there is evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory yearly.
8) EPS Evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase.
9) Tardive dyskinesia evaluation – every 12 months.

   For high risk patients (including the elderly), every 6 months.
10) Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision – yearly
11) Ocular evaluations – yearly for patients older than age 40 years; every 2 years for younger patients

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

DECANOATES

fluphenazine decanoate (Prolixin®, Decanoate), haloperidol decanoate (Haldol®, Decanoate)

INDICATIONS

1) Chronic psychotic disorder requiring prolonged parenteral treatment

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed or structurally related medication
2) Severe CNS depression

Relative:

1) Pregnancy/nursing mothers
2) History of drug induced agranulocytosis or leukopenia
3) Breast cancer
4) History of neuroleptic malignant syndrome
5) Impaired hepatic function
6) Parkinson's disease
7) Severe cardiovascular diseases

Precautions

Alcoholism (active), recent or current blood dyscrasias, hepatic function impairment, angina, hypotension, congestive heart failure, arrhythmias, breast cancer, , history of neuroleptic malignant syndrome, Parkinson's disease, poorly controlled seizure disorder.

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Concomitant use of CNS depressants
2) Antithyroid agents
3) Concomitant use of agents that cause EPS (including droperidol, metoclopramide, amoxapine, metyrosine, pimozide, reserpine)
4) Levodopa

DECANOATES - continued
fluphenazine decanoate (Prolixin®, Decanoate), haloperidol decanoate (Haldol®, Decanoate)

PRECAUTIONS TO CONSIDER

Age-Specific Considerations

Conservative dosing and careful monitoring are advised in children and the elderly

Side Effects Which Require Medical Attention

1) Extrapyramidal side effects
2) Akathisia
3) Rashes
4) Tardive dyskinesia or other late-onset EPS
5) Early symptoms of agranulocytosis (fever, sore throat, weakness)
6) Fluctuating vital signs
7) Altered consciousness
8) Galactorrhea
9) Amenorrhea
10) Gynecomastia
11) Signs and symptoms of neuroleptic malignant syndrome

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test – as clinically indicated
2) BMI measurement – when a new antipsychotic is initiated, at every visit (monthly for inpatients) 6 months after the new antipsychotic is initiated, and quarterly when the antipsychotic dose is stable.
3) Fasting plasma glucose level or hemoglobin A_{1c} – before initiating a new antipsychotic, then yearly.

   If a patient has significant risk factors for diabetes and for those that are gaining weight – before initiating a new antipsychotic, 4 months after starting an antipsychotic, and then yearly.
4) Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides] – Every 2 years or more often if lipid levels are in the normal range, every 6 months if the LDL level is > 130 mg/dl
5) Sexual function inquiry – inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbance yearly.

   If a patient is receiving an antipsychotic known to be associated with prolactin elevation, then at each visit (quarterly for inpatients) for the first 12 months after starting an antipsychotic or until the medication dose is stable and then yearly.
6) Prolactin level if there is evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory yearly.
7) EPS Evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase

DECANOATES - continued
fluphenazine decanoate (Prolixin®, Decanoate), haloperidol decanoate (Haldol®, Decanoate)

8) Tardive dyskinesia evaluation – every 6 months.

   For high risk patients (including the elderly), every 3 months.
9) Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision – yearly
10) Ocular evaluations – yearly for patients older than age 40 years; every 2 years for younger patients

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.

Exceptions to maximum dosage must be justified as per medication rule.

RISPERIDONE (RISPERDAL®, RISPERDAL CONSTA®), OLANZAPINE (ZYPREXA®), QUETIAPINE (SEROQUEL®), ZIPRASIDONE (GEODON®), AND ARIPIPRAZOLE (ABILIFY)

INDICATIONS

1) Disorders with psychotic symptoms (schizophrenia, schizoaffective disorder, manic disorders, depression with psychotic features, drug-induced psychosis, psychosis associated with other medical conditions)
2) Severe aggression secondary to a psychiatric disorder
3) Self Injurious Behavior secondary to a psychiatric disorder

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed
2) Severe CNS depression
3) Known or suspected clinically significant QTc prolongation
4) For ziprasidone - Recent myocardial infarction, uncompensated congestive heart failure or when other drugs are being used that also prolong the QT interval such as (not complete list) quinidine, dofetilide, pimozide, sotalol, thioridazine, moxiflocin, and sparfloxacin

Relative:

1) Pregnancy/nursing mothers
2) History of drug induced agranulocytosis or leucopenia
3) Breast cancer
4) History of neuroleptic malignant syndrome
5) Impaired hepatic function
6) Parkinson's disease
7) Severe cardiovascular diseases

Precautions

Alcoholism (active), cataracts (quetiapine) recent or current blood dyscrasias, diabetes mellitus (olanzapine), hepatic function impairment, , angina, hypotension, congestive heart failure, arrhythmias, breast cancer, , history of neuroleptic malignant syndrome, , obesity Parkinson's disease, poorly controlled seizure disorder.

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Concomitant use of CNS depressants
2) Concomitant use of agents that cause EPS (including droperidol, metoclopramide, amoxapine, metyrosine, pimozide, reserpine)
3) Concomitant use of hypotension producing agents
4) levodopa
5) Antithyroid agents
6) Drugs that prolong the QT interval

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

RISPERIDONE (RISPERDAL®, RISPERDAL CONSTA®), OLANZAPINE (ZYPREXA®), QUETIAPINE (SEROQUEL®), ZIPRASIDONE (GEODON®), AND ARIPIPRAZOLE (ABILIFY)
- continued

PRECAUTIONS TO CONSIDER - continued

Age-Specific Considerations

Safety and efficacy have not been established in children under the age of 18. Conservative dosing is advised in the elderly.

Side Effects Which Require Medical Attention

1) Anticholinergic effects
2) Acute extrapyramidal side effects (dystonia, pseudo-Parkinsonism)
3) Akathisia
4) Hypotension
5) Rashes, photosensitivity and altered pigmentation
6) Tardive dyskinesia or other late-onset EPS
7) Visual changes
8) Early symptoms of agranulocytosis (fever, sore throat, weakness)
9) Fluctuating vital signs
10) Altered consciousness
11) Galactorrhea (risperidone)
12) Amenorrhea (risperidone)
13) Gynecomastia (risperidone)
14) Hyperglycemia (olanzapine)
15) Weight gain
16) Cataracts (quetiapine)
17) QTc > 500 msec

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test – as clinically indicated
2) BMI measurement – when a new antipsychotic is initiated, at every visit (monthly for inpatients) for 6 months after the new antipsychotic is initiated, and quarterly when the antipsychotic dose is stable.
3) Fasting plasma glucose level or hemoglobin A_{1c} – before initiating a new antipsychotic, then yearly.

   If a patient has significant risk factors for diabetes and for those that are gaining weight – before initiating a new antipsychotic, 4 months after starting an antipsychotic, and then yearly.
4) Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides] – Every 2 years or more often if lipid levels are in the normal range, every 6 months if the LDL level is > 130 mg/dl
5) EKG – before initiating treatment with ziprasidone (Geodon®) and subsequently if the patient demonstrates symptoms (e.g., syncope) associated with QT interval prolongation.

RISPERIDONE (RISPERDAL®, RISPERDAL CONSTA®), OLANZAPINE (ZYPREXA®), QUETIAPINE (SEROQUEL®), ZIPRASIDONE (GEODON®), AND ARIPIPRAZOLE (ABILIFY)
- continued

6) Sexual function inquiry – inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbance yearly

   If a patient is receiving an antipsychotic known to be associated with prolactin elevation, then at each visit (quarterly for inpatients) for the first 12 months after starting an antipsychotic or until the medication dose is stable and then yearly.
7) Prolactin level – if there is evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory yearly.
8) EPS Evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase
9) Tardive dyskinesia evaluation – every 12 months.

   For high risk patients (including the elderly), every 6 months.
10) Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision – yearly
11) Ocular evaluations – yearly for patients older than age 40 years; every 2 years for younger patients

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

SEDATING ANTIHISTAMINES

diphenhydramine HCL (Benadryl®), hydroxyzine HCL (Atarax®)

INDICATIONS

1) Anxiety
2) Aggression and agitation
3) Parkinsonism and other EPS
4) Insomnia

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) Delirium
2) Anticholinergic intoxication

Relative:

1) Nursing mothers
2) Renal impairment
3) Hepatic impairment
4) Elderly, debilitated patients
5) Lower respiratory tract symptoms (asthma)
6) Diseases states where increased anticholinergic activity may complicate disease course (narrow-angle glaucoma, benign prostatic hypertrophy)

Precautions

1) Photosensitivity
2) Respiratory impairment

Pregnancy and Breast-Feeding

FDA Pregnancy Category B (diphenhydramine), Category C (hydroxyzine)

Drug Interactions of Major Significance

1) Concomitant use of monoamine oxidase (MAO) inhibitors

Age-Specific Considerations

1) May cause excitability in children, elderly and persons with developmental disabilities

Side Effects Which Require Medical Attention

1) Worsening confusion or agitation
2) Somnolence
3) Nausea
4) Headache
5) Dizziness or lightheadedness

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

ZALEPLON (SONATA®)

INDICATIONS

1) Short term treatment of insomnia

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly significant hypersensitivity to the medication prescribed

Relative:

None

Precautions

1) Pregnancy/nursing mothers
2) Impaired hepatic function
3) History of alcohol or drug abuse
4) Sleep Apnea

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category C.

Drug interactions of major significance

1) Alcohol or CNS Depressants
2) Cimetidine

Age-Specific considerations

1) Safety and efficacy not established for those under 18 years old.

Side Effects Which Require Medical Attention

1) Ataxia
2) Confusion or disorientation
3) Rash
4) Falling or dizziness
5) Worsening agitation, disinhibition or aggression

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
See medication rule for exceptions (documentation required).

ZOLPIDEM (AMBIEN®)

INDICATIONS

1) Short term treatment of insomnia

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly significant hypersensitivity to the medication prescribed

Relative:

None

Precautions

1) Pregnancy/nursing mothers
2) Impaired hepatic function
3) History of alcohol or drug abuse
4) Sleep Apnea

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category B.

Drug interactions of major significance

1) Alcohol or CNS Depressants

Age-Specific considerations

1) Safety and efficacy not established for those under 18 years old.

Side Effects Which Require Medical Attention

1) Ataxia
2) Confusion or disorientation
3) Rash
4) Falling or dizziness
5) Worsening agitation, disinhibition or aggression

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
See medication rule for exceptions (documentation required).

BETA-BLOCKERS

propranolol (Inderal®), atenolol (Tenormin®), metoprolol (Lopressor®), nadolol (Corgard®)

INDICATIONS

1) Aggressive behavior
2) Performance anxiety
3) Lithium- or valproic acid- induced tremors
4) Akathisia

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) Second and third degree heart block
2) Cardiogenic shock
3) Sinus bradycardia
4) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed

Relative:

1) Impaired pulmonary function (COPD, etc.)
2) Pregnancy/nursing mothers
3) Diabetes mellitus
4) Asthma

Precautions

1) Hyperthyroidism
2) Peripheral vascular disease
3) Diabetes mellitus
4) Hepatic function impairment
5) Myasthenia Gravis
6) Psoriasis
7) Renal function impairment
8) Hyperlipidemia
9) Discontinuation or rapid dose reduction
10) Congestive heart failure

Pregnancy and Breast-Feeding

See relative contraindications. Most beta-blockers are Pregnancy Category B, C, or D.

Drug Interactions of Major Significance

1) Allergy extracts
2) Antidiabetic agents
3) Antihypertensives
4) Sympathominetics
5) Xanthenes (caffeine, theophylline)

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

BETA-BLOCKERS- continued
propranolol (Inderal®), atenolol (Tenormin®), metoprolol (Lopressor®), nadolol (Corgard®)

PRECAUTIONS TO CONSIDER (continued)

Age-Specific Considerations

None

Side Effects Which Require Medical Attention

1) Dizziness
2) Difficulty breathing
3) Edema or swelling
4) Cold hands or feet
5) Tiredness or weakness
6) Nightmares
7) Confusion or disorientation
8) Bradyardia or hypotension

PATIENT MONITORING

Patient Monitoring Parameters

1) EKG (Age 45 or over) - baseline and as clinically indicated
2) Pregnancy Test - as clinically indicated
3) Pulse rate, blood pressure – baseline, prior to each dosage increase, quarterly, and as clinically indicated

Dosing

See TDMHMR Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

CLOMIPRAMINE (ANAFRANIL®)

INDICATIONS

1) Obsessive - compulsive disorder

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Recovery phase of myocardial infarction
3) Pheochromocytoma

Relative:

1) Pregnancy/nursing mothers

Precautions

Alcohol intoxication, bipolar disorder in the absence of a mood stabilizer, recent or current blood dyscrasias, cardiovascular disorders including arrhythmia, diseases states where increased anticholinergic activity may complicate disease course (narrow-angle glaucoma, benign prostatic hypertrophy), heart block and failure, hepatic function impairment, hyperthyroidism, renal failure, diagnosis of a seizure disorder

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category D.

Drug Interactions of Major Significance

1) Concomitant monoamine oxidase inhibitors (furazolidone, procarbazine, selegiline, tranylcypromine, phenelzine, isoniazid)
2) Concomitant use of CNS depressants
3) Cimetidine
4) Concomitant use of medications with anticholinergic effects
5) Noradrenergic anti-hypertensive agents (clonidine, guanabenz, guanadrel, guanethidine)
6) SSRI

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**

Age-Specific Considerations

Not recommended for use in children under age 10, conservative dosing is advised. EKG prior to dosage increase.

Side Effects Which Require Medical Attention

1) Anticholinergic effects
2) Sexual function impairment
3) Seizures
4) Dizziness, lightheadedness or fainting (orthostatic hypotension)
5) Tachycardia greater than 100 beats/min.
6) Jaundice
7) QTc >500 msec

CLOMIPRAMINE (ANAFRANIL®) - continued

PATIENT MONITORING

Patient Monitoring Parameters

1) EKG – baseline and as clinically indicated.
2) Pregnancy test – as clinically indicated.

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

GABAPENTIN (NEURONTIN®)

INDICATIONS

1) Chronic Pain Disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed

Relative:

1) Renal Failure
2) Pregnancy/nursing mothers

Precautions

1) Compromised renal function

Pregnancy and Breast-Feeding

See relative contraindications. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Antacids
2) Cimetidine
3) Oral contraceptives

Age-Specific Considerations

Safety and efficacy in children <12 has not been established

Side Effects Which Require Medical Attention

1) Blurred or double vision
2) Clinically significant weight gain
3) Rhinitis
4) Tremor
5) Nausea, vomiting diarrhea or abdominal discomfort
6) Drowsiness, lethargy
7) Nystagmus

PATIENT MONITORING

Patient Monitoring Parameters

1) Renal Function Test - baseline and as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

NALTREXONE (REVIA®)

INDICATIONS

1) Alcoholism
2) Narcotic addiction
3) Self injurious behavior
4) Eating disorders

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction and similarly severe significant hypersensitivity to medication prescribed
2) Acute hepatitis or liver failure

Relative:

1) Hepatic function impairment
2) Renal impairment

Precautions

1) Pregnancy/nursing mothers

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category C.

Drug Interactions of Major Significance

Concomitant opioid-containing products

Age-Specific Considerations

Safety and efficacy not established for those under 18 years old.

Side Effects Which Require Medical Attention

1) Hepatoxocity
2) Opioid withdrawal
3) Nausea
4) Headache, chronic or recurrent
5) Dizziness or lightheadedness

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy Test - as clinically indicated
2) Hepatic Function Panel - baseline and as clinically indicated

Dosing

See TDMHMR Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.

STIMULANTS

methylphenidate (Ritalin®, Concerta™), dextroamphetamine (Dexedrine®), dextroamphetamine/amphetamine mixture (Adderall®)

INDICATIONS

1) Attention deficit disorder, with or without hyperactivity
2) Narcolepsy (methylphenidate; dextroamphetamine; dextroamphetamine/amphetamine mixture)
3) Severe treatment resistant depression or depression in medically compromised patients

PRECAUTIONS TO CONSIDER

Contraindications

Absolute

1) History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
2) Severe depression in children (methylphenidate)

Relative

1) Tourette's syndrome or other motor or vocal tics
2) Pre-existing psychosis
3) Hypertension
4) Cardiovascular disease (dextroamphetamine, dextroamphetamine/amphetamine mixture)
5) Glaucoma (dextroamphetamine, methylphenidate, dextroamphetamine/amphetamine mixture)
6) History of drug abuse/dependence
7) Hyperthyroidism
8) Pregnant or nursing mothers

Precautions

1) Family history of tics
2) Epilepsy or other seizure history

Pregnancy and Breast-Feeding

See relative contraindications. Stimulant either are FDA Pregnancy Category C or unknown.

Drug Interactions of Major Significance

1) Monoamine oxidase (MAO) inhibitors
2) Stimulants/Sympathomimetics
3) Beta-Blockers (amphetamine)
4) Antidepressants (amphetamine)
5) Digitalis glycosides (amphetamine)
6) Meperidine (amphetamine)
7) Thyroid hormones (amphetamine)

STIMULANTS - continued

methylphenidate (Ritalin®, Concerta™), dextroamphetamine (Dexedrine®), dextroamphetamine/amphetamine mixture (Adderall®)

PRECAUTIONS TO CONSIDER (continued)

Age-Specific Considerations

None

Side Effects Which Require Medical Attention

1) Hypertension
2) Tachycardia
3) Weight loss
4) Abnormal motor movements or tics
5) Psychosis
6) Hyperthermia
7) Irritability or nervousness
8) Insomnia
9) Chest pain

PATIENT MONITORING

Patient Monitoring Parameters

1) Height and weight in children (baseline and as clinically indicated)

Dosing

See TDMHMR Drug Formulary for dosage guidelines

Exceptions to maximum dosage must be justified as per medication rule.

DULOXETINE (CYMBALTA®)

INDICATIONS

1) Depressive Disorders
2) Chronic pain

PRECAUTIONS TO CONSIDER

Contraindications

Absolute:

1) History of anaphylactic reaction or similarly severe significant hypersensitivity reaction to the medication prescribed
2) Use of monoamine oxidase inhibitor within 14 days
3) Uncontrolled narrow-angle glaucoma

Relative:

1) Severe renal function impairment (creatinine clearance < 30mL/min)
2) Severe hepatic disease or substantial alcohol use
3) Pregnancy/nursing mothers

Precautions

Impaired renal function, impaired hepatic function, alcohol use, bipolar disorder in the absence of a mood stabilizer, history of seizure disorder, hypertension, tachycardia

Pregnancy and Breast-Feeding

See precautions. FDA Pregnancy Category C.

Drug Interactions of Major Significance

1) Concurrent administration of MAOIs, or within 14 days of MAOI
2) Alcohol
3) Thioridazine

SEE TABLE A: **Cytochrome P450 Drug Metabolism/Inhibition**
Duloxetine is a substrate of 1A2 and 2D6
Duloxetine is a moderate inhibitor of 2D6

Age-Specific Considerations

Safety and efficiency have not been established in the pediatric population. No difference in safety or efficacy observed in patients 65 years of age and over.

Side Effects Which Require Medical Attention

1) Elevated liver enzymes
2) Hypertension or Hypotension
3) Tachycardia
4) Sexual dysfunction
5) Increased suicidality
6) Seizure
7) Severe GI distress
8) Hypersensitivity reaction

DULOXETINE (CYMBALTA®) - *continued*

PATIENT MONITORING

Patient Monitoring Parameters

1) Pregnancy test - as clinically indicated
2) Blood pressure prior to initiating treatment, during dosage titration, and as clinically indicated
3) Monitor for emergence of suicidal ideation or behavior
4) Hepatic function testing - baseline and as clinically indicated

Dosing

See DSHS/DADS Drug Formulary for dosage guidelines.
Exceptions to maximum dosage must be justified as per medication rule.