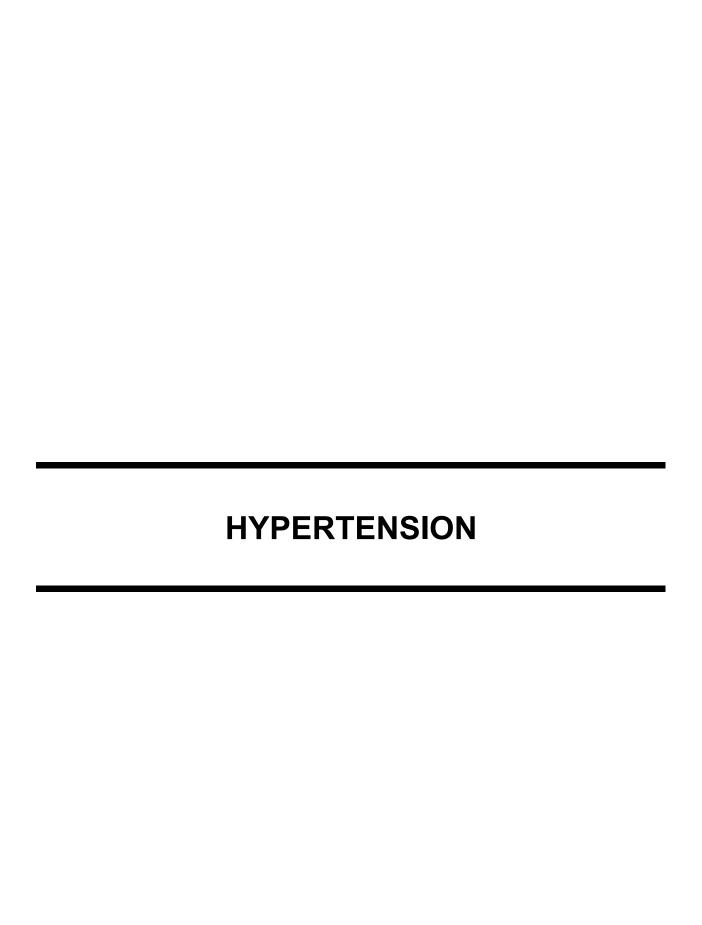


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Please note that the *Clinician Notes* are extracted from the more comprehensive *Clinical Treatment Guidelines*. The focus of the *Clinician Notes* is more narrowly drawn. For this reason, not all appendices may be found in this document, but rather, only key clinical appendices. To view all appendices, as well as more inclusive textual material on a particular subject matter, please refer to the appropriate *Clinical Treatment Guideline*.



## Risk Stratifications for Treating Hypertension with Lifestyle Modifications and Drug Therapy

Blood Pressure Stages (mm Hg)	Risk Group A (no risk factors, no TOD/CCD)**	Risk Group B (at least 1 risk factor, no DM no TOD/CCD)	Risk Group C (TOD/CCD and/or diabetes)	
High-normal (130-139/85-89)	Lifestyle Modification	Lifestyle Modification	Drug therapy	
Stage 1 (140-159/90-99)	Lifestyle Modification (Up to 12 months)	Lifestyle Modification (Up to 6 mon	Drug therapy	
Stage 2 and 3 (≥ 160/≥ 100)	Drug therapy	Drug therapy	Drug therapy	

<sup>\*</sup> Lifestyle modification should be adjunctive therapy for all inmates recommended for pharmacologic therapy.

Source: Adapted from the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, *Archives of Internal Medicine*, Vol. 157, November, 1997.

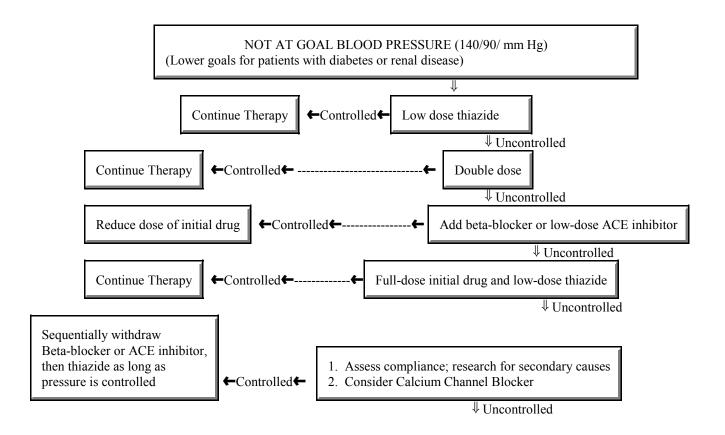
<sup>\*\*</sup>TOD/CCD indicates target organ disease/clinical cardiovascular disease, including heart disease, stroke or transient ischemic attack, nephropathy, peripheral arterial disease, and retinopathy.

# **Drug Treatment Considerations for Hypertension**

INMATE CHARACTERISTICS	PREFERRED DRUGS	NOT PREFERRED (May Have Adverse Effects)
Demographic characteristics Age over 65	Thiazide diuretic, Ca-channel blocker, ACE inhibitor	Alpha 2-receptor agonist
African-American	Thiazide diuretic	Beta-blocker, ACE inhibitor
Caucasian	Beta Blocker, ACE Inhibitor	
Concomitant diseases Coronary heart disease	Beta Blocker, calcium-channel blocker	Direct vasodilator
Post-myocardial infarction	Beta Blocker ACE inhibitor/with systol. dysfunc.	
Congestive heart failure	ACE inhibitor, direct vasodilator, thiazide diuretic	B-blocker, Ca-channel blocker
Supraventricular tachyarrhythmias	Verapamil, Beta Blocker	
Bradycardia, sick sinus		B- blocker, diltiazem, verapamil
Cerebrovascular disease		Alpha2-receptor agonist
Dyslipidemia	Alpha-blocker	Diuretics (high dose), B-blocker (non-ISA)
Migraine	Beta-blocker	
History of depression		Alpha 2-receptor agonist, reserpine, Beta-blocker
Peripheral vascular disease	ACE inhibitor, Ca-channel Blocker, Alpha blocker	B-blocker
Renal insufficiency	Loop diuretic, minoxidil, ACE inhibitor	Thiazide diuretic, Potassium-sparing agent
Collagen disease	ACE inhibitor, Ca-channel blocker	Methyldopa, hydralazine
Diabetes mellitus	ACE inhibitor, Alpha 2-receptor agonist, Alpha-blocker	Thiazide diuretic, Beta-blocker
Gout		Diuretic
Asthma		B-blocker
Osteoporosis	Diuretic	

## **Treatment Strategies for Hypertension**

Begin or continue lifestyle modifications



- 1. Add another anti-adrenergic agent (e.g. clonidine), peripheral vasodilator (e.g., hydralazine), or Calcium Channel Blocker (if not initially used), or combinations thereof.
- 2. When controlled, sequentially withdraw drugs initially used, as long as pressure is controlled.

#### (Adapted and modified from JNC VI)

NOTE: In the absence of contraindications, or the presence of a co-morbid condition such as angina, all newly-diagnosed hypertensive inmates should be started on a low dose thiazide, such as 12.5 - 25 mg of hydrochlorothiazide. Calcium antagonists have no clear advantage over thiazides in uncomplicated hypertension. Inmate without co-morbid conditions or contraindications to thiazides should be converted from calcium antagonists such as amlodipine to a thiazide, following the above algorithm to assess response.

#### **Causes of Treatment Failure in Hypertension**

#### 1. Nonadherence to Therapy:

- a. Inmate concerned about confidentiality
- b. Inadequate inmate education
- c. Lack of involvement of the inmate in the treatment plan
- d. Adverse effects of medication
- e. Organic brain syndrome

#### 2. Pseudoresistance:

- a. "White-coat hypertension" or clinic elevations
- b. Pseudohypertension in older inmates
- c. Incorrect cuff size (use of regular cuff on large arm)

#### 3. Drug related causes:

- a. Doses too low
- b. Wrong type of drug
- c. Inappropriate combinations
- d. Drug interactions and actions including NSAID's, oral contraceptives, sympathomimetics, antidepressants, adrenal steroids, nasal decongestants, licorice (as may be found in chewing tobacco), cocaine, cyclosporine, tacrolimus, erythropoietin

#### 4. Associated Conditions:

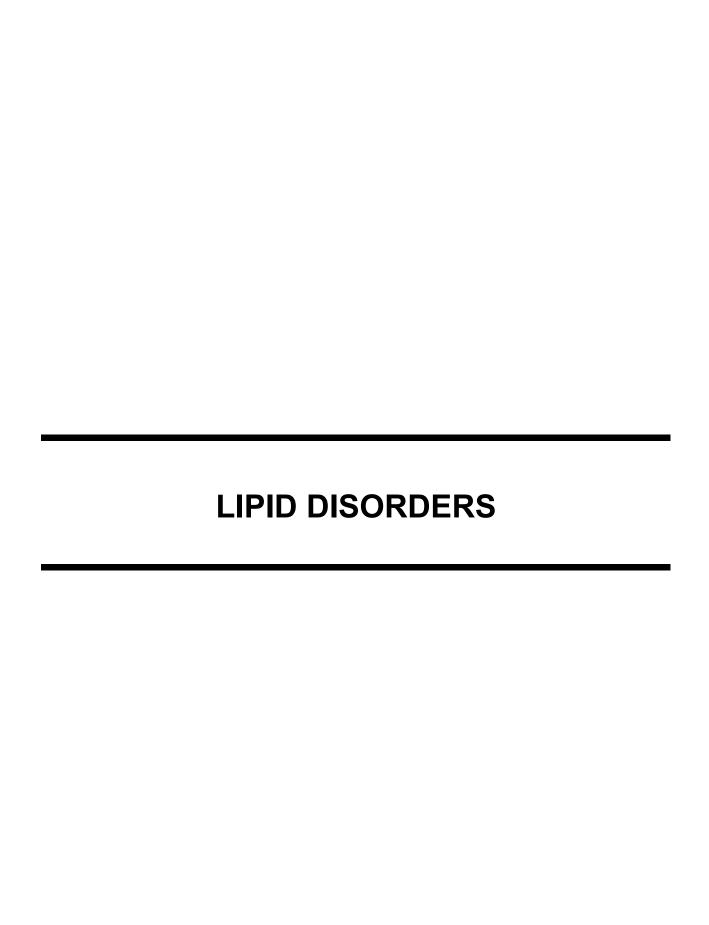
- a. Smoking
- b. Increasing obesity
- c. Excessive alcohol use
- d. Sleep apnea

#### 5. Volume Overload:

- a. Excessive salt intake
- b. Progressive renal damage (nephrosclerosis)
- c. Inadequate diuretic therapy
- d. Fluid retention from reduction of blood pressure

#### 6. Secondary Hypertension:

- a. Renal insufficiency
- b. Renovascular hypertension
- c. Pheochromocytoma
- d. Primary aldosteronism



# FRAMINGHAM SCORE FOR MEN (ESTIMATING 10-YEAR RISK FOR CHD)

Age, y	Points
20-34	-9
35-39	-4
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	11
70-74	12
75-79	13

Total			Points		
Total Cholesterol, mg/dL	Age 20-39 y	Age 40-49 y	Age 50-59 y	Age 60-69 y	Age 70-79 y
<160	0	0	0	0	0
160-199	4	3	2	1	0
200-239	7	5	3	1	0
240-279	9	6	4	2	1
≥280	11	8	5	3	1

Systolic BP, mm Hg	If Untreated	If Treated
<120	0	0
120-129	0	1
130-139	1	2
140-159	1	2
≥160	2	3

### **Points**

	Age 20-39 y	Age 40-49 y	Age 50-59 y	Age 60-69 y	Age 70-79 y
Nonsmoker	0	0	0	0	0
Smoker	8	5	3	1	1

HDL, mg/dL	Points
≥60	-1
50-59	0
40-49	1
<40	2

Point Total	10-Year Risk, %
<0	<1
0	1
1	1
2	1
3	1
4	1
5	2
6	2
0 1 2 3 4 5 6 7	3
8	1 2 2 3 4 5
9	5
10	6
11	8
12	10
13	12
14	16
15	20
16	25
≥17	≥30

# FRAMINGHAM SCORE FOR WOMEN (ESTIMATING 10-YEAR RISK FOR CHD)

Age, y	Points
20-34	-7
35-39	-3
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	12
70-74	14
75-79	16

Total			Points		
Total Cholesterol, mg/dL	Age 20-39 y	Age 40-49 y	Age 50-59 y	Age 60-69 y	Age 70-79 y
<160	0	0	0	0	0
160-199	4	3	2	1	1
200-239	8	6	4	2	1
240-279	11	8	5	3	2
≥280	13	10	7	4	2

Systolic BP, mm Hg	If Untreated	If Treated
<120	0	0
120-129	1	3
130-139	2	4
140-159	3	5
≥160	4	6

	Points				
	Age	Age	Age	Age	Age
	20-39 y	40-49 y	50-59 y	60-69 y	70-79 y
Nonsmoker	0	0	0	0	0
Smoker	9	7	4	2	

HDL, mg/dL	Points
≥60	-1
50-59	0
40-49	1
<40	2

Point Total	10-Year Risk, %		
<9	<1		
9	1		
10	1		
11	1		
12	1		
13	2		
14	1 2 2 3		
15	3		
16	4 5		
17	5		
18	6		
19	8		
20	11		
21	14		
22	17		
23	22		
24	27		
≥25	≥30		

## LDL CHOLESTEROL GOALS AND CUT POINTS FOR TREATMENT\*

Risk Category	LDL Goal (mg/dL)	LDL Level for Therapeutic Lifestyle Changes (mg/dL)	LDL Level at Which to Consider Drug Therapy (mg/dL)
High Risk CHD or CHD risk equivalents (10-year risk >20%)	<100	≥100	≥130 (100-129: drug optional)**
Moderate Risk (a) 2+ Risk factors (10-year risk 10- 20%)	<130	≥130	≥130
Moderate Risk (b) 2+ Risk factors (10-year risk < 10%)	<130	≥130	≥160
Low Risk 0-1 Risk factor	<160	≥160	≥190 (160-189: drug optional)

<sup>\*</sup>Adapted from NCEP (ATP III), National Institutes of Health, 2001

<sup>\*\*</sup>Some experts recommend use of LDL-lowering drugs in this category if an LDL cholesterol level of < 100 mg/dL cannot be attained by therapeutic lifestyle changes. Other experts prefer medications that primarily modify triglycerides and HDL cholesterol such as nicotinic acid and fibrate. Deferring drug treatment is also acceptable on a case by case basis.

# PATIENT GUIDE TO SELECTING A FAT/CHOLESTEROL CONTROLLED DIET

	Choose	Go Easy On	Decrease
Meat, Poultry and Fish (up to 6 oz per day)	<ul> <li>- Lean cuts of meat with fat trimmed</li> <li>- Baked unbreaded poultry without skin</li> <li>- Baked, unbreaded fish</li> <li>- Canned chicken, tuna, or sardines (water packed or rinsed)</li> <li>- Dried beans and peas as a meat substitute</li> </ul>		<ul> <li>Fried meat</li> <li>Breaded meat</li> <li>Organ meats, like liver</li> <li>Sausage</li> <li>Bacon</li> <li>Lunch meats</li> <li>Hot dogs</li> <li>Fatty cuts of meat brisket, ribs</li> </ul>
Eggs (no more than 4 egg yolks per week)	<ul><li>Egg whites</li><li>Cholesterol-free egg substitutes</li></ul>		- Egg yolks
Dairy Products (at least 2 servings per day)	<ul> <li>Skim milk,</li> <li>1% milk, low fat buttermilk, or nonfat powdered milk</li> <li>Low-fat yogurt (plain and frozen)</li> <li>Low-fat cottage cheese</li> </ul>	<ul><li>- 2% milk</li><li>- Yogurt</li><li>- Part-skim cheeses like mozzarella, or string cheese</li></ul>	- Whole milk cream, half-and-half, most nondairy creamers and products, real or nondairy whipped cream - Cream cheese - Sour cream - High-fat cheeses like Swiss, Cheddar, American
Fats and Oils (up to 6 teaspoonfuls per day)	- Low fat dressings	-Unsaturated vegetable oils: olive, peanut, canola, safflower, soybean - Margarine - Nuts/seeds - Peanut butter - Olives - Avocados - Mayonnaise - salad dressings	<ul> <li>Butter, lard, bacon fat</li> <li>Coconut oil</li> <li>Palm oil</li> <li>Palm kernel oil</li> <li>Bacon</li> <li>Hydrogenated fat or oil</li> </ul>
Fruits and Vegetables (2-4 servings of fruit and 3-5 servings of vegetables per day)	- Fresh, frozen, canned, or dried fruits and vegetables		<ul><li>Vegetables prepared in butter, cream, or sauce</li><li>Fried vegetables</li></ul>

	Choose	Go Easy On	Decrease
Breads, Pasta, Cereals, Rice, Dried Beans, and Peas (6 to 11 servings per day)	- Breads, like white, whole wheat, rye, pita, pumpernickel - Bagels, English muffins, sandwich buns, rice cakes - Low-fat crackers, like matzo, bread sticks, rye krisp, saltines, zwieback - Rice, pasta, dried beans and peas prepared without fat	<ul><li>- Pancakes</li><li>- Waffles</li><li>- Biscuits</li><li>- Cornbread</li></ul>	<ul> <li>Croissants, butter rolls,</li> <li>sweet rolls, Danish pastry,</li> <li>doughnuts</li> <li>Cheese or butter crackers</li> <li>Granola-type cereals</li> <li>Pasta and rice prepared</li> <li>with cream, butter, or</li> <li>cheese sauce</li> </ul>
Sweets and Snacks (avoid too many sweets)	- Fat-free desserts, like sherbet, Italian ice, frozen yogurt, popsicles - Fat-free cakes, like angel food cake - Fat-free candy, like jelly beans and hard candy - Very low-fat snacks, like popcorn, pretzels - Non-fat beverages, like carbonated drinks, juices, tea, coffee	- Low-fat frozen desserts, like ice milk - Low-fat cookies, like fig bars, ginger snaps, animal crackers, graham crackers	- High-fat frozen desserts, like ice cream - High-fat cakes - pound cake and frosted cakes - Pastries and cookies - Most candy, like chocolate bars and candies that contain chocolate - Potato chips, corn chips, and other snack chips - Buttered popcorn - High-fat beverages like milkshakes and egg nog

## **Label Ingredients**

To avoid too much fat or saturated fat, read the ingredient labels and go easy on products that list any fat or oil first, or that list many fat and oil ingredients. (Ingredients are listed in order of how much is in the product. For example, if lard or coconut oil is listed as one of the first three ingredients, that food product has a very high fat content).

#### WEIGHT CONTROL INFORMATION FOR INMATES

- Cutting down on calorie intake (or eating less food) is the first step to losing weight. One pound of body fat is equal to 3,500 calories. A person must reduce calorie intake 500 calories per day to lose one pound in a week.
- Write down what you eat each day. This record will help you identify the amount of calories you are eating and potential "problem foods."
- Note your pattern of eating and the time of day you are likely to overeat. Try and maintain a regular eating pattern. Avoid skipping meals.
- Ask the server to give you small portions. Leave off the gravy and high fat sauces.
- Avoid sweetened beverages such as lemonade, koolade, punch, and soft drinks. Fruit juices, although they contain vitamins, should be limited also. Diet drinks are an alternative choice.
- Limit the number of desserts on your tray. Cakes, pies, ice cream, and cookies are concentrated sources of calories. If you don't put them on your tray, you won't eat them. Consider sugar substitutes to sweeten food.
- Remove the breading/skin from fried meats. Most of the fat is found in the skin or absorbed in the outer breaded layer of fried foods. Avoid fried foods such as onion rings and fried potatoes.
- Try foods without adding butter, margarine, cream, or sugar.
- Don't add creamy salad dressings to your salad (1 tablespoon of mayonnaise type salad dressing = 100 calories).
- Drink water with meals and between meals. Drink you tea or coffee black.
- Eat slowly. Eat your salad first.
- Learn to stop eating before you are "full" or "stuffed." The slight hunger you feel will disappear about one-half hour after mealtime.
- Minimize idle time through recreational and work activities. Establish a regular schedule for exercise as much as possible so it becomes routine.
- Restrict your commissary items. What you don't buy, you can't eat. Avoid buying concentrated sweets, high fat crackers, cookies, and snack items.
- **NOTE**: If you eat just 100 extra calories a day, you will gain 10 pounds in the course of a year. If you eat just 100 fewer calories a day, you will lose 10 pounds in the course of a year. Small changes in your daily eating habits make a big difference!

## DRUG TREATMENT OPTIONS FOR LIPID DISORDERS

	Medication	Dosage	Labs	Toxicities	Comments
tins")	lovastatin (Mevacor <sup>TM</sup> )	20-80 mg/day	ALT/AST (base-line & q6w x 2, repeat p dose ↑ & q6m	rhabdomyolysis hepatotoxicity	- contraindicated in active liver disease, pregnancy, unexplained elevated LFT's  - ↑ risk rhabdomyolysis when administered w/ fibrates or niacin  - lower dose if creatinine clearance ≤ 30 L/min
ors ("Statins")	simvastatin (Zocor <sup>TM</sup> )	line and q6m) hepatotoxicity or niacin	- ↑ risk rhabdomyolysis when administered w/ fibrates or niacin - lower dose if renal insufficiency is severe		
Reductase Inhibitors	fluvastatin (Lescol <sup>TM</sup> )  20-80 mg/day	20-80 mg/day	ALT/AST (baseline & @ 12 weeks, repeat p dose †, & q6m)	rhabdomyolysis hepatotoxicity pancreatitis hypersensitivity	- ↑ risk rhabdomyolysis when administered w/ fibrates or niacin - no adjustment for renal insufficiency
C0A -	pravastatin (Pravachol <sup>TM</sup> )	10-40 mg/day	ALT/AST (baseline and dose ↑, & q6m	rhabdomyolysis hepatotoxicity	- ↑ risk rhabdomyolysis when administered w/ fibrates or niacin     - lower dose if creatinine clearance is ≤ 60 L/min
HMG	atorvastatin (Lipitor™)	10-80 mg/day	ALT/AST (baseline & @ 12 weeks, repeat p dose †, & q6m)	rhabdomyolysis hepatotoxicity	- ↑ risk rhabdomyolysis when administered w/ fibrates or niacin     - no adjustment for renal insufficiency

Only one "Statin" at a time should be used, and titrated to the target LDL, side effects, or maximum dose before switching statins.

<u>Statin Drug Interactions</u>: cyclosporine, itraconazole, ketoconazole, gemfibrozil, niacin, erythromycin, clarithromycin, verapamil, diltiazem, nefazodone, fluvoxamine, and protease inhibitors (except pravastatin).

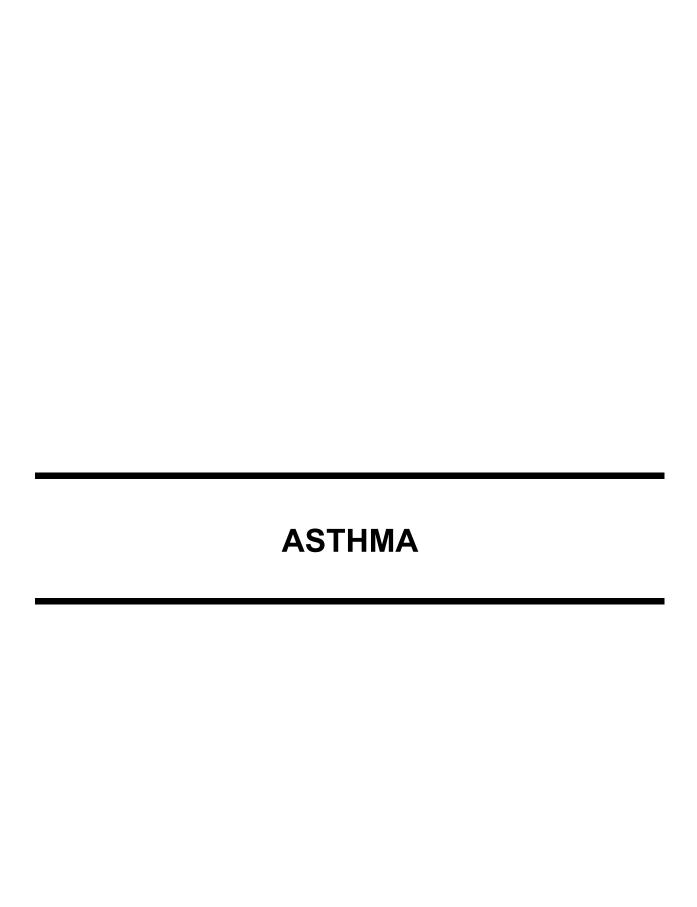
	Medication	Dosage	Labs	Toxicities	Comments
questrants	cholestyramine (LoCholest <sup>TM</sup> , Questran <sup>TM</sup> , Prevalite <sup>TM</sup> )	8-24 gm/day	LDL cholesterol and TG levels	fecal impaction	- dosed once to six times daily - take before meals - do not consume dry powder - may cause constipation - may prevent absorption of folic acid and fat soluble vitamins (A-D-E-K)
Bile Acid Sequestrants	colestipol (Colestid <sup>TM</sup> )	10-30 gm/day	LDL cholesterol and TG levels	fecal impaction GI bleed	- dosed once or twice daily - do not consume dry powder - do not crush, cut, or chew - may cause constipation - may prevent absorption of folic acid and fat soluble vitamins (A-D-E-K)
	colesevelam (Welchol™)	2.5-4.375 gm/day	LDL cholesterol and TG levels	none reported	- take with water and meals - dosed once or twice daily - monotherapy or combination with HMG-CoARIs - may cause constipation - may prevent absorption of folic acid and fat soluble vitamins (A-D-E-K)
Niacin	niacin	1.5-6 gm/day	ALT/AST (baseline, q6-12w x 1 year, then q6m)  Uric acid/fasting glucose - baseline, at 6 wks/annually	arrhythmias hepatotoxicity peptic ulcer fulminant hepatic necrosis	- contraindicated in active peptic ulcer, alcoholism, unexplained ↑ LFT's, severe liver dysfunction  - use with caution w/ hx of PUD, DM, gout, ↓ renal fx  - ASA ½ hour before administration to ↓ flushing take with meals

	Medication	Dosage	Labs	Toxicities	Comments
	clofibrate (Atromid-S <sup>TM</sup> )	2000 mg/day	monitor: - serum lipids - CBC - LFT's	anemia leukopenia hepatotoxicity cholelithiasis pancreatitis	<ul> <li>possible myalgia, myositis, myopathy, and rhabdomyolysis (w or w/o ↑ CPK)</li> <li>↑ risk rhabdomyolysis when administered w/ HMG CoARIs</li> <li>contraindicated in significant hepatic or renal dysfunction, primary biliary cirrhosis, pregnancy, lactation</li> <li>uncertain risk of malignancy</li> <li>-reserve for inmates refractory to other tx strategies</li> </ul>
	gemfibrozil (Lopid™)	1200 mg/day	monitor: - serum lipids - CBC - LFT's - blood glucose	myositis myopathy thrombocytopenia rhabdomyolysis hepatotoxicity pancreatitis cholelithiasis hypersensitivity cholestatic jaundice	- † risk rhabdomyolysis when administered w/ HMG CoARIs  contraindicated in hepatic or severe renal dysfunction, primary biliary cirrhosis, preexisting gallbladder disease  - take ½ hour before morning & evening meals
	fenofibrate (Tricor™)	200 mg/day	monitor: - serum lipids - CBC	pancreatitis cholelithiasis rhabdomyolysis hepatotoxicity hypersensitivity myopathy toxic epidermal necrolysis	- ↑ risk rhabdomyolysis when administered w/ HMG CoARIs     - contraindicated in hepatic or severe renal dysfunction, primary biliary cirrhosis, unexplained persistent liver function abnormality; preexisting gallbladder disease     - take with meals

# COMPARISON OF HMG-CoA INHIBITORS (STATINS)

Drug	Equiv. Dose	Effect on Lipids (% change from b				Drug Interactions
Atorvastatin <i>Lipitor</i>	10 mg	20 mg -41-46	<u>TC</u> -27-29 -32-35 -37-39 -42-45	TG -13-19 -20-26 -29-32 -25-37	HDL +4-6 +5-9 +5-6 +5	- interacts with drugs metabolized by CYP3A4 enzyme system*
Fluvastatin Lescol	40 mg	20 mg -17-22 40 mg -23-27 80 mg -33-36	-13 -18-22 -27	-10-20	+1 +4-8 +4-8	<ul><li>metabolized by CYP2C9</li><li>can increase cyclosporine and phenytoin levels</li></ul>
Lovastatin Mevacor	20 mg		-18-22 -23-27 -32-36	-12-13 -2-10 -13-15	+6-8 +5 +4-8	- interacts with drugs metabolized by CYP3A4 enzyme system*
Pravastatin Pravachol	20 mg	10 mg -19-22 20 mg -24-32 40 mg -33-34	-13-16 -18-24 -24-27	-3-15 -11-15 -10-24	+7-10 +2-3 +6-12	- not metabolized by cytochrome P450, less likely to have drug interactions
Simvastatin Zocor	10 mg	10 mg -28-30 20 mg -35-38 40 mg -40-41 80 mg -47-48	-21-23 -26-28 -30-31 -36	-12-15 -15-17 -15-18 -24	+7-12 +5-8 +9-10 +8	- metabolized by CYP3A4 enzyme system*

<sup>\*</sup>Erythromycin, clarithromycin, azole antifungals, verapamil, diltiazem, nefazodone, fluvoxamine, cyclosporine, protease inhibitors. (Adapted from *Pharmacist's Letter*, January 2002, *Pharmacotherapy* 2000;20(7):819-822, *Circulation* 2000;101:207-213)



# **Classification of Asthma Severity**

Step	Symptoms	Nighttime Symptoms	Pulmonary Function
Step # 1 Mild Intermittent	*Symptoms < 2 times a week  *Asymptomatic & normal PEF between exacerbations  *Exacerbations brief (from a few hours to a few days); intensity may vary	< 2 times a month	*FEV1 or PEF > 80% of predicted  *PEF variability < 20 %
Step # 2 Mild Persistent	*Symptoms 2 times a week but < 1 time a day  *Exacerbations may affect activity	> 2 times a month	*FEV1 or PEF > 80% of predicted  *PEF variability < 20%
Step # 3 Moderate Persistent	*Daily symptoms  *Daily use of inhaled short- acting beta 2-agonist  *Exacerbations affect activity  *Exacerbations > 2 times a week; may last days	> 1 time a week	*FEV1 or PEF > 50% and < 80% predicted  *PEF variability > 30%
Step # 4 Severe Persistent	*Continual symptoms  *Limited physical activity  *Frequent exacerbations	Frequent	*FEV1 or PEF < 50% of predicted  *PEF variability > 30 %

PEF variability = Morning peak flow X 100 or Pre-bronchodilator PEF X 100 Afternoon peak flow Post-bronchodilator PEF X 100

#### Asthma Medication Dosage Guidelines

#### Quick-Relief Medications

1. Short-acting inhaled beta<sub>2</sub>-agonists

Albuterol MDI, 90 mcg/puff, 200 puffs per canister 2 puffs 5 minutes prior to exercise 2 puffs t.i.d.-q.i.d. PRN
-May double dose for mild exacerbations

#### Albuterol Nebulizer 5 mg/ml (0.5%)

1.25-5 mg (0.25-1 cc) in 3 cc of saline every 4 to 8 hours

-May double dose for mild exacerbations -May mix with cromolyn or ipratropium nebulizer solutions.

**Caution:** In the presence of hyperthyroidism, diabetes, cardiovascular disorders, and hypertension, beta<sub>2</sub>-agonists may decrease serum K+ level. Decreased effect by concomitant use of beta blocker medications. Increased effect and duration with concomitant use of ipratropium.

2. Anticholinergic Agents

Ipratropium MDI, 18 mcg/puff, 200 puffs per canister
 2-3 puffs every 6 hours

Ipratropium Nebulizer 0.25 mg/ml (0.025%)
 0.25-0.5 mg every six hours

3. Systemic Corticosteroids

Prednisone, 1, 2.5, 5, 10, 20, and 25 mg tabs
-Short course "burst" 40 -60 mg/day in single or
divided doses for 3 -10 days. A burst should be
continued until the inmate achieves 80% of personal
best PEF, or until symptoms resolve. Tapering of dose
following improvement will not prevent relapse, so the
drug may simply be discontinued to minimize the total
number of days of exogenous steroid.

#### Asthma Medication Dosage Guidelines

#### Long-Term Control Medications

1. Systemic Corticosteroids

**Prednisone**, 1, 2.5, 5, 10, 20, and 25 mg tablets or 5 mg/cc solution.

7.5 - 60 mg daily in single or divided doses as needed for control.

-For long-term treatment of severe persistent asthma, administer single dose in A.M. either daily or on alternate days (alternate day therapy may produce less adrenal suppression). Short courses or "bursts" may be indicated if condition deteriorates off steroids, or for establishing control when initiating therapy.

2. Mast Cell Stabilizers

Cromolyn MDI, 1 mg/puff 2-4 puffs tid-qid

Nedocromil MDI, 1.75 mg/puff 2-4 puffs bid-qid

3. Long-Acting Beta, -Agonists

Salmeterol MDI, 21 mcg/puff 2 puffs q 12 hours

4. Methylxanthines

Theophylline sustained release tabs

200-300 mg bid-tid

-Titrate to serum level between 5-15 mcg/dL. Levels above 15 mcg/dL rarely result in clinical improvement, but do increase risk of toxicity.

#### 5. Leukotriene modifiers

-Should not be used for the treatment of acute asthma. These medications need to be taken daily, even during periods of worsening asthma.

#### Zafirlukast 20 mg tablets

1 tablet BID, one hour before or two hours after meals. -Use with extreme caution if alcoholic liver cirrhosis is present. Caution with concomitant use of erythromycin, theophylline. Increases effects of aspirin and warfarin.

# Zileuton 300 and 600 mg tablets 600mg QID, with or without food

-Use with extreme caution in the presence of liver disease and never initiate therapy if liver transaminases are greater than three time normal; monitor liver transaminases at baseline before initiating treatment and periodically thereafter.

#### Montelukast 10 mg tablets

10 mg/day

-Rarely may present a clinical picture of systemic eosinophilia and possibly vasculitis similar to Churg-Strauss syndrome.

# Dosage Guidelines for Inhaled Anti-Inflammatory Agents

Agent	Low dose	Medium dose	High dose
Corticosteroids Beclomethasone (Beclovent, 42 and 84 mcg per	2 puffs BID to 3 puffs QID at 42 mcg per puff;	3 to 5 puffs QID at 42 mcg per puff;	6 to 8 puffs QID at 42 mcg per puff;
puff; Vanceril, 84 mcg per puff)	1 puff BID to 2 puffs TID at 84 mcg per puff	2 to 3 puffs TID at 84 mcg per puff	3 puffs QID at 84 mcg per puff (exceeds PDR maximum recommended dosage of 840 mcg per day)
Triamcinolone acetonide (Azmacort): 100 mcg per puff	2 puffs BID to 3 puffs TID (Some patients may do well with BID dosing)	3 puffs TID to 4 puffs QID	5 or more puffs QID (exceeds PDR maximum recommended dosage of 1200 mcg per day)
Flunisolide (Aerobid): 250 mcg per puff	1 to 2 puffs BID	2 to 4 puffs BID	5 puffs BID (exceeds PDR recommended dosage of 2 mg per day)
Fluticasone (Flovent): 44 mcg, 110 mcg and 220 mcg per puff	2 to 6 puffs BID at 44 mcg per puff; or 2 puffs BID at 110 mcg per puff	2 to 6 puffs BID at 110 mcg per puff	7 to 8 puffs BID at 110 mcg per puff; or 4 puffs BID at 220 mcg per puff
Budesonide (Pulmicort): 200 mcg per puff	1 or 2 puffs BID	2 or 3 puffs BID	4 puffs BID
Mast Cell Stabilizers Cromolyn sodium MDI (Intal): 800 mg per puff	2 puffs TID	3 to 4 puffs TID, or 3 puffs QID	4 puffs QID
Nedocromil (Tilade): 1.75 mg per puff	2 puffs BID to TID	3 to 4 puffs TID	4 puffs QID

# **Classifying the Severity of Asthma Exacerbations**

SYMPTOMS	Mild	Moderate	Severe	Respiratory Arrest Imminent
Breathlessness	*While walking *Can lie down	*Walking *Prefers Sitting	*While at rest *Sits upright	
Talks in:	*Sentences	*Phrases	*Words	
Alertness	*May be agitated	*Usually agitated	*Usually Agitated	*Drowsy or confused
SIGNS	Mild	Moderate	Severe	Respiratory Arrest Imminent
Respiratory Rate	Increased	Increased	Often > 30 min	
Use of accessory muscles, suprasternal retraction	*Usually not	*Commonly	*Usually	*Paradoxical thoraco-abdominal movement
Wheeze	*Moderate, often only end expiratory	*Loud throughout exhalation	*Usually loud; throughout inhalation and exhalation	*Absence of wheeze
Pulse/minute	*< 100	*100-120	* > 120	Bradycardia
Pulsus Paradoxus	*Absent < 10 mmHg	*May be present 10-25 mmHg	*Often present > 25 mmHg	Absence suggest respiratory muscle fatigue
FUNCTIONAL ASSESSMENT	Mild	Moderate	Severe	Respiratory Arrest Imminent
PEF predicted or % of personal best	* > 80%	*Approx. 50-80 %, or response lasts < 2 hours	* < 50 % predicted or personal best	*Note: performing peak flow during severe attacks may provoke laryngospasm
PaO2 (on air) and/or	*Normal	* > 60 mmHg	* < 60 mmHg *possible cyanosis	
PCO2	* < 42 mmHg	* < 42 mmHg	* > 42 mmHg *possible respiratory failure	
SaO2(on air) at sea level	*>95%	* 91-95%	* < 91%	



## TREATMENT GOALS FOR NONPREGNANT INMATES WITH DIABETES\*

	Normal	Goal	Intervention
Plasma values			
Average preprandial glucose (mg/dl)	<110	90-130	<90/>150
Average bedtime glucose (mg/dl)	<120	110-150	<110/>180
Whole blood values			
Average preprandial glucose (mg/dl)	<100	80-120	<80/>140
Average bedtime glucose (mg/dl)	<110	110-140	<100/>160
A1C(%)	<6	<7	>8

<sup>\*</sup>Adapted from American Diabetes Association guidelines, 2002

Oral Agents for the Treatment of Type 2 Diabetes

Agent	Initial Dose & Treatment	Maximum Dose	Initial Elderly Dose	Side Effects	Drug Interaction	
Second Generation Sulfonylureas Glyburide (DiaBeta, Micronase)	2.5 - 5 mg/day; increase dose by 2.5- 5 mg no more often than every 7 days	20 mg	1.25-2.5 mg	hypoglycemia and weight gain	alcohol; coumarin; zole antifungals; asparaginase; corticosteroids; thiazide diuretics; lithium; beta blockers; cimetidine; ranitidine; cyclosporine; quinolones; MAO inhibitors; chloramphenicol; octreotide; pentamidine	
Glyburide, microcrystalline (Glynase)	1.5 -3 mg/day; increase by $\leq$ 1.5 mg weekly if needed	12 mg	1.25 mg	hypoglycemia and weight gain	same as above	
Glipizide, short-acting (Glucotrol)	5 mg/day, 30 min before breakfast; increase dose by 2.5 - 5 mg a week as needed	40 mg give bid when dose reaches 15 mg	2.5 - 5 mg	hypoglycemia and weight gain	same as above	
Glipizide, extended release (Glucotrol XL)	5 mg/day at breakfast; increase dose by 2.5 - 5 mg at 3 month intervals based on HbA1C	20 mg	2.5 mg	hypoglycemia and weight gain	same as above	
Glimepiride (Amaryl)	1-2 mg daily with breakfast or first main meal; increase at 1-2 mg increments every 1-2 weeks as needed	8 mg once daily	0.5 - 1 mg	hypoglycemia and weight gain	same as above	
Biguanides Metformin (Glucophage) **Contraindications to metformin therapy: elevated creatinine (>1.4mg/dL in women or >1.5mg/dL in men), or a creatinine clearance < 60mL/min in the elderly; history of renal insufficiency, hepatic dysfunction, or serious cardiovascular or pulmonary compromise	500 mg with a meal; on the basis of patient's tolerance to metformin and glycemic response, increase dosage by 500 mg/day at weekly intervals, adding a dose to another meal; tid dosing not required for efficacy but may decrease GI complaint; doses >1000 mg/day with meals will likely be needed for therapeutic effect as monotherapy; doses >2000 mg/day have little added benefit.	2550 mg/day (850 mg tid); OR 2500 mg/day (500 mg tab)	500 mg	nausea and diarrhea that usually subside over 1 week may limit rate of dose increase; hypoglycemia only if metformin is given with sulfonylurea or insulin	alcohol - cimetidine - amiloride - digoxin - morphine - procainamide - quinidine - ranitidine - triamterene -trimethoprim - vancomycin - furosemide - calcium channel blocking agents especially nifedipine  *withhold 48 hours prior to and following surgery or IV contrast x-ray studies.	
Alpha-Glucosidase Inhibitors Acarbose (Precose)	25 mg tid with first bite of meals; lower dose may be needed if gastrointestinal distress is noted. Increase dose to 50 mg tid with meals after 4-8 weeks	100 mg tid with meals or 50 mg tid with meals (In patients ≤ 60 kg)	25 mg	diarrhea (33%) abdominal pain (12%) flatulence (77%) * serum transaminase elevations may occur at doses >50mg tid.	absorbents, intestinal agents such as activated charcoal digestive, enzyme preparations containing carbohydrate - splitting enzymes such as amylase or pancreatin	
Thiazolidinediones Rosiglitazone (Avandia)	4 mg qd or 2 mg bid; increase to 8 mg qd or 4 mg bid in 12 weeks as needed	8 mg/day	2 mg	edema; fluid retention may cause or exacerbate CHF.	erythromycin- calcium channel blocker- corticosteroids -cyclosporine - hmg coa reductase inhibitors - triazolam - trimetrexate - ketoconazole - itraconazole	
Pioglitazone (Actos)	15 or 30 mg qd; increase to 45 mg qd monotherapy or 30 mg qd as combo therapy	45 mg/day monotherapy; 30 mg/day combo therapy	15 mg	edema * decreases oral contraceptive efficacy	same as above	
Meglitinides Repaglinide (Prandin)	0.5 mg with each meal if HbA1C <8%, 1 - 2 mg with each meal if HbA1C ≥8%; Increase by 1 mg weekly as needed	4 mg with meals (max 16 mg total per day)	0.5 mg	hypoglycemia and weight gain	*contraindicated in moderate-severe hepatic dysfunction beta- adrenergic blocking agents; drugs metabolized by the cytochrome p450 system; erythromycin; ketoconazole; miconazole; sulfonamides; MAO inhibitors; NSAIDS; anticoagulants (warfarin derivatives)	
Nateglinide (Starlix)	60 mg, 1 to 30 min before each meal if HbA1C < 8%; 120 mg if > 8%	180 mg tid	60 mg	hypoglycemia and weight gain	same as above	

## **Type 2 Diabetes Mellitus - Combination Drug Therapy Options**

Sulfonylurea + Biguanide

Sulfonylurea + Insulin

**Biguanide + Insulin** 

Sulfonylurea + Alpha-glucosidase inhibitor

Sulfonylurea + Biguanide + Insulin\*

Biguanides + Alpha-glucosidase inhibitor\*

Thiazolidinedione + Insulin

**Biguanide** + **Meglitinide** 

Rosiglitazone or Pioglitazone + Sulfonylurea

Alpha-glucosidase inhibitor + Insulin\*

Sulfonylurea + Biguanide + Thiazolidinedione\*

<sup>\*</sup> Denotes less frequently used therapy/less studied therapy

#### THE CARVILLE DIABETIC FOOT SCREEN

This appendix was adapted directly from the LEAP program at the Hansen's Disease Center, Carville, Louisiana. A BOP-designed progress note for documenting these examinations is found in **Appendix 6**, a Word Perfect version of the Form 600 with the outline of the examination overprinted. This form may be printed and inserted in chronological order in section 1 of the Inmate Medical Record.

#### **Section I**

In the first section of the Foot Screen, the five questions can be answered in the Yes or No blank with an R, L, or B to indicate a positive or negative finding in the right, left, or both feet.

#### 1. Has there been a change in the foot since the last evaluation?

On a first visit, enter N/A unless the inmate has noticed a change in strength or sensation within the past year. If that is the case, then check Yes. The purpose of this question is to determine from the inmate if he/she has perceived a change in the strength or sensation of their feet. Any change is significant in a foot screen.

For example, an improvement in the inmate's perception of sensation could be a sign that the inmate is having a reversal of some of the neuropathic changes. Alternatively, if the inmate perceives a change for the worse, this could be a sign of worsening of the neuropathy.

#### 2. Is there a foot ulcer now, or history of foot ulcer?

The purpose of this question is to determine if the inmate has now, or has ever had an ulcer on the foot. A positive history of a foot ulcer places the inmate permanently in Risk Category 3. Once an inmate has ulcerated, he or she is always at an increased risk of developing another foot ulcer. The inmate is also at risk of developing a progressive deformity of the foot and ultimately amputation of the lower extremity.

#### 3. Does the foot have an abnormal shape?

This is determined by inspecting the general shape of the inmate's foot. Conditions to consider include: foot drop, eversion or inversion deformity, partial or complete amputations of the foot or toes, clawed toes, bunions, and especially a "Charcot Foot."

A Charcot Foot is a foot which is moderately to severely deformed as a result of insensitivity and repeated injury. Fractures in an insensitive foot frequently fail to heal properly and can progress to the so-called boat shaped foot. These feet are at extreme risk of amputation and require immediate, expert care. A patient with a Charcot Foot is always in Category 3.

#### 4. Is there weakness in the ankle or foot?

Unless the inmate has an open ulcer or infection of the foot, a rough estimate of strength can be made by asking the inmate to walk alternately on their heels and then on their toes.

#### 5. Are the nails thick, too long, or ingrown?

If severe nail problems are present or if there is uncertainty about the vascular status of the toes, refer the inmate to an appropriate evaluator.

#### **Section II**

In the next section of the foot screen, the examiner does a sensory exam of the foot using the 10 gram monofilament and records the findings on the form in the circles on the foot drawing.

There are ten places on each foot that are routinely tested. If the inmate can feel the filament, put a "+" in the appropriate circle. If they cannot feel it, put a "-".

The sensory exam should be done in a quiet and relaxed setting, where the inmate can lie down. The inmate should not watch while the examiner applies the filament.

#### **Section III**

Next, examine the foot and record the problems identified by drawing or labeling as appropriate on the Foot Screen form.

If there are callouses, pre-ulcerative lesions (a closed lesion, such as a blister or hematoma) or open ulcers, draw or describe them as accurately as possible.

Then, draw in and label areas that are significantly red, warm (warmer than the other parts of the foot or the opposite foot), dry or macerated (friable, moist, soft tissue).

#### Section IV

This is the vascular assessment. Vascular studies are an important part of a foot evaluation in patients with diabetes and should at least include the palpation of pulses. More extensive evaluations such as doppler studies and angiography should be considered on a case by case basis.

#### **Section V**

Footwear is discussed under the appropriate Risk Category below.

#### **Section VI**

**Risk Categorization**: The accurate categorization of inmates into their respective Risk Category is a key element in the Foot Screen. The higher the Risk Category, the higher the risk an inmate has of recurrent foot ulceration, progressive deformity and ultimately, amputation of the foot.

Category 0: No loss of protective sensation.

This is a patient who has essentially no risk of developing foot complications as a result of their disease. This patient does not need special footwear.

Category 1: Loss of protective sensation, no deformity or history of plantar ulceration.

This patient has lost sensation to the point that they are defined as not having "protective sensation." These patients cannot feel the 10 gram monofilament and therefore cannot trust their sensation to prevent injury. The patients in this and the following two categories should **never** walk barefoot. They do not have enough sensation to prevent injuring themselves (e.g. as a result of stepping on sharp objects).

Patients in this and the following two categories need to pay special attention to the fit and style of their shoes and should avoid pointed toed shoes or high heels. Category 1 patients do not need "custom" shoes. They usually do well in a jogging shoe or a well-fitting street shoe.

Category 2: Loss of protective sensation and deformity, no history of plantar ulceration.

This patient, in addition to the loss of protective sensation, also has additional abnormalities, but has not progressed to the point of ulceration (current or past). They may need extra depth shoes with custom molded insoles to accommodate deformity of their feet. These patients can frequently wear a jogging shoe with a soft insert.

#### Category 3: History of plantar ulcer.

This patient has loss of protective sensation and has progressed to the point of plantar ulceration (current or past). They will need extra depth shoes with soft molded inserts to accommodate any deformity of their feet. They may need custom-made shoes to manage their foot problems once their ulcer is healed.

#### FILAMENT APPLICATION INSTRUCTIONS

The sensory testing device used with the Foot Screen is a nylon filament mounted on a holder that has been standardized to deliver a 10 gram force when properly applied. Hansen's disease researchers have shown that a patient who can feel the 10 gram filament in selected sites are not at increased risk to develop ulcers.

1. Sites to be tested:

<u>Dorsal foot</u>: center of the top of the foot

Plantar foot:

- (1) center of the heel pad
- (2) medial arch
- (3) "ball" of foot
- (4) over distal 3<sup>rd</sup> metatarsal head
- (5) over distal 5<sup>th</sup> metatarsal head
- (6) over proximal 5<sup>th</sup> metatarsal
- 2. Apply the filament perpendicular to the skin's surface.
- 3. The approach, skin contact and departure of the filament should be approximately 1 ½ seconds duration.
- 4. Apply sufficient force to cause the filament to bend.
- 5. Do not allow the filament to slide across the skin or make repetitive contact at the test site.
- 6. Randomize the selection of test sites and time between successive tests to reduce the potential for patient guessing.
- 7. Ask the patient to respond "yes" when the filament is felt and record the responses.
- 8. Apply the filament along the perimeter of and NOT on an ulcer site, callus, scar or necrotic tissue.

HEALTH RECORD		CHRONOLOGICAL RECORD OF MEDICAL CARE					
DATE	SYMPTOMS,	DIAGNOSIS, TREATMENT, TREATING ORGANIZATION (Sign each entry)					
	S/O: Date of DM Onset						
1	Does this patient report nu	numbness/tingling of feet? YES NO If Yes, indicate below.					
	Does this patient have a hi	istory of ulceration on bottom NOT felf YWES indicate below.					
	DEFORMITIES (Check if deformities are preseRANGE OF MOTION/STRENGTH TESTING						
	LEFT	RIGHT LEFT RIGHT					
	Hammer/Claw Toes	ANKLE - dorsi / /					
	Bony Prominence	- plantar /					
	Rigid Great Toe	- eversion /					
	Hallus Valgus	- inversion / /					
-	Foot Drop	TOES - flexion /					
	Rigid Ankle	- extension /					
	Partial Foot Resection						
	OBSERVATION:						
	Hygiene:	LEFT RIGHT					
'	Nails:						
·	SENSATION/SKIN: 0= Sensatio	on Absent					
	+= Sensation Presen	ent to 5.07 monofilame <del>nt</del>					
	PULSES:						
	- Dorsalis Pedis - (Left) - S W A (Right) S W A						
·	- Post Tibial -(Left) -	- S W A (Right) - S W A					
	DOTWEAR: Type: Fit: Socks:						
	Weight bearing shoe si	size/width: (Brannock Device)					
	Weight bearing shoe si						
		ate risk category					
	ASSESSMENT: Check appropria	ate risk category oss - Follow-up in 1 year)					
	ASSESSMENT: Check appropria	ate risk category oss - Follow-up in 1 year)					
IENT'S IDENTIFICA	ASSESSMENT: Check appropria Category 0 (No sensory los Category 1 (Sensory Loss -	ate risk category  oss - Follow-up in 1 year)  - Follow-up in 6 months)    RECORDS					
IENT'S IDENTIFICA	ASSESSMENT: Check appropria Category 0 (No sensory los Category 1 (Sensory Loss -	ate risk category  DSS - Follow-up in 1 year)  - Follow-up in 6 months)  RECORDS  MAINTAINED  AT:  PATIENT'S NAME (Last, First, Middle Initial)					
IENT'S IDENTIFICA	ASSESSMENT: Check appropria Category 0 (No sensory los Category 1 (Sensory Loss -	ate risk category  oss - Follow-up in 1 year)  - Follow-up in 6 months)  RECORDS  MAINTAINED  AT:					
IENT'S IDENTIFICA	ASSESSMENT: Check appropria Category 0 (No sensory los Category 1 (Sensory Loss -	ate risk category  DSS - Follow-up in 1 year)  - Follow-up in 6 months)  RECORDS  MAINTAINED  AT:  PATIENT'S NAME (Last, First, Middle Initial)					
IENT'S IDENTIFICA	ASSESSMENT: Check appropria Category 0 (No sensory los Category 1 (Sensory Loss -	ate risk category  pss - Follow-up in 1 year)  - Follow-up in 6 months)  RECORDS  MAINTAINED   AT:  PATIENT'S NAME (Last, First, Middle Initial)  RELATIONSHIP TO SPONSOR   STATUS					

DATE	SYMPTOMS, DIAGNOSIS, TREATMENT, TREATING ORGANIZATION (Sign each entry)				
	Category 2 (Sensory Loss and Deformity - Routine visits every 3 months)				
	Category 3 (Sensory Loss, History of Ulcers and Deformity - Routine visits every month)				
	PLAN: Patient Education/Instruction				
	Inspection				
	Callus/Nail Care				
	Institutional footweaY: / N				
	Custom footwear: Y / N Type: Size:				
	Skin care (including moisturizing)				
	Discharge, no intervention needed				
	Consultation:				
	GOALS:				
	Clinician: Date:				

## **Recommendations for Diabetic Chronic Care Clinic Monitoring**

#### Patient Evaluation / Routine Exam - SOAP Format

**S:** < Observations and patient complaints >

O: Vital signs: blood pressure, pulse, respiration rate, temperature, weight, height

HEENT: (include fundoscopic exam and neck evaluation)

Lungs/Heart:

Abdomen:

Extremities/ Peripheral pulses / Neuropathy / Visual Foot Examination

Labs, X-Rays, Other Studies

A: Assessment, Analysis of data, Diagnosis

**P:** Therapeutic regimen

Diagnostic studies

Education - adherence to all self care aspects, exercise evaluation,

follow-up of referrals, smoking cessation

Procedure, Test, Examination	Baseline Visit	Quarterly Visit	Semiannual Visit	Annual Visit
Routine physical exam	x	x		
Fasting blood sugar (record results of self-monitoring where applicable)	X	x		
Fasting complete metabolic panel (electrolytes, creatinine, total cholesterol)	x			x
Fasting Lipid profile *more often if managing a lipid disorder, less often if low risk	X			X
HBA1C	x	(x) if treatment changes, or clinically indicated	x	
Urinalysis (dipstick)	x			X
Urine microalbumin	x if standard dipstick urinalysis is negative for protein			X if standard dipstick urinalysis is negative for protein
Ophthalmologic exam (preferably dilated )	x			x
Fundoscopic exam (performed by primary provider)	x	x		
Foot Exam: visual monofilament	x x	X		x x
EKG	x			

Fasting or random glucose (finger stick) monitoring - methods and times must be determined on a case-by-case basis depending on the medical needs of the inmate and severity of the condition.

# **Keys to Diabetes Control**

Years ago, the diabetic diet was strict and boring. Today, you do not need special foods; in fact, the foods that are good for you are good for everyone. Diabetes can not be cured, but it can be controlled so that you can lead a normal life and when your diabetes is in good control, complications may be prevented or delayed. There are three keys to controlling diabetes: 1) Diet - weight control or maintenance; 2) Exercise; and 3) Medication - pills or insulin. All three are equally important. Your food intake and activity needs to balance with your medication for good blood glucose control. By making the proper food choices, exercising, and taking prescribed medication throughout the day, you will be able to maintain a healthy weight and blood glucose control.

## **Steps to Control Blood Glucose**

- <u>Eat a wide variety of foods every day:</u> Increase high fiber foods such as: grains, beans, vegetables, and fruits to fill you up.
- <u>Limit concentrated sweets</u> such as: sugar, honey, jelly, syrup, cakes, cookies, candy, ice cream, pies, pastries, regular soda or kool-ade. Concentrated sugars do not cause diabetes, and do not need to be totally avoided. However, they are concentrated calories the more calories you eat, the higher your blood glucose.
- <u>Limit fats</u> such as: butter, margarine, cheese, fried foods, cream soups, gravy, salad dressings, mayonnaise, and breakfast meats (bacon, sausage, etc.).
- <u>Control portion sizes</u>: Too much of even the right foods can also cause high blood glucose. If you want to lose weight, cut down on portion sizes.
- <u>Never skip meals</u>: Eat all three meals and include snacks as needed. Eat at about the same time every day.
- <u>Exercise</u>: Increase your activity level (as permitted by your doctor). This will decrease your blood glucose level.
- <u>Monitor your weight</u>: Weigh yourself only once a week to determine if your diet is effective. If you are overweight, a weight loss of 1-2 pounds per week is a good goal.
- <u>Medication</u>: If you take pills or insulin for your diabetes, always take your medication as your doctor has recommended.

# INMATE FACT SHEET (Diabetes)

#### 1. What is diabetes?

Diabetes is a chronic disease for which there is no cure. It can be controlled by a combination of diet, exercise, and medical care. Diabetes means having too much sugar (glucose) in the blood. In people who have diabetes, sugar builds up in the blood instead of going into the cells.

## 2. What are the symptoms of diabetes?

Most people with diabetes do not notice any symptoms. However, some symptoms of diabetes are:

- Frequent urination
- Increased thirst and increased hunger
- Unexplained weight loss

- Weakness, fatigue, drowsiness
- Wounds and cuts that heal slowly
- Blurred vision or changes in vision

## 3. What puts you at risk for diabetes?

- You are age 45 and older
- You are a member of a high-risk ethnic group (African American, Hispanic/Latino, American Indian, Asian American, Pacific Islander)
- You are overweight
- You have high blood pressure (at or above 140/90)
- You have a family history of diabetes
- You have a history of diabetes during pregnancy
- You weighed more than 9 pounds at birth

## 4. What are the complications of diabetes?

- Eve damage poor vision, retina damage, cataracts, glaucoma, blindness
- Kidney damage progressive failure may require hemodialysis or organ transplantation
- Heart problems damaged blood vessels leading to heart attacks and strokes
- Nerve damage problems with nerve sensations and moving muscles, loss of reflexes
- Decreased ability to fight infections
- Sores and ulcers of the legs and feet

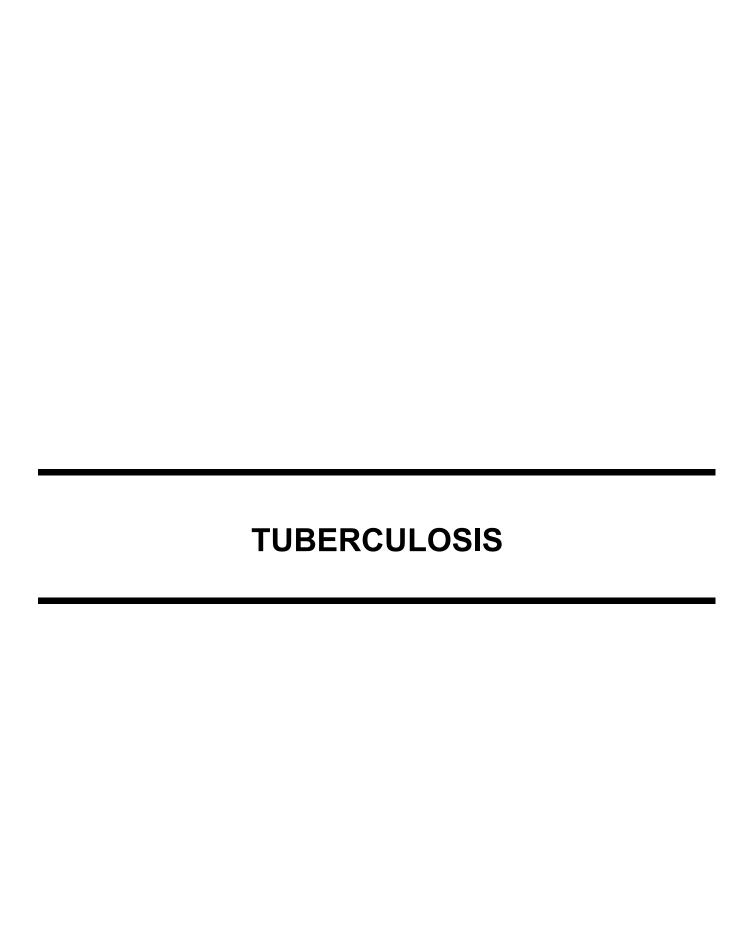
## 5. How is diabetes controlled?

Diabetes is controlled by a combination of diet, exercise, and medication. Treatment goals are to keep blood sugar near normal, control blood pressure, lower cholesterol and fat levels, and lose weight or maintain a healthy weight. Research shows that keeping blood sugar as near to normal as possible means fewer complications of the disease. Strict control of blood sugar helps to prevent kidney failure, amputations, blindness, heart attacks, and stroke.

## 6. What are the symptoms of hypoglycemia (low blood sugar)?

- Shakiness
- Sweating and clammy feeling
- Extreme fatigue
- Hunger

- Irritation or confusion
- Rapid heart rate
- Blurred vision



# Federal Bureau of Prisons Treatment Regimens for Latent Tuberculosis Infection (LTBI)

Treatment of LTBI	Treatment	Do	sages	Administration	Side Effects	Monitoring Parameters
(Comments)	Regimens	DAILY DOSE (MAXIMUM)	TWICE WEEKLY DOSE (MAXIMUM)			-
LTBI treatment should not be initiated until active TB disease has been eliminated as a potential diagnosis.  Also, refer to clinical guidelines on "Indications for LTBI treatment" and "Special considerations related to HIV coinfection, pregnancy, old TB."  Consultation with a TB expert is recommended when treating contacts of persons with MDR-TB. An alternative regimen is indicated.	#1: INH, 6 to 9 months  (9 mo is preferred regimen)  #2: RIF/PZA, 2 months  Many drug interactions with RIF: review drug regimen carefully	#1: INH 5 mg/kg (300 mg/day)  Daily dose x 180 doses (within 6 mo) to 270 doses (within 9 mo)  Note: give pyridoxine (vitamin B <sub>6</sub> ) 50 mg/day concurrently with INH.  #2: † RIF 10 mg/kg (600 mg/day) and PZA 15 - 30 mg/kg (2g/day)  Daily dose X 60 doses within 2- 3 mos.  † RFB may be substituted for RIF when given with certain PIs+NNRTIs (consult pharmacist for drug dosages)	#1: INH 15 mg/kg (900 mg/dose)  Twice weekly x 52 doses (6 mo) or 78 doses (9 mo)  Note: administer twice weekly, at least two days between doses.  #2:RIF 10 mg/kg (600 mg) and PZA 50-70 mg/kg (4 g/day)  Consider this regimen only for select inmates if alternative regimens are not feasible. Note: RIF twice weekly dosage the same as daily dosage.  Regimen should consist of at least 16-24 doses within 2-3 mo	#1: Offer 6 mo if 9 mo Tx not feasible. If 6 mo not feasible, consider alternative regimen.  Always give 9 mo regimen for HIV+  B <sub>6</sub> 50 mg/day to prevent INH-associated peripheral neuropathy.  #2: Consider RIF+PZA if:  -INH is not tolerated.  -A close contact of an active TB case with INH-resistance and RIF-sensitivity.  -HIV+ on ART: RIF given without concurrent protease inhibitors (PI) or non-nucleoside reverse transcriptase inhibitors (NNRTIs)/ See RFB note	-anorexia -nausea, vomiting -dark urine -icterus, rash -paresthesias of hands and/or feet -fatigue or weakness lasting > 3 days -abdominal pain -easy bruising or bleeding -arthralgias.  RIF/ RFB colors body fluids orange; stains contact lenses.  Risk of leukopenia and low platelets with RFB.  PZA is not recommended if chronic gout exists.	Baseline: CXR to rule out active TB (if suggestive of old healed TB, should have 3 consecutive sputum samples to rule out active TB disease). If sputum-negative, further diagnostic evaluation should be pursued.  Conduct clinical evaluation. Obtain baseline hepatic enzymes (ALT and AST) and HIV test if not previously done. Bilirubin/LFTs if hepatic enzymes are elevated.  Monitoring ALT/AST is not routinely necessary during LTBI Tx, but is indicated periodically if: -baseline LFTs were sig. † -chronic liver disease -pregnancy -taking other hepatotoxic drugs  Other lab: CBC, platelets, if on RIF or RFB; uric acid if on PZA Other labs at physician discretion  Monitor for drug side effects at 2, 4, and 8 weeks if receiving RIF + PZA; and monthly if receiving INH or RIF monotherapy.
	#3: RIF 4 months	#3: RIF 10 mg/kg (600 mg/day)  Daily dose X 120 doses within 4 - 6 months.	#3: RIF ALONE TWICE WEEKLY IS NOT RECOMMENDED	#3: Indicated primarily if inmate is intolerant to INH and/or PZA.	Same as #2	

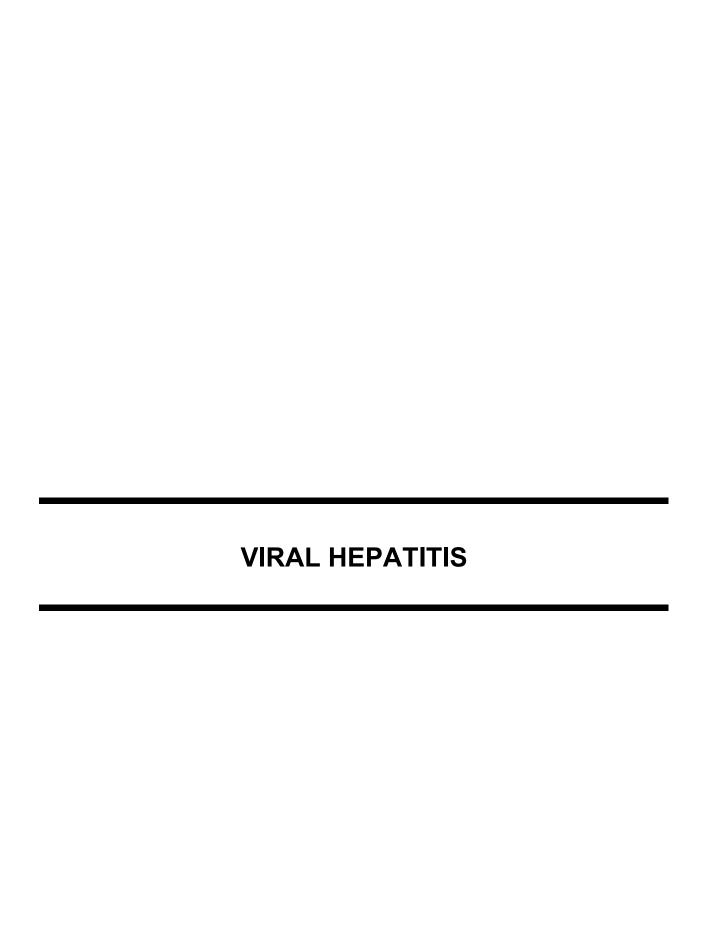
## FEDERAL BUREAU OF PRISONS TUBERCULOSIS TREATMENT GUIDELINES

Diagnostic Category	Length of Regimen	Initial Phase INH/RIF/PZA/EMB (or SM) for 8 weeks (daily for 2 weeks, then biweekly for 6 weeks)		CONTINUATION PHASE INH/RIF for 16 weeks (2 OPTIONS)		MONITORING PARAMETERS
Adults - TB  Culture positive - pulmonary or extrapulmonary	6 months minimum  Longer treatment may be required for TB meningitis or bone/joint TB	DAILY DOSE (MAXIMUM DOSE) Daily dose x 14 doses  INH 5 mg/kg (300 mg/day)  RIF 10 mg/kg (600 mg/day)  PZA 15-30 mg/kg (2g/day)  EMB 15-25 mg/kg  or  SM 15 mg/kg ≤ 60 yr. (1.0 g/day)  SM 10 mg/kg if > 60 yr. Old (750 mg - 1 g)  Note: EMB should be started at 15 mg/kg to reduce the risk of ocular toxicity. The use of 25 mg/kg should be reserved for patients requiring retreatment, or treatment of drug resistant TB.	TWICE WEEKLY DOSE (MAXIMUM DOSE) Twice weekly x 6 weeks.  INH 15 mg/kg (900 mg/dose)  RIF 10 mg/kg (600 mg/dose)  PZA 50-70 mg/kg (4g/dose)  EMB 50 mg/kg/dose  or  SM 25-30 mg/kg ≤60 yr. (1.5 g/dose)  SM 750 mg - 1 gram if > 60 yrs)  Note: Pyridoxine - 50 mg/day should be given concurrently with INH to prevent INH-associated peripheral neuropathy.  Drugs prescribed twice weekly should be administered 2 or 3 days apart.	DAILY DOSE (MAXIMUM DOSE)  INH 5 mg/kg (300 mg/day)  RIF 10 mg/kg (600 mg/day)  Note: AFTER 8 WEEKS OF 4 DRUG THERAPY NEVER SWITCH TO 2 DRUGS UNTIL SUSCEPTIBILITY TO INH AND RIF IS DEMONSTRATED.	TWICE WEEKLY DOSE (MAXIMUM DOSE)  INH 15 mg/kg (900 mg/dose)  RIF 10 mg/kg (600 mg/dose)  Note: Drugs prescribed twice weekly should be administered 2 or 3 days apart.	Baseline: Chest x-ray, morning sputums for AFB X 3, CBC, platelet count, creatinine, uric acid, bilirubin, hepatic enzymes, visual acuity/red-green color perception(EMB), and audiogram(SM).  Do susceptibility drug testing with first sputum cultures and as needed.  Ongoing: Monthly evaluation by a physician for symptoms and targeted exam  ALT/AST monthly if elevated at baseline Creatinine/audiogram monthly on SM  Visual acuity/red-green color vision monthly, eye doctor evaluation every 3 months while on EMB  Certain high-risk groups, may have increased propensity for INH-induced hepatitis and require monthly liver enzymes. Presence of hepatitis does not preclude treatment for TBpatient must be monitored closely. Other labs at discretion of physician.  Obtain 3 consecutive daily sputums for smear and culture every month until conversion. Repeat drug susceptibility testing if patient fails to respond clinically or remains culture positive after 2 months. Chest x-ray, sputum smear and culture at end of treatment for future comparisons.
Adults - Pulmonary with	minimum INH/RIF/PZA/F		INITIAL PHASE INH/RIF/PZA/EMB (or SM) for 8 weeks		JATION PHASE IF for 8 weeks	Same as above Chest x-ray at 3 months. Failure of x-
negative smear and culture. Patient is symptomatic.	6 months if HIV infected.	Same as above	Same as above	Doses same as above. Continue EMB and PZA if drug resistance likely.	Doses same as above. Continue EMB and PZA if drug resistance likely.	ray to respond to treatment within 3 months suggestive of previous (not current) TB or another disease.

## FEDERAL BUREAU OF PRISONS TUBERCULOSIS TREATMENT GUIDELINES - SPECIAL CONSIDERATIONS

DIAGNOSTIC CATEGORY	REGIMEN	MEDICATIONS	MONITORING PARAMETERS
Pregnancy	9 months minimum. Treatment should begin as soon as TB is suspected.	Treat with appropriate doses of INH/RIF/EMB. Do not use PZA unless dealing with drug-resistant disease with no alternatives. Inadequate tetratogenicity data for PZA  Give Pyridoxine (B6) 50 mg/day concurrently.  SM has documented harmful effects on the fetus and should not be used.  Discontinue EMB once INH/RIF sensitivity results are documented.  Consult with physician expert for appropriate treatment regimen	Baseline: Chest x-ray, morning sputums for AFB X 3, CBC, platelet count, serum creatinine, uric acid, liver enzymes, visual acuity, and red-green color vision.  Ongoing: Monthly symptom review and exam by clinician. Assess visual acuity/ red-green color perception monthly and eye doctor evaluation every 3 months while on EMB. With hepatic disease, renal disease or gout obtain monthly liver function tests, creatinine, or uric acid respectively. Certain high-risk groups for isoniazid-induced hepatitis require monthly liver enzymes. Presence of hepatitis does not preclude treatment for TB. Patient must be monitored closely. Other laboratory studies at the discretion of the physician.  Obtain 3 consecutive daily sputums every month until conversion. Do susceptibility drug testing with first cultures and as needed. Repeat drug susceptibilities if patient fails to respond clinically or remains culture positive after 2 months.  Chest x-ray, sputum smear and culture at end of treatment and more frequently as indicated. If pregnant woman is HIV positive or has drug resistant TB, consult infectious disease consultant.
HIV Infection	Standard 6 month regimen, unless patient on certain antiretroviral drugs - then consult CDC guidelines and TB expert for treatment recommendations	Treatment may need to be prolonged due to adverse drug reactions or poor drug absorption. RIF contraindicated with protease inhibitors and nonnucleoside reverse transcriptase inhibitors. RFB can be substituted for RIF with certain antiretroviral drugs (consult pharmacist)	Adverse reactions more common. Monitoring same as for adult standard. If rifabutin prescribed, monitor for uveitis, arthralgia, and leukopenia. If there is no culture conversion at the end of 2 months, reevaluate patient and repeat drug susceptibility tests. Treatment should be prolonged with any evidence of suboptimal response with therapy.
INH Resistance/ Intolerance	6 months of 4-drug standard regimen effective. After INH resistance/intolerance identified, discontinue INH. Tx with RIF/ PZA/EMB for duration of therapy given twice weekly.	Same as adult standard excluding INH from regimen.	Same as adult standard. Monitor cultures and drug sensitivities closely.
INH/Rifampin resistance (MDR-TB)	Continue treatment until bacteriologic sputum conversion followed by 12-24 months of at least 3 drug treatment.	Give at least three new drugs to which the organism is susceptible.  Consult with tuberculosis expert to ensure effective medical management.	Same as adult and children standards with monthly monitoring of cultures and drug sensitivities until conversion.

INH-isoniazid, RIF-rifampin, PZA-pyrazinamide, EMB-ethambutol, SM-streptomycin, RFB-rifabutin. Adjust dosages as weight changes/ Administer all drugs by DOT.



# **Evaluation Strategy for Treatment of Chronic Hepatitis B**

Confirm chronic infection HBsAg+ HBe+

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ALT 1.5 x normal x 3 over 6-12 months

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Physician clearance No evidence of decompensated cirrhosis No contraindications to interferon tx

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Psychiatry or psychology clearance

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**Viremic- HBV DNA+** 

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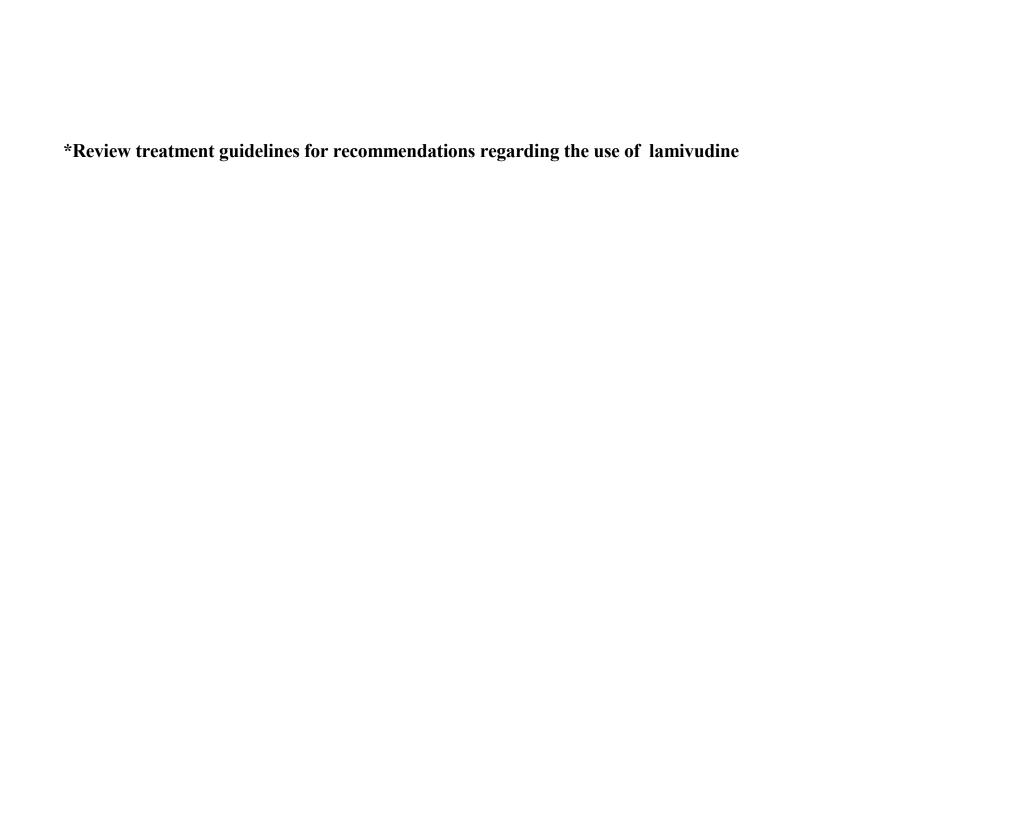
Screening liver ultrasound

1

**Subspecialty evaluation Liver biopsy** 

1

**Consider interferon tx if indicated \*** 



# Contraindications for Interferon or Ribavirin Therapy\*

## **INTERFERON**

## **Absolute Contraindications:**

Decompensated cirrhosis - e.g. albumin < 3, jaundice, ascites, varices, coagulopathy Hyperthyroidism or hypothyroidism that is uncontrolled Autoimmune disease that is poorly controlled Solid organ transplantation

Major depression or other neuropsychiatric condition that is poorly controlled Active illicit drug or alcohol usage

## **Relative Contraindications:**

 $Age > 60 \ years \\ Bone \ marrow \ dysfunction \ - \ neutrophils < 1,000/mm^3, \ platelets < 75,000/mm^3 \\ History \ of \ psychiatric \ diagnoses \\ HIV \ infection \\ Hepatitis \ B \ and \ C \ coinfections \\ Diabetes \ that \ is \ poorly \ controlled- \ Hemoglobin \ A_{1c} > 8.5\% \\ Renal \ insufficiency; \ creatinine \ clearance < 50 \ ml/min \\ History \ of \ alcohol \ or \ substance \ abuse \ within \ the \ past \ 6-12 \ months \\ Cirrhosis \ of \ the \ liver \ on \ biopsy \ without \ evidence \ of \ decompensation$ 

## **RIBAVIRIN**

## **Absolute contraindications**

Pregnancy - due to risk of fetal malformations and fetal death (pregnancy test required prior to initiating therapy; and women of childbearing potential and men must use two forms of effective contraception during treatment and during the six-months post-treatment follow-up period)

Hemogloblinopathies, hemolytic anemias or other severe anemias; with hemoglobin < 11 gm/dL or < 33% hematocrit

Ischemic cardiovascular disease or cerebrovascular disease

Renal insufficiency - creatinine > 2 mg/dL

<sup>\*</sup>Refer to drug manufacturer's warnings in addition to highlighted contraindications

# Post-exposure\* Prophylaxis for Hepatitis B Virus†

Vaccination Status/Antibody Desponse	Treatment Based on Source's Hepatitis B Viral Infection Status				
Vaccination Status/Antibody Response	HBsAg positive	HBsAg negative	Status Unknown		
Unvaccinated	HBIG** X 1; Initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series		
Vaccinated - Known Responder***	No treatment	No treatment	No treatment		
Vaccinated - Known Non-responder	HBIG X 1 and revaccination series, OR HBIG X 2 ****	No treatment	If known high-risk source, treat as if source were HBsAg positive		
Vaccinated - Unknown Response Status	Test exposed person for anti-HBs: If adequate - no tx  If inadequate - HBIG X 1 PLUS vaccine booster	No treatment	Test exposed person for anti-HBs: If adequate - no tx  If inadequate - give vaccine booster/recheck titer in 1-2 months		

<sup>\*</sup> Exposure is percutaneous (laceration, needlestick, bite) or permucosal (ocular or mucous-membrane) contact with blood.

<sup>\*\*</sup> HBIG dose is 0.06 ml/kg administered IM at different site than vaccine preferably < 24 hours of exposure; efficacy > 7 days after exposure is unknown.

<sup>\*\*\*</sup> Adequate anti-HBs levels is ≥10 mIU/ml.

<sup>\*\*\*\*</sup> Give 1 dose of HBIG and reinitiate vaccine series for nonresponders who have not completed second 3-dose vaccine series; Give HBIG X2 for nonresponders who have failed second vaccine series

<sup>†</sup> Adapted from CDC guidelines, MMWR, 2001; 50 (No. RR-11)

## **Evaluation Strategy for Treatment of Chronic Hepatitis C**

## <u>Diagnose HCV infection</u> EIA+ - high risk inmate EIA+/RIBA+ - low risk inmate

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## **Baseline Evaluation**

Counseling/examination/basic laboratory studies
Review substance abuse history, particularly injection drug and alcohol use
Refer to drug treatment program if indicated and available
Determine if sentence length allows for evaluation/completion of treatment
If ALT is elevated - pursue further evaluation

**Physician Clearance** 

Assess adherence to previously prescribed treatment plans CBC & differential/platelet count/serum chemistries/liver function studies/creatinine

ANA/TSH/ferritin/pregnancy test/others studies as indicated Urinalysis toxicology screen for illegal drugs if active substance abuse suspected

Review contraindications to interferon/ribavirin therapy

1

Psychologist or Psychiatrist Clearance
Evaluation for active mental health problems
Rule out major depression or suicidal ideation
Review previous treatment of psychiatric conditions

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Confirm Viremia
HCV RNA - qualitative assay; or
HCV RNA - quantitative assay

# Liver Biopsy/Subspecialty Evaluation Assess degree of inflammation Assess degree of fibrosis Evaluate for co-morbid liver disease If liver biopsy normal, monitor, rebiopsy in 4-5 years

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# **HCV Genotype Determination**

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## **Drug Therapy**

HCV Genotype 2 or 3 - interferon/ribavirin combination therapy for 24 weeks

HCV Genotype 1 - interferon/ribavirin therapy - check HCV RNA at 24 weeks
if HCV RNA negative continue for 48 weeks of combination therapy

If ribavirin contraindicated, consider interferon monotherapy for 12 months - discontinue interferon at 3 months if HCV RNA is still detectable and abnormal ALT

1

## **Monitoring Post-treatment**

Repeat ALT every 2 months for 6 months after completion of effective therapy Measure HCV RNA 6 months after completion of effective therapy Referral to drug treatment program if indicated and not previously completed

## DOSING OF RIBAVIRIN/INTERFERON alfa-2b

## Recommended Dosing

Body weight	Ribavirin dose	Intron A inj.
75 kg or less	2 X 200mg in AM 3 X 200mg in PM	3 million IU SC 3 times per wk
> 75 kg	3 X 200mg in AM 3 X 200mg in PM	3 million IU SC 3 times per wk

\*\* Ribavirin capsules are limited to pill-line.

Guidelines for Dose Adjustment Based on Hematologic Parameters

Reduce Ribavirin to 600 mg daily (200mg AM, 400mg HS) if:

> Hemoglobin is less than 10 g/dL

Reduce Interferon to 1.5 million units 3 times per week if:

- > WBC is less than 1500
- > Neutrophil count is less than 750
- > Platelet count is less than 50,000

Discontinue treatment (both drugs) if:

- > Hemoglobin is less than 8.5 g/dL
- > WBC is less than 1000
- > Neutrophil count is less than 500
- > Platelet count is less than 25,000

For inmates being treated with Interferon/Ribavirin who have a history of cardiac disease (CHF, previous history of MI, angina, or known coronary artery disease by angiography), follow additional recommendations below:

- 1. Reduce Ribavirin to 600 mg daily (200mg AM, 400mg HS) AND reduce Interferon to 1.5 million units 3 times per week if there is a 2 g/dL drop in hemoglobin during any four week period of treatment.
- 2. Discontinue Ribavirin and Interferon in cardiac patients if the hemoglobin is less than or equal to 12 g/dL after 4 weeks at the reduced dose (see #1).

Resources: Prevention and Treatment of Viral Hepatitis

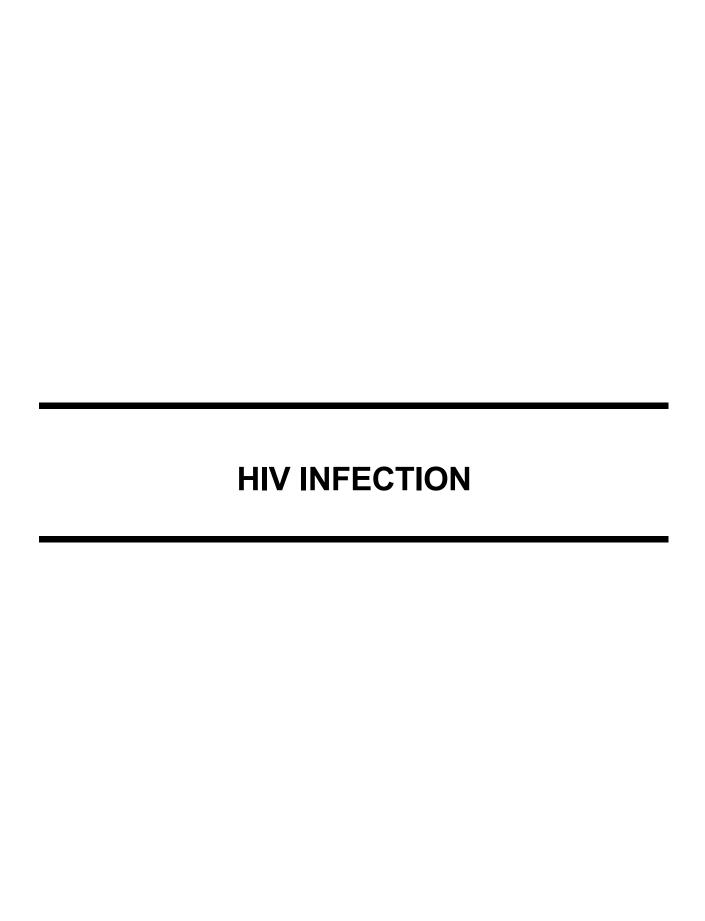
Centers for Disease Control and Prevention 1-888-443-7232 (4HEPCDC) http://www.cdc.gov

National Institutes of Health
National Digestive Diseases Information Clearinghouse
<a href="http://www.niddk.nih.gov/health/digest/digest.htm">http://www.niddk.nih.gov/health/digest/digest.htm</a>
1-301-654-3810
\*Provides excellent overview of disease management
strategies for hepatitis C

National Clinicians' Post-Exposure Prophylaxis Hotline 1-888-448-4911

American Liver Foundation 1-800-223-0179h (GOLIVER) 1-888-443-7222 (4HEPABC)

Hepatitis Foundation International 1-800-891-0707 <a href="http://www.hepfi.org/">http://www.hepfi.org/</a>



# **Appendix 1 - Medical Evaluations for Inmates with HIV Infection by Immunologic Status**

#### **Baseline Evaluation:**

(1) history/PE including: fundoscopic exam/PAP smear for women; (2) dental exam; (3) CBC/platelets; (4) CD4+ T-cell count, absolute and %; (5) HIV RNA (viral load); (6) electrolytes/creatinine/LFTs; (7) RPR/FTA (review tx history); (8) PPD/symptom review and chest x-ray; (9) toxoplasma IgG; (10) viral hepatitis serologies; (11) pneumococcal vaccine; (12) hepatitis A and B vaccines if at-risk; (13) lipid profile prior to antiretroviral therapy.

## **Periodic Evaluation:**

(1) CBC/platelet count, LFTs/creatinine/electrolytes - q 3-4 months on anti-retroviral tx; (2) periodic RPR as clinically indicated; (3) Pap smear - at 6 months x 1 then annually (refer to gynecologist as indicated for colposcopy); (4) influenza vaccination annually; (5) other laboratory tests as indicated.

CD4+ T-cells/mm <sup>3</sup>	CD4+ T-cells assessment	Viral load	Clinician exam	Special Evaluations/Treatments
> 350	q 3-6 months	q 6 months off tx q 3-4 mon. on tx	q 3 months	Observe most inmates off therapy Consider antiretroviral tx if viral load is elevated Carefully weigh adherence issues and patient motivation prior to treating
200-350	q 3-6 months	q 3-4 months	q 3 months	Consider antiretroviral therapy for most patients
100-199	q 3-6 months	q 3-4 months	q 2 months	Initiate antiretroviral therapy regardless of plasma HIV RNA levels Initiate PCP prophylaxis
50-99	q 3-6 months	q 3-4 months	monthly	Initiate antiretroviral therapy regardless of plasma HIV RNA levels Initiate toxoplasmosis prophylaxis/maintain PCP prophylaxis Baseline fundoscopic exam by eye doctor to screen for CMV
0-49	q 6 months	q 3-4 months	monthly	Initiate antiretroviral therapy regardless of plasma HIV RNA levels Maintain PCP/toxoplasmosis prophylaxis Initiate MAC prophylaxis Fundoscopic exam q 6 months by eye doctor to screen for CMV

# Appendix 2 - 1993 Revised CDC Classification System for HIV Infection

CD4+ T-cells/ mm <sup>3</sup>	CD4+ (%)	A Asymptomatic	B Symptomatic Disease	C AIDS Indicator Conditions
≥ 500	≥ 29%	A1	B1	C1
200-499	14-28	A2	B2	C2
< 200	< 14	A3	В3	C3
		* acute (primary) HIV infection  *PGL (persistent generalized lymphadenopathy)	Symptomatic conditions that are attributed to HIV infection; or the conditions have a clinical course complicated by HIV.  Conditions include but are not limited to the following:  * bacillary angiomatosis * oral candidiasis * vulvovaginal candidiasis:     persistent ( > 1 month or poorly responsive to tx) * cervical dysplasia (moderate-severe or CIS) * ITP * oral hairy leukoplakia * listeriosis * herpes zoster (involving more than 1 dermatome or 2 separate episodes)	* candidiasis: esophageal  * coccidiomycosis: extrapulmonary  * cryptococcoses: extrapulmonary  * cervical cancer, invasive  * cryptosporidiosis: chronic (> 1 month)  * cytomegalovirus retinitis (or CMV in organs other than liver/spleen/nodes)  * HIV encephalopathy  * herpes simplex: esophagitis, genital/oral ulcers > 1 month  * histoplasmosis: extrapulmonary/disseminated  * isosporiasis: chronic diarrhea (> 1 month)  * Kaposi's sarcoma  * lymphoma: Burkitt's, immunoblastic, brain primary  * MAC or M. Kansasii: extrapulmonary/disseminated  * M. tuberculosis: pulmonary or extrapulmonary  * other mycobacterium: extrapulmonary/disseminated  * Pneumocystis carinii pneumonia (PCP)  * pneumonia (recurrent: 2 or more episodes within 12 months)  * progressive multifocal leukoencephalopathy (PML)  * salmonella septicemia (> 1 occurrence)  * toxoplasmosis (CNS)  * wasting syndrome secondary to HIV infection

Category B conditions take precedence over those in Category A; and Category C conditions take precedence over those in Category B.
 For classification purposes, the lowest accurate CD4+ T-lymphocyte count or percentage (not necessarily the most recent) should be utilized.

<sup>-</sup> Categories A3, B3, and C1, C2, and C3 are reported as AIDS cases.

# **Appendix 3 - Prophylaxis for HIV-Related Opportunistic Infections**

Pathogen	Drug	Dosage	Toxicities	Comments
Pneumocystis carinii  Indications:  (1) CD4+ T-cells  < 200 /mm³ or < 14%  (2) prior PCP  (3) oral candidiasis   Toxoplasmosis  Indication: Toxo IgG+ and CD4+ T-cells:  < 100 cells/mm³	TMP-SMX (Bactrim, Septra)  Dapsone  Pentamidine  TMP-SMX (Bactrim, Septra)  Dapsone + Pyrimethamine + Leucovorin	1 SS/day (1st choice) 1 DS/day 1 DS 3x/week  100 mg/day; or 50 mg BID  300 mg q month aerosolized (administer by Respirgard II nebulizer)  1 DS/day (1st choice) 1 SS/day 50 mg/day 50 mg/week 25 mg/week	rash/fever/nausea leukopenia/hepatitis hemolysis methemoglobinemia bronchospasm/cough (responds to bronchodilator tx)  rash/fever/nausea leukopenia/hepatitis hemolysis/anemia	prevents toxo and bacterial infections use 1 DS/day if toxo IgG+  screen for G-6-PD deficiency  obtain screening chest x-ray for TB  can stop primary and secondary PCP prophy if CD4+ T-cells > 200/mm³ for 3 months  repeat toxo IgG if previously negative when CD4+ T-cells < 100/mm³  monitor for anemia/leukopenia with either regimen - CBC q 3-4 months  can stop primary toxo prophy if CD4+ count is > 200/mm³ for 3 months; can stop secondary prophy if CD4+ T-cell count is > 200/mm³ for 6 months
Mycobacterium avium *  Indication:  CD4+ < 50 cells/mm³  *R/O disseminated MAC infection with blood culture before giving prophylaxis	Azithromycin Clarithromycin Rifabutin	1200 mg/week (1st choice) 500 mg BID 300 mg/day	nausea/vomiting nausea/vomiting uveitis, arthralgias hepatitis	can stop primary prophy if CD4+ count is > 100/mm³ for 3 months; can stop secondary prophy if CD4+ count is > 100/mm³ for 6 months.  uveitis when given with fluconazole creates rifampin resistance review drug interactions

# **Appendix 4 - Treatment Indications for Antiretroviral Therapy for HIV Infection**

Immune Status	Treatment Options	Comments
Asymptomatic High CD4+ T-cell count  CD4+ T-cells > 350/mm <sup>3</sup>	Observe most patients  Initiate treatment on case by case basis for inmates with HIV RNA > 55,000 by (RT-PCR) or 30,000 by (bDNA)	Monitor HIV RNA, CD4+ T-cell count, and clinical presentation for disease progression. Inmates with CD4+ T-cells between 350-500/mm³ or significant elevations in HIV RNA, e.g. > 55,000 c/mL (RT-PCR), should be monitored closely.
Asymptomatic Depressed CD4+ T-cell count  CD4+ T-cells 200-350/mm³  AIDS or severe symptoms	Antiretroviral therapy per DHHS guidelines for most patients; some experts recommend deferring drug therapy with careful monitoring for patients with low HIV RNA, e.g. < 20,000 cps/mL  (Confirm depressed CD4+ T-cell count with second test before treating)	HAART should be initiated in accordance with current DHHS guidelines. The goal of treatment is to reduce plasma HIV RNA to undetectable levels (50 cps/mL) within 16-20 weeks of initiating antiretroviral treatment Effective treatment is predicted by a one log (10 fold) decline in HIV RNA levels within 8 weeks of initiating treatment. Inmates who fail to attain undetectable plasma HIV RNA after 6 months of therapy should be reevaluated. The HIV RNA level nadir strongly predicts the durability of antiviral suppression.  > 95% adherence to the antiretroviral regimen is necessary to have an 80% chance of achieving viral suppression 6 months after initiating therapy. Only 30% of treated patients achieve viral suppression when adherence to therapy falls to 70-80%. Adherence improves with inmate education,
Asymptomatic with CD4+ T-cell count < 200/mm <sup>3</sup> HIV RNA = any value	guidelines	simplifying pill burden/treatment regimen, and effectively treating drug side effects.  If the inmate has been on antiretroviral therapy in the past or requires a change in antiretroviral medications; consult with a physician with expertise in managing antiretroviral therapy.

# **Appendix 5 - Antiretroviral Therapy - NucleoSIDE Reverse Transcriptase Inhibitors (NRTIs)**

Antiretroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Zidovudine (ZDV) (azidothymidine) (AZT) Retrovir  100 mg caps. 300 mg tabs.	200 mg TID or 300 mg BID Combivir 1 BID Trizivir 1 BID	CBC/diff	CBC/diff 2,6, and 12 weeks after starting tx. every 3-4 months if stable	*granulocytopenia *anemia neutropenia myalgia *lactic acidosis *hepatomegaly *myopathy headache insomnia	marrow toxicity with gancyclovir hematologic toxicities with interferon reduce dose for moderate toxicities good CNS penetration with 3TC as Combivir with 3TC and abacavir as Trizivir Do not use with stavudine (antagonizes)
Lamivudine (3TC) Epivir 150 mg caps.	150 mg BID	none	none	*lactic acidosis *hepatomegaly	with AZT as Combivir with AZT and abacavir as Trizivir do not administer with zalcitabine sulfamethoxazole/trimethoprim lamivudine AUC 44% best tolerated NRTI
Stavudine (d4T) Zerit  15, 20, 30, 40 mg caps.	> 60kg: 40 mg BID < 60kg: 30 mg BID	CBC/diff	CBC/diff	neuropathy (dose related) *lactic acidosis *hepatomegaly * pancreatitis	reduce dose for renal disease based on creatinine clearance NRTI with highest probability of lactic acidosis Do not use with zidovudine (antagonizes)

Didanosine (ddI) Videx Videx EC 25, 50, 100, 150, 200 buffered tabs. 400 mg EC caps. also powder form.	> 60kg:200 mg BID < 60kg:125 mg BID; OR, 250-400 mg daily, but BID preferred take on empty stomach	CBC/diff amylase liver function	CBC/diff amylase/liver function tests with GI symptoms	diarrhea nausea *pancreatitis neuropathy *lactic acidosis *hepatomegaly	do not prescribe with history of pancreatitis or hx of alcohol abuse adjust dose in renal/hepatic disease multiple drug interactions using buffered ddI: e.g., IDV and RTV Videx EC does not have buffer.  do not give with ddC (overlapping toxicities)
Abacavir Ziagen 300 mg tabs.	300 mg BID	none	none	*hypersensitivity reaction (fever, rash, GI symptoms) *lactic acidosis *hepatomegaly	DO NOT restart abacavir following a hypersensitivity reaction alcohol ↑ abacavir AUC combined with 3TC and AZT as Trizivir

# **Antiretroviral Therapy - NucleoTIDE Analog Reverse Transcriptase Inhibitors (NARTIs)**

Tenofovir (PMPA) Viread  300 mg once daily	transaminases creatinine/clearance if abnormal	transaminases CPK	*lactic acidosis *hepatomegaly nausea/vomiting diarrhea flatulence	2 hours before or 1 hour after ddI take with meals do not administer if Ccr < 60ml/min
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<sup>-</sup> Review updated antiretroviral drug information/interactions from DHHS guidelines; dosage adjustments frequently required depending on drug regimen

<sup>-</sup> Nucleotides are phosphorylated nucleosides with similar mechanisms of action.

<sup>\*</sup> Indicates Black Box Warning

# Appendix 6 - Antiretroviral Therapy - Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Antiretroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Nevirapine Viramune 200 mg tabs.	200 mg tabs one daily for 14 days, then if tolerated advance to 200 mg BID	CBC liver transaminases	transaminases periodically	rash *Stevens-Johnson *hepatotoxicity	rash reduced by gradual dose escalation when drug is stopped; restart at 200 mg daily for 14 day lead-in period rash is worse than other NNRTI's methadone dose may need increased
Delavirdine Rescriptor 100, 200 mg tabs.	400 mg TID  no dose escalation required	CBC liver transaminases	CBC transaminases periodically (more often with saquinavir)	rash neutropenia with nelfinavir	multiple drug interactions: review all drugs serious toxicities with cisapride, terfenadine, astemizole; absorption decreased with antacids; administer separately from ddI. increases serum concentration of PI's potential for rapid resistance
Efavirenz Sustiva 50, 100, 200, 600 mg caps.	600 mg daily, HS  no dose escalation required	CBC liver transaminases	CBC transaminases periodically cholesterol	dizziness psychiatric symptoms hallucinations vivid dreams nightmares rash - mild fetal anomalies	extremely potent antiviral effect not recommended for pregnant women do not administer concurrently with cisapride, midazolam, triazolam, or ergot derivatives avoid high fat meals methadone dose may need increased

<sup>-</sup> Non-nucleoside analogues should never be prescribed in combination with one another.

<sup>-</sup> Review updated antiretroviral drug information/interactions from DHHS guidelines; dosage adjustments frequently required depending on drug regimen

<sup>\*</sup> Indicates Black Box Warning

# **Appendix 7 - Antiretroviral Therapy - Protease Inhibitors (PIs)**

Antiretroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities also see footnotes	Comments
Nelfinavir Viracept 250 mg tabs.	750 mg TID; OR 1250 BID	transaminases glucose fasting lipid profile	transaminases glucose every 3-4 months lipids as needed	diarrhea	take with light snack or with meals do not coadminister with terfenadine, astemizole, cisapride, rifampiin, triazolam or midazolam best tolerated PI diarrhea usually resolves with continued use
Indinavir Crixivan 200, 333, 400 mg caps.	800 mg q 8 h	transaminases renal function glucose fasting lipid profile	transaminases renal function glucose every 3-4 months lipids as needed	kidney stones nausea vomiting dry skin alopecia	take 1 hr before or 2 hrs after meal can take with skim milk, juice, coffee, tea or low fat, low calorie, and low protein meal separate dosing with ddI by 1 hour drink at least 1.5 liters of water per day sensitive to moisture, dispense/store in original container or no more than 1 wk supply in Rx vial do not concurrently give with terfenadine, astemizole, cisapride, triazolam, or midazolam asymptomatic increase in bilirubin
Ritonavir Norvir 100 mg caps. 600 mg/7.5 mL sol.	600 mg BID  Initiate lower dose then escalate to reduce GI effects	transaminases glucose fasting lipid profile CPK uric acid	transaminases renal function glucose every 3-4 months  CPK uric acid lipids as needed	nausea vomiting abdominal pain taste perversion parenthesis lipid disorders	take with food multiple drug interactions do not coadminister with amiodarone, bepridil, bupropion, cisapride, clozapine, encainide, flecainide, meperidine, piroxicam, propafenone, propoxyphene, quinidine, rifabutin, alprazolam, clorazepate, diazepam, estazolam, flurazepam, midazolam, triazolam, zolpidem (these are absolute contraindications) PI most correlated with lipid abnormalities combined with lopinavir as Kaletra

Saquinavir Fortovase (soft-gel) 200 mg caps  Invirase (hard-gel) 200 mg caps	Fortovase 1200 mg TID; 400 mg BID with ritonavir 400 mg BID  Invirase no longer recommended as a sole PI in any regimen given 400 mg BID only with ritonavir	transaminases glucose fasting lipid profile	transaminases glucose every 3-4 months lipids as needed	diarrhea nausea abdominal discomfort dyspepsia	Take within 2 hours after a meal Use capsules within 3 months after removed from refrigeration  Avoid coadministration with cisapride, triazolam, midazolam and ergot derivatives  Do not use saquinavir HGC (Hard Gel Capsule) (Invirase®) except with ritonavir
Amprenavir Agenerase 50, 150 mg caps.	> 50 kg:1200 mg BID  < 50 kg: 20 mg/kg BID max: 2400 mg daily  NOTE: oral solution - different dosaging	transaminases glucose fasting lipid profile	transaminases glucose every 3-4 months	Stevens-Johnson rash nausea diarrhea perioral paresthesias	avoid high fat meals avoid vitamin E supplementation  do not coadminister with astemizole, bepridil, cisapride, dihydroergotamine, ergotamine, midazolam, triazolam, rifampin severe drug interactions possible cross-sensitivity with sulfonamides  take 1 hour before or after antacids or ddI many patients can continue or restart amprenavir if rash is mild to moderate
Lopinavir Kaletra (contains ritonavir)	400/100 mg bid (533/133 mg bid considered with efavirenz or nevirapine)	transaminases glucose cholesterol triglycerides	transaminases glucose cholesterol triglycerides	pancreatitis diarrhea (mild) asthenia nausea headaches	available only with ritonavir take with food use within 2 months after taken from refrigerator do not give with flecainide, propafenone, dihydroergotamine, orgonovine, ergotamine, methylerfonovine, pimozide, midazolam, triazolam many other drug interactions take ddI 1 hour before or 2 hours after Kaletra

- Dose escalation for ritonavir: 300 mg BID (day 1-2); 400 mg BID (day 3-5); 500 mg BID (day 6-13); then 600 mg BID
- Protease inhibitors may have serious interactions with certain drugs metabolized by the liver, e.g. astemizole, cisapride; review drug interactions carefully.
- All protease inhibitors may cause hyperglycemia, diabetic ketoacidosis, lipid abnormalities, and fat redistribution.
- Review updated antiretroviral drug information/interactions from DHHS guidelines; dosage adjustments frequently required depending on drug regimen

# Appendix 8 - HIV Post-exposure Prophylaxis (PEP) Guidelines\*

TYPE OF INJURY	Exposure Type		HIV INFECTION STATUS OF SOURCE (class/viral load)**			COUNSEL  Based on any one X:	TREATMENT REGIMEN  (Base treatment on resistance patterns, and if
	(severity)	low	high	unknown status or source	HIV(-) NoPEP	(no. of PEP drugs)	needed, obtain consult)
Needle stick (i.e. puncture, or percutaneous)	Deep or more severe	X	X			Recommend (3)	► EXPANDED: BASIC 2 drug regimen plus 1 of the following (NFV or EFV or IDV or ABC)
percutaneous)	Severe			X		Generally NO PEP, however, consider (2)	► <u>BASIC 2</u> - drug regimen: (ZDV + 3TC); or (3TC + d4T); or (ddI + d4T)
Needle stick OR Mucous membrane (splash, spray) OR Open, compromised	Superficial/ less severe OR large volume of a	X	X			Recommend (3) Recommend (2)	<ul><li>▶ BASIC 2 + 1 EXPANDED (above)</li><li>▶ BASIC 2-drug regimen (above)</li></ul>
skin, i.e. dermatitis, chapped, abrasion, open wound, bites)	blood splash			X		Generally NO PEP, however, consider (2)	► BASIC 2-drug regimen (above)
Mucous membrane (splash, spray) OR	Small volume		X			Recommend (2)	► BASIC 2-drug regimen (above)
Open, compromised skin exposures***	or few drops	X				Consider (2)	► BASIC 2-drug regimen (above)
defined above, bites.				X		Generally NO PEP, however, consider (2)	► BASIC 2-drug regimen (above)

<sup>\*</sup> Review CDC guidelines: MMWR, Vol. 50 (RR-11) June 29, 2001 for complete guidance

<sup>\*\*</sup> If the source has known HIV infection, PEP is recommended or considered based on type of injury and infection status of the source (low viral load is < 1,500 c/mL or asymptomatic HIV infection and high viral load is > 1,500 c/mL or AIDS); if infection status of source is unknown PEP is usually not indicated, but can be considered; If the source is HIV seronegative PEP is not warranted.

<sup>\*\*\*</sup> For skin exposures, follow-up is indicated if there is open, compromised non-intact skin (defined above) resulting in bloodborne/other potentially infectious material (OPIM) exposure to either person. Otherwise, no PEP is warranted. OPIM includes: semen, vaginal secretions; and CSF, synovial, pleural, peritoneal, pericardial, and amniotic fluids.

# **Appendix 8 - HIV Post-exposure Prophylaxis (PEP) - Definitions**

## **INJURY TYPE**

- (1) Needle stick, puncture or percutaneous injury, i.e. contaminated needle or sharp instrument that penetrates or cuts the skin.
- (2) Mucous membrane is a splash or spray of blood or OPIM into the eyes, nose, ear, mouth; or that inoculates into compromised, open skin.
- (3) <u>Open, compromised skin exposures</u> without barrier protection that has resulted in direct exposure to blood/OPIM, should be clinically evaluated. For human <u>bites</u>, include the possibility that both the person bitten and the person who inflicted the bite were exposed to bloodborne pathogens/OPIM. Transmission of HBV or HIV infection has only rarely been reported by this route.

## **EXPOSURE TYPE (SEVERITY FACTOR)**

- (1) More severe or deep: large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.
- (2) Superficial or less severe: solid needle or superficial scratch injury.
- (3) <u>Large volume</u> is a major blood volume
- (4) Small volume is a few drops.

#### HIV INFECTION STATUS OF SOURCE

- (1) Low viral load or HIV-Positive CLASS I: asymptomatic or viral load is < 1,500 RNA cps/mL.
- (2) High viral load or HIV-Positive CLASS II: asymptomatic HIV infection, AIDS, acute seroconversion, or viral load is > 1,000 RNA cps/mL.
- (3) Source of *unknown HIV status*: i.e. deceased, or person refuses testing, or no samples available; consider clinical assessment & risk behaviors.
- or *Unknown source*: i.e. exposure from inappropriately disposed blood; from a sharp container; consider the infection among the patient setting.

## COUNSEL

- (1) Recommend: means the exposure represents an increased risk of transmission could take place and the use of PEP is recommended.
- (2) <u>Consider</u>: means PEP is optional: an individualized "decision" is made between the exposed person and provider. If PEP is initiated and the source is later determined to be HIV-negative, PEP should be discontinued.
- (3) *Generally none*: means no PEP is warranted; however in settings where exposure to HIV-infected persons is likely, PEP should be considered.
- (4) None indicated: No PEP is warranted when the source is HIV negative (-).

**TREATMENT:** PEP tx is 4 weeks (at least 28 days) of 2 or 3 oral drugs: (1) Basic 2-drug PEP = ZDV + 3TC; or 3TC + d4T; or ddI + d4T, or base tx on resistance patterns. If resistance, obtain ID consult. (2) 3-drug PEP = Basic 2-drug combination + (NFV, or IDV or EFV or ABC), or base tx on resistance patterns. Drug toxicity monitoring: CBC and renal and hepatic function tests at baseline and 2 weeks after starting PEP.

**MEDICATIONS/DOSING:** Zidovudine (ZDV) = 600 mg per day in two or three divided doses, Lamivudine (3TC) = 150 mg BID; Stavudine (d4T) = > 60 kg: 40 mg BID, or < 60 kg: 30 mg BID; Didanosine (ddI) = > 60 kg: 200 mg BID, or < 60 kg: 125 mg BID, or 300 - 400 mg daily on empty stomach; Indinavir (IDV) = 800 mg every 8 hours on empty stomach; Efavirenz (EFV) = 600 mg daily at bedtime; Abacavir (ABC) = 300 mg BID; Nelfinavir (NFV) = 750 mg TID with food, or 1250 mg twice daily.

## **Appendix 10 - Resources: Prevention and Treatment of HIV Infection**

#### **Centers for Disease Control and Prevention**

## **National Prevention Information Network**

P.O. Box 6003, Rockville, MD 20849-6003

Telephone 1-800-458-5231

Internet address: <a href="http://www.cdcnpin.org">http://www.cdcnpin.org</a>

PEP-Line, DHHS/CDC, managing work exposures with post-exposure prophylaxis.

Internet address: <a href="http://www.epi-center.uscf.edu/warmline">http://www.epi-center.uscf.edu/warmline</a>

Post-exposure prophylaxis hotline/24 hours per day/7 days per week - 1-888-448-4911

# National Center for HIV, STD, and TB Prevention Division of HIV/AIDS Prevention

Information on prevention, surveillance, research, and training.

Internet address: <a href="http://www.cdc.gov/hiv/dhap.htm">http://www.cdc.gov/hiv/dhap.htm</a>

## Department of Health and Human Services/U.S. Public Health Service

The HIV/AIDS Treatment Information Service (ATIS) AIDS Treatment Information Service: 1-800-448-0440

Interagency website: <a href="http://www.hivatis.org">http://www.hivatis.org</a>

National AIDS Hotline (English): 1-800-342-2437 National AIDS Hotline (Spanish): 1-800-344-7432

## **Drug Treatment Directory**

National Institutes of Health Center of Pharmacology Internet address: <a href="http://www.cc.nih.gov/phar">http://www.cc.nih.gov/phar</a>

## **Health Resources and Services Administration (HRSA)**

5600 Fishers Lane, Rm-746; Rockville, MD; 20857

Telephone: (301) 443-6652

AIDS Drug Assistance Program (ADAP); Getting HIV/AIDS Care, State ADAP Contacts.

Internet address: <a href="http://hab.hrsa.gov/getting.html">http://hab.hrsa.gov/getting.html</a>

HRSA/AIDS ETC National HIV Telephone Consultation Service (Warmline),

**1-800 -933-3413,** 7:30 AM - 5:00 PM PST (Mon.-Fri.)

HIV/AIDS Information Center; Journal of the American Medical Association

Internet address: http://www.ama-assn.org/special/hiv/hivhome.htm

## HIV and Hepatitis. com

P.O. Box 14288

San Francisco, CA 94114

An on-line publication providing educational information about the treatment for HIV/AIDS, chronic hepatitis B and C, and co-infection with HIV/hepatitis C and HIV/hepatitis B. The information is not intended to serve as a substitute for professional medical advice from a trained licensed physician.

Internet address: <a href="http://www.hivandhepatitis.com">http://www.hivandhepatitis.com</a>

## **International AIDS Society**

Treatment guidelines for HIV infection Antiretroviral drug resistance testing guidelines Internet address: <a href="https://www.jama.ama-assn.org">www.jama.ama-assn.org</a>

## **Pocket Guide to HIV/AIDS Treatment**

Developed by Johns Hopkins University

Sponsored by HRSA/ AIDS Education Treatment Center's National Resource Center

Internet address: <a href="http://www.aids-ed.org">http://www.aids-ed.org</a>

## The Clinician's Educational Resource

An educational provider/professional healthcare resource; managed by World Health CME, with interactive services provided by InterActions Healthcare Communications.

Internet address: http://www.HIVLine.com

## **Substance Abuse and Mental Health Services Administration**

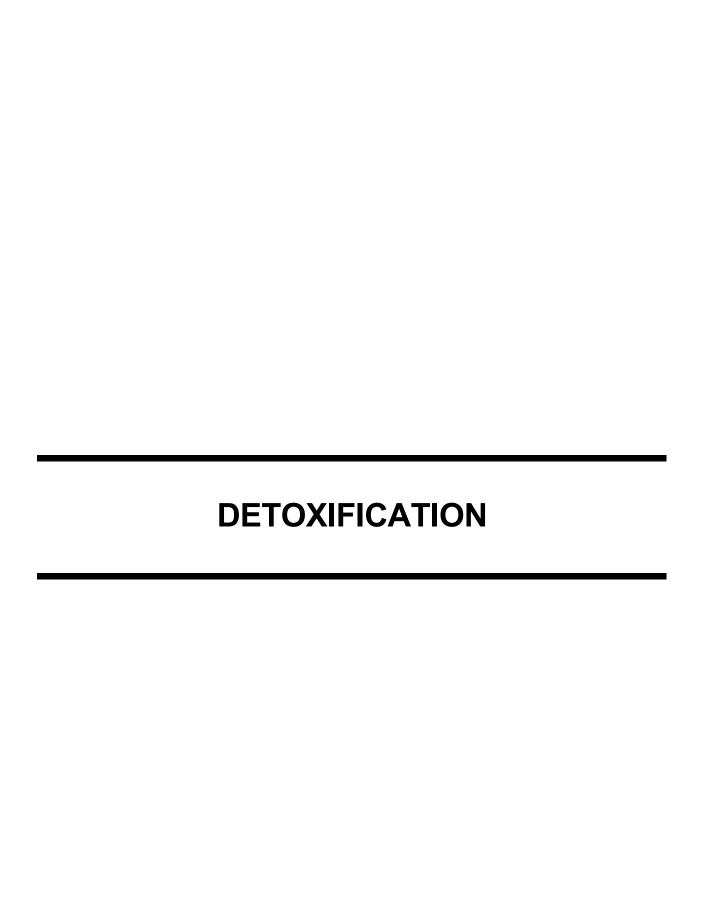
Room 12-105 Parklawn Building; 5600 Fishers Lane; Rockville, MD 20857

Internet address: <a href="http://www.samhsa.gov">http://www.samhsa.gov</a>

## U.S. Food and Drug Administration; Office of Special Health Needs

HFI-40; Rockville, MD; 20857

Telephone: 1-888-463-6332 (1-888-INFO-FDA) Internet address: http://www.fda.gov/oash/aids/hiv.html



## Symptoms and Signs of Drug Abuse

Acute Intoxication and Overdose

Withdrawal Syndrome

Hallucinogens
LSD①; psilocybin;
mescaline; PCP②; STP③;
MDMA④; Bromo-DMA⑤

Drug

Pupils dilated (normal or small with PCP); BP elevated, heart rate increased, tendon reflexes hyperactive; temperature elevated; face flushed; euphoria, anxiety or panic; paranoid thought disorder; sensorium often clear; affect inappropriate; time/visual distortions; visual hallucinations; depersonalization; with PCP: drooling, blank stare, mutism, amnesia, analgesia, nystagmus (sometimes vertical), ataxia, muscle rigidity, impulsive/often violent behavior

None

CNS Stimulants
amphetamines; cocaine;
methylphenidate;
phenmatrazine;
phenylpropanolamine; most
anti-obesity drugs

Pupils dilated and reactive; respiration shallow; BP elevated; heart rate increased; tendon reflexes hyperactive; temperature elevated; cardiac arrhythmias; dry mouth; sweating; tremors; sensorium hyperacute or confused; paranoid ideation; hallucinations; impulsivity; hyperactivity; stereotypy; convulsions; coma

Muscular aches; abdominal pain; chills, tremors; voracious hunger; anxiety; prolonged sleep; lack of energy; profound psychological depression, sometimes suicidal; exhaustion

Cannabis Group marijuana; hashish; THC®; hash oil

Pupils unchanged; conjunctiva injected; BP decreased on standing; heart rate increased; increased appetite; euphoria, anxiety; sensorium often clear; dreamy, fantasy state; time-space distortions; hallucinations rare

Nonspecific symptoms including anorexia, nausea, insomnia, restlessness, irritability, anxiety

Opioids
heroin; morphine;
codeine; meperidine;
methadone; hydromorphone;
opium; pentazocine;
propoxyphene

Pupils constricted (may be dilated with meperidine or extreme hypoxia); respiration depressed; BP decreased, sometimes shock; temperature decreased; reflexes diminished to absent; stupor or coma; pulmonary edema; constipation; convulsions with propoxyphene or meperidine

Pupils dilated; pulse rapid; gooseflesh; abdominal cramps; muscle jerks; "flu" syndrome; vomiting, diarrhea; tremulousness; yawning; anxiety

CNS Sedatives
barbiturates;
benzodiazepines;
glutethimide;
meprobamate; methaqualone

Pupils in mid position and fixed (but dilated with glutethimide or in severe poisoning); BP decreased, sometimes shock; respiration depressed; tendon reflexes depressed; drowsiness or coma; nystagmus; confusion; ataxia, slurred speech; delirium; convulsions or hyper-irritability with methaqualone overdosage; serious poisoning rare with benzodiazepines alone

Tremulousness; insomnia; sweating; fever; clonic blink reflex; anxiety; cardiovascular collapse; agitation; delirium; hallucinations; disorientation; convulsions; shock

Anticholinergics atropine; belladonna; henbane; scopolamine; trihexyphenidyl; benztropine mesylate; procyclidine; propantheline bromide Pupils dilated and fixed; heart rate increased; temperature elevated; decreased bowel sounds; drowsiness or coma; flushed, dry skin and mucous membranes, sensorium clouded; amnesia; disorientation, visual hallucinations; body image alterations; confusion

Gastrointestinal and musculoskeletal symptoms

\*Mixed intoxications produce complex combinations of signs and symptoms

①LSD (d-lysergic acid diethylamide)
②PCP (phencyclidine)

③STP (2,5-dimethoxy-4-methylamphetamine)

MDMA (3,4 methylenedioxymethamphetamine)
⑤Bromo-DMA(4 Bromo2/5dimethoxyamphetamine)

## Benzodiazepine Dose Equivalents

Dose equivalencies are only estimates. Many individual factors affect the metabolism of benzodiazepines. For example, the presence of liver disease can decrease the metabolism and increase the accumulation of the benzodiazepine. The presence of active metabolites will also increase the half-life of the medication. Dosages may need to be adjusted based on clinical findings. Half-lives are also estimates as these vary widely from individual to individual. Generally the older the person, the slower the metabolism. For example, the half-life of flurazepam in an elderly individual may be as long as 200 hours.

Generic Name (Trade Name)	Equivalent Dose (mg)	Half-life (Hours)
Alprazolam (Xanax)	0.5	6-15
Chlordiazepoxide (Librium)	25	24-48
Clonazepam (Klonopin)	1-2	30-40
Clorazepate (Tranxene)	7.5-15	30+
Diazepam ( <i>Valium</i> )	10	20-50
Estazolam ( <i>ProSom</i> )	1	10-24
Flurazepam (Dalmane)	15-30	50-200
Lorazepam (Ativan)	1	10-20
Oxazepam (Serax)	15-30	5-10
Temazepam (Restoril)	15-30	3-20
Triazolam ( <i>Halcion</i> )	0.25	1-5
Zolpidem ( <i>Ambien</i> )	10-20	2-5

Adapted from multiple sources including: Kasser, C.,  $\underline{\text{et}}$  al., and The Physicians' Desk Reference, 2000

## Barbiturate Dose Equivalents

Dose equivalencies are estimates and dosages should be adjusted according to clinical response. Barbiturates have a narrow therapeutic window such that toxicity can develop quickly above doses needed to manage withdrawal symptoms. Long term use produces tolerance to the sedative and euphoric effects without concurrent development of tolerance to respiratory depression. Careful attention to vital signs, particularly respiratory status is imperative during withdrawal and detoxification. Phenobarbital is the drug of choice for detoxification from barbiturates and barbiturate-like medications. One exception may be meprobamate. Meprobamate itself can be used to detoxify inmates dependent on meprobomate.

Generic Name (Trade Name)	Equivalent Dose in mgs.					
Amobarbital (Amytal, others)	100					
Butabarbital (Many combinations)	100					
Butalbital (Fiorinal, others)	100					
Pentobarbital (Nembutal, others)	100					
Phenobarbital (Donnatal, others)	30					
Secobarbital (Seconal, others)	100					
Barbiturate-like Drugs						
Chloral Hydrate (Many)	250-350					
Ethchlorvynol ( <i>Placidyl</i> )	200-500					
Glutethimide (Doriden, others)	250					
Meprobamate* (Miltown, others)	400					
Methaqualone (Quaalude, others)	300					

<sup>\*</sup>See notation above regarding detoxification from meprobamate.

Adapted from multiple sources including Kasser, C.,  $\underline{\text{et}}$  al., and the Physician Desk Reference, 2000.



## DSM-IV Criteria for Major Depressive Episode

Five (or more) of the following nine symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure (Note: Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations).

- Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g. feels sad or empty) or observation made by others (e.g. appears tearful)
- Anhedonia: Markedly diminished interest or pleasure in all, or almost all, activities most of the day nearly every day (as indicated by either subjective account or observation made my others)
- Weight change: weight loss or gain when not dieting or attempting to gain weight (e.g., a change of more than 5% body weight in a month), or decrease or increase in appetite nearly every day
- Insomnia or hypersomnia nearly every day
- Psychomotor changes: agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
- Fatigue or loss of energy nearly every day
- Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
- Poor concentration: Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
- Suicidal thoughts: Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

#### Also:

- The symptoms do not meet criteria for a mixed episode.
- The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).
- The symptoms are not better accounted for by bereavement, i.e., after the loss of a loved one; the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

## DSM-IV Criteria for Major Depressive Disorder, Single Episode

- A. Presence of a single major depressive episode.
- B. The major depressive episode is not better accounted for by schizoaffective disorder and is not superimposed on schizophrenia, schizophreniform disorder, delusional disorder, or psychotic disorder not otherwise specified.
- C. There has never been a manic episode, a mixed episode, or a hypomanic episode. Note: This exclusion does not apply if all of the manic-like, mixed-like, or hypomanic-like episodes are substance or treatment-induced or are due to the direct physiological effects of a general medical condition.

## DSM-IV Criteria for Major Depressive Disorder, Recurrent

- A. Presence of two or more major depressive episodes.
- B. The major depressive episode is not better accounted for by schizoaffective disorder and is not superimposed on schizophrenia, schizophreniform disorder, delusional disorder, or psychotic disorder not otherwise specified.
- C. There has never been a manic episode, a mixed episode, or a hypomanic episode. Note: This exclusion does not apply if all of the manic-like, mixed-like, or hypomanic-like episodes are substance or treatment-induced or are due to the direct physiological effects of a general medical condition.

## Risk Assessment for Patients with Depression

The risk assessment should be documented at each inmate visit for inmates diagnosed with major depressive disorder. Note: some patients are more likely to act on suicidal thoughts during the early phase of recovery than during the acute phase of the disease.

The following factors should be considered and/or reviewed in all inmates with depression until symptoms are in full remission, (The presence of these factors may indicate an increased risk of suicide or violence towards others).

- Past history of acts of harm towards self or others
- Presence of thoughts of harm towards self or others
- Presence of plan to harm self or others
  - -Lethality of plan
  - -Presence of means to carry out plan
  - -Presence of intent to carry out plan
- Family history of suicide or violence
- Presence of psychotic symptoms
- History of substance abuse
- Lack of support systems
- Recent severe stressor or loss
- Presence of comorbid personality disorder or anxiety disorder

## Pharmacologic/Toxic Agents Which Can Cause or Exacerbate Depressive Symptoms

Cardiovascular	alpha-methyldopa, reserpine, propranolol, clonidine, guanethidine, thiazide diuretics, digoxin/digitoxin	
Hormones	oral contraceptives, ACTH, glucocortocoids, anabolic steroids	
Anti-Inflammatories and Anti-Infectives	NSAIDs, sulfonamides	
Anti-Cancer Agents	cycloserine, vincristine, vinblastine, others	
Anti-Emetics	droperidol, metoclopramide, prochlorperazine, perphenazine	
Psychiatric medications	benzodiazepines, sedatives/hypnotics, antipsychotics, anticholinergics	
Others	narcotics, cimetidine, ranitidine, baclofen, other muscle relaxants, ethambutol, disulfiram	
Illicit substances	all can cause or exacerbate depression during any phase of use, i.e. intoxication, chronic use, withdrawal	
Toxins	heavy metals, alcohol, thallium, anticholinesterase insecticides	

# Medical Conditions Associated with Depression (May cause or can present as depression)

Endocrine	Hypo- or Hyperthyroidism Hyperparathyroidism Hypopituitarism Adrenal disease: Cushing's or Addison's disease Diabetes
Infectious Diseases	Pneumonia Hepatitis Infectious mononucleosis HIV infection Toxoplasmosis Tertiary syphilis
Connective Tissue Disorders	Lupus Rheumatoid arthritis Mixed connective tissue disease
Nutritional disorders	Excessive intake of B-6 B-12 or folate deficiency Thiamine deficiency Pellagra (niacin deficiency)
Neurologic disorders	Stroke Multiple sclerosis Parkinson's disease Dementia Head injury Subdural hematoma (chronic) Seizure disorder CNS tumors Sleep disorders
Malignancies	Any, but especially abdominal or gastrointestinal Paraneoplastic syndrome Carcinomatosis Hematologic
Cardiac disease	Ischemic heart disease Congestive heart failure
Miscellaneous	Anemia Asthma/COPD/emphysema Chronic pain syndromes Smoking cessation Any chronic illness

## Antidepressant Medications: Indications and Dosaging

Class	Name	Indications*	Start Dose (mg) daily unless noted otherwise	Usual Dose** (mg) daily, unless noted otherwise
TCA	Amitriptyline Doxepin Imipramine Desipramine	D, A	25-50	100-300***
TCA	Nortriptyline	D, A	10-25	50-200***
SSRI	Citalopram	D, A	20	20-60
SSRI	Fluoxetine	D, d, A, OCD, E	10-20	20-60
SSRI	Sertraline	D, d, A, OCD	25-50	75-200
SSRI	Paroxetine	D, d, A, OCD	20	20-60
SDRI	Buproprion	D, D in Bipolar pts, ADD, ADHD, Sm	75 BID, or 150 daily in time release	100 TID, or 150 BID in time release
NaSSA	Mirtazapine	D, S, A	7.5-15	7.5-45
SSNI	Venlafaxine	D, d, A, OCD	37.5-75 per day (BID dosing in non time release)	75-225 total daily dose (BID dosing in non time release)
Triazolopyridine	Trazodone	S(D? efficacy)	25-50	50-150 for S 150-300 for D
Phenylpiperazine	Nefazodone	D, A(?)	50-100 BID	200 BID

<sup>\*</sup>D=Depressive Disorders; d=Dysthymia; A=Anxiety disorders other than OCD; OCD=Obsessive Compulsive Disorder; S=Sleep Disturbance-insomnia; ADD=Attention Deficit Disorder; ADHD=Attention Deficit Hyperactivity Disorder; Sm=Smoking Cessation; E=Eating Disorder

<sup>\*\*</sup>Severely depressed inmates may need higher doses. See PDR for indications. Elderly inmates may need lower doses, both as starting dose and as therapeutic dose.

<sup>\*\*\*</sup>Blood levels vary as much as factor of 10 between individuals. Blood levels should be checked during titration and once steady state is reached. Nortriptyline has definitive therapeutic window, above or below which it has decreased effectiveness.

# Side Effects of Antidepressant Medications (For complete list of side effects consult the PDR)

Class of Drug	Examples	Examples Side Effects	
Selective Serotonin Reuptake Inhibitors (SSRIs)	fluoxetine fluvoxamine paroxetine sertraline citalopram	headache, nausea, flatulence, somnolence, insomnia, agitation, anxiety, weight loss or anorexia, weight gain, tremor, sexual dysfunction, myoclonus, restless legs, bruxism, akathisia, increased dreaming/nightmares, bradycardia, galactorrhea, paresthesias, mania	
Selective Dopamine- Reuptake Inhibitor (SDRI)	buproprion	increased risk of seizures: do not use in inmates with eating disorders or with seizure disorders; insomnia, anxiety, agitation, headache, tremor, myoclonus, tinnitus, palpitations	
Selective Serotonin Norepinephrine Reuptake Inhibitor (SNRI)	venlafaxine	headache, agitation, anxiety, insomnia, somnolence, dry mouth, sweating, urinary retention, constipation, increased blood pressure-dose related; nausea, dizziness, tachycardia, orthostatic hypotension, sexual dysfunction, mania	
Noradrenergic/ Specific Serotonergic Antidepressant (NaSSA)	mirtazapine	weight gain, sedation, dry mouth, constipation, increased sweating, blurred vision, urinary retention, dizziness, orthostatic hypotension, tachycardia, decreased WBC, increased LFT's, mania	
Tricyclic Antidepressants (TCAs)	amitriptyline clomipramine doxepin imipramine trimipramine desipramine nortriptyline protriptyline	anticholinergic-dry mouth, constipation, urinary retention, blurred vision, dry eyes, sweating, confusion; antihistaminic-weight gain, somnolence, nightmares, confusion; other-cardiac arrhythmia, prolonged conduction time, orthostatic hypotension, seizures, tachycardia, tremor, sexual dysfunction, mania	

## Antidepressant Side Effects (Appendix 7, p. 2)

Class of Drug	Examples	Side Effects
Tetracyclic Antidepressant	maprotiline	same as Tricyclics, and maprotiline has increased risk of seizures
MAOIs	phenelzine tranylcypromine	constipation, anorexia, weight gain, headache, anxiety, insomnia, somnolence, nausea, vomiting, dry mouth, urinary retention, sexual dysfunction, paresthesias, orthostatic hypotension, increased blood pressure, myoclonus, edema, electrolyte imbalance, mania
Triazolopyridine	trazodone	somnolence, dizziness, tachycardia, orthostatic hypotension, priapism, nausea, dry mouth, mania
Phenylpiperazine	nefazodone	dry mouth, nausea, constipation, somnolence, orthostatic hypotension, mania
Dibenzoxazepine	amoxapine	amoxapine can cause <b>tardive dyskinesia</b> , extrapyramidal side  effects and all the same side  effects as other typical  antipsychotics as well as TCAs

## Augmentation Strategies

A thorough treatment reassessment should occur if the inmate does not show a significant response to treatment for depression after 6-8 weeks of acute phase therapy.

## RE-ASSESSMENT: Review steps 1 through 9, prior to altering therapy

- 1. Thorough review of presentation, symptoms, and diagnosis: Consider another cause for depressive symptoms.
- 2. Evaluate for complicating medical condition or illness not yet diagnosed, e.g. an autoimmune disorder, infectious process, B-12 deficiency, etc.
- 3. Review compliance with inmate and pharmacy (pill line attendance via MAR forms.) Nonadherence is the most likely cause of poor response to treatment.
- 4. Ensure adequate dose and trial period of medication.
- 5. Check blood levels in medications with known therapeutic levels or when compliance is in doubt.
- 6. Consider drug-drug interactions that may be lowering plasma level of antidepressant.
- 7. Consider active substance abuse.
- 8. Review with inmate possible presence of ongoing or new significant stressors that may be impacting the inmate's functioning.
- 9. Consider consultation for second opinion.

## TREATMENT: If the above steps yield no specific answer, adjustment of the treatment regimen is reasonable; Consider the following options:

- 1. Increase dose of current medication.
- 2. Switch to another medication (different SSRIs have different efficacy in individual inmates).
- 3. Add another antidepressant to medication, e.g. add low dose TCA to SSRI, but monitor blood level of TCA.
- 4. Add triiodothyronine, 25-50 micrograms per day. If no improvement after 3 weeks, discontinue.
- 5. Add lithium. Blood levels of 0.5-0.8 mEq/L of lithium are usually sufficient for treating depression not complicated by a bipolar disorder. If no response is evident by 6 weeks, discontinue.
- 6. Add, change type, or increase frequency or intensity of psychotherapy.
- 7. ECT

Wait 6-8 weeks (unless otherwise indicated) after treatment augmentation, while monitoring the inmate closely. If incomplete or no response: repeat assessment steps 1-9 and then reconsider treatment options 1-7.

## Severe Drug-Drug Interactions With MAOIs\*

## Absolutely Contraindicated

Class of Drug	Example	Effect/Interaction
Anorexiants	fenfluramine defenfluramine	serotonin syndrome
Antidepressants (See Appendix 11 for Washout Periods)	clomipramine trazodone nefazodone venlafaxine fluoxetine paroxetine sertraline buproprion mirtazapine	serotonin syndrome
Herbs, supplements	L-tryptophan St. John's Wort	serotonin syndrome
Antimigraine	sumatriptan zolmatriptan	serotonin syndrome
Sympathomimetics	cocaine amphetamines ephedrine pseudoephedrine dopamine tyramine phenylpropanolamine methylphenidate	hypertensive crisis
Narcotics	meperidine dextromethorphan diphenoxylate tramadol	encephalopathy, death serotonin syndrome

\*Many other potential drug-drug interactions exist and have been reported with MAOIs. Check with your pharmacist prior to adding MAOIs to any medications or any medications to MAOIs. Over-the-counter medications, especially cold, hay fever and sinus medications can be dangerous and potentially life threatening. Caution inmates on these issues.

## Foods to Avoid During Treatment with MAOIs\*

#### Very High Tyramine Content

- All matured or aged cheeses (e.g. cheddar, brick, blue, Gruyere, Stilton, brie, Swiss, Camembert, Parmesan, mozzarella)
- ▶ Broad beans (fava)
- ▶ Orange pulp
- Meat extract, e.g. Marmite, Bovril
- Concentrated yeast extracts or yeast vitamin supplements
- Dried, salted, pickled or smoked fish
- ▶ Sauerkraut
- ► Aged sausage (e.g., salami, pepperoni)
- Tap beer, Chianti, other beer and wine
- ▶ Chicken or beef liver
- Packaged soup
- Summer sausage

## Moderately High Tyramine Content or reactions have been reported with these foods (no more than 1-2 servings per day)

- Soy sauce
- ▶ Sour cream, yogurt
- Meat tenderizers
- Caviar, snails
- Ripe bananas
- Caffeine
- ► Avocados
- Plums, raisins
- Chocolate
- Overripe fruit
- Chinese food
- Spinach
- ► Tomatoes

<sup>\*</sup>Adapted from <u>Clinical Handbook of Psychotropic Drugs</u>, See References

## Drug Washout Times Between Antidepressant Trials

Antidepressant Change	Minimum Washout Period	
From SSRI to SSDI, SNRI, NaSSA	2-5 days (Recommended) *	
From SSRI, SSDI, SNRI, NaSSA to SSRI	2-5 days (Recommended) *	
From TCA to TCA	None	
From SSRI, SSDI, SNRI, NaSSA to TCA	1-2 weeks depending on half-life of SSRI and its active metabolites (Recommended) *	
From TCA to SSRI, SNDI, SNRI, NaSSA	5-7 days (Recommended)*	
From drug with short half-life metabolites, e.g., paroxetine, fluvoxamine, venlafaxine, TCA to MAOI	2 weeks (Required)	
From drug with long half-life metabolites, e.g., fluoxetine, to MAOI	5 weeks (Required)	
From MAOI to non-MAOI	2 weeks (Required)	
From MAOI to MAOI	2 weeks (Required)	

<sup>\*</sup>An absolute washout of the previous medication is not necessary prior to instituting the new medication. The first medication may be tapered down as the new medication is gradually tapered upwards, while remaining cognizant of potential drug-drug interactions and half-lives of the medication and its active metabolites.



## TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD)

### **DIAGNOSIS**

history/physical examination heartburn/acid indigestion chest discomfort/ R/O cardiac dx

### **IDENTIFY HIGH RISK PATIENTS**

refer directly for upper endoscopy for dysphagia, history of Barrett's esophagus, GI bleeding otherwise pursue STEP therapy

## STEP 1 - LIFESTYLE CHANGES/ANTACID TX

patient education/ smoking cessation/avoid caffeine small meals/reduce fat content/weight reduction as indicated no lying down after eating/no eating 2 hours before bedtime drug adjustments when appropriate antacid therapy

## STEP 2 - H<sub>2</sub> BLOCKER THERAPY

 $H_2$  antagonist drug trial for 8 weeks +/- prokinetic agent (long term treatment not recommended)

## STEP 3 - PROTON PUMP INHIBITOR DRUG THERAPY (LOW DOSE)

PPI drug trial for 4 weeks (maximize one daily therapy)

## STEP 4 - PROTON PUMP INHIBITOR DRUG THERAPY (HIGH DOSE)

first pursue further diagnostic tests to confirm diagnosis
- ambulatory pH monitoring +/- upper endoscopy
high dose PPI therapy if GERD confirmed

### **STEP 5 - SURGICAL INTERVENTION**

Obtain subspecialty consultation for refractory cases Specialized surgical intervention may be indicated

## TREATMENT OF DYSPEPSIA, PEPTIC ULCER DISEASE & H. PYLORI

#### **DIAGNOSIS**

+ dyspepsia without heartburn or acid indigestion history/physical examination laboratory studies as necessary

### RISK STATUS ASSESSMENT - IDENTIFY HIGH RISK PATIENTS

any alarm symptoms such as GI bleeding, unexplained anemia, unintentional weight loss age > 50 who fails to respond to brief trial of  $H_2$  antagonist or prokinetic agent previous gastric surgery

1

refer directly for upper endoscopy/stop NSAIDs /biopsy all gastric ulcers ulcer positive/ *H. pylori* + → tx with *H. pylori* regimen ulcer negative → tx as non-ulcer dyspepsia (*H. pylori* tx not recommended) ulcer positive/ *H. pylori* negative → targeted diagnostic workup

#### PURSUE STEP THERAPY FOR LOW RISK PATIENTS

(at every step - monitor closely for alarm symptoms/refer directly for upper endoscopy as indicated)

STEP 1 - smoking cessation/dietary changes/drug adjustments (stop NSAIDs)/antacid trial

**STEP 2** - 8 week trial of H<sub>2</sub> antagonist or prokinetic agent\* (choice dependent on symptom presentation and patient characteristics)

STEP 3 - test for *H. pylori* if ulcer symptoms present and treat if positive if *H. pylori* negative or no response to treatment

STEP 4 - pursue any or all of the following actions dependent on patient characteristics

 observe and monitor closely for alarm symptoms
 trial of PPI if dyspepsia is complicated by GERD symptoms
 further diagnostic study - upper endoscopy/biliary ultrasound/abdominal CAT scan
 GI subspecialty consultation

<sup>\*</sup> Long term treatment with metoclopramide is not recommended due the abatement of drug efficacy over time and the potential for extrapyramidal side effects and tardive dyskinesia.

# Drug Treatment Options for GERD and $\emph{H. pylori-}$ associated Peptic Ulcer Disease

Medications Used in the Treatment of GERD			
*Please refer to current BOP National Formulary*			
DRUG	DOSAGE	COMMENTS	
ANTACIDS			
Liquid or Tablet Antacid (magnesium, aluminum, or calcium carbonate)	1-2 tablets or 15-30 cc, one hour before meals, two hours after meals, and at HS (additional doses may be supplemented PRN)	Aluminum: constipation Magnesium: diarrhea	
H <sub>2</sub> RECEPTOR BLOC	KERS (Low dose, over-the-counter)		
Cimetidine 200 - 400 mg BID		Caution: Inhibits cytochrome P-450 system, many drug interactions; gynecomastia	
Ranitidine	75 mg BID	Rare side effects	
Famotidine	10 mg BID	Rare side effects	
Nizatadine	75 mg BID	Rare side effects	
PROKINETIC AGENT	es		
Metoclopramide	10 mg TID - QID	Avoid long-term use due to potential for extrapyramidal effects (e.g. tardive dyskinesia)	
H <sub>2</sub> RECEPTOR BLOC	KERS (High dose for GERD)		
Ranitidine	150 mg BID to QID <u>or</u> 300 mg BID		
Famotidine	20 - 40 mg BID		
Nizatadine 150 mg BID			
Continued, next page (Proton Pump Inhibitors)			

Medications Used in the Treatment of GERD				
	*Please refer to current BOP National Formulary*			
PROTON PUMP I	PROTON PUMP INHIBITORS (Tend to be well-tolerated)			
Lansoprazole	LOW DOSE: 15 - 30 mg once daily HIGH DOSE: 30 mg BID			
Omeprazole	LOW DOSE: 10 - 20 mg once daily HIGH DOSE: 20 mg BID	Headache is most common side effect.		
Pantoprazole	40 mg once daily	Do not split, crush or chew tablets. Higher doses not indicated. (Current indication is for 8 week course for erosive esophagitis)		
Esomeprazole	LOW DOSE: 20 mg once daily HIGH DOSE: 40 mg once daily	Contains only one isomer of which Omeprazole contains both d and l. May be emptied into applesauce but not crushed or chewed.		
Rabeprazole	20 mg once daily	Do not split, crush or chew tablets.		

## TREATMENT OF HELICOBACTER PYLORI INFECTION

	PREFERRED REGIMENS FOR	TREATMENT OF H. PYLORI	(14 day regimens)
1	Lansoprazole 30 mg BID	Clarithromycin 500 mg BID	Amoxicillin 1000 mg BID
2	Lansoprazole 30 mg BID	Clarithromycin 500 mg BID	Metronidazole 500 mg BID
3	Ranitidine-Bismuth Citrate (RBC) 400 mg BID	Clarithromycin 500 mg BID	Amoxicillin 1000 mg BID  or Metronidazole 500 mg BID or Tetracycline 500 mg BID
4	Lansoprazole 30 mg <b>once</b> daily	Metronidazole 500 mg TID	Tetracycline 500 mg QID and Bismuth subsalicylate 525 mg QID
5	Ranitidine 150 mg BID or Famotidine 20 mg BID <b>THEN</b> Continue the $\mathrm{H}_2$ blocker for an additional two weeks after antibiotics	Metronidazole 250 mg QID	Tetracycline 500 mg QID  and Bismuth subsalicylate 525 mg QID

Regimens are all greater than 90% effective in eradicating H. pylori; specific regimen should be selected based on adherence issues, patient tolerance, prior treatment regimens, and cost.