**University Health System Hyperlipidemia Guidelines (Based on NCEP ATP III Guidelines with Update)**

**September 2004**

1. **Determine fasting lipid levels (9 to 12 hour fast).**

2. **Does the patient have coronary heart disease (CHD) or CHD risk equivalents?**
   1 CHD (myocardial infarction, unstable angina, stable angina, angioplasty, bypass surgery, evidence of clinically significant myocardial ischemia)
   2 Risk equivalents
      - Noncoronary atherosclerotic disease (peripheral arterial disease, abdominal aortic aneurysm, carotid artery disease)
      - Diabetes mellitus
      - 2 + risk factors (RFs) with a 10 year risk of hard CHD > 20 %

3. **How many major risk factors for CHD does the patient have?**
   1 Cigarette smoking
   2 Hypertension (BP > 140/90 or on antihypertensive medication)
   3 HDL < 40 mg/dL
   4 Family history of premature CHD (male first degree relative < 55 yo, female first degree relative < 65 yo)
   5 Age (men ≥ 45 yo, women ≥ 55 yo)
   6 Note: HDL ≥ 60 mg/dL counts as a negative risk factor (-1 RF).

4. **If the patient has 2 + RFs without CHD or risk equivalents, assess the patient's 10 year risk of developing CHD (see Framingham tables or electronic version at http://www.nhlbi.nih.gov/guidelines/cholesterol).**

5. **Determine risk category and LDL goal.**

6. **Initiate therapeutic lifestyle changes (TLC) if LDL is above goal.**
   1 TLC Diet
      - Saturated fat < 7 % of calories, total cholesterol < 200 mg/day.
      - Consider increased viscous fiber (10 to 25 g/day) and plant stanols/sterols (2 g/day) to enhance LDL lowering.
   2 Weight management
   3 Increased physical activity
   4 Smoking cessation

| Risk Category | LDL Goal (mg/dL) | Initiate TLC (mg/dL) | Consider Drug Therapy (mg/dL) |
|---|---|---|---|
| **High Risk**<br>CHD or risk equivalents | < 100<br>(optional: < 70)* | > 100<br>(optional: > 70)* | > 100<br>(optional: > 70)* |
| **Moderately High Risk**<br>2 + RFs with 10 year risk of 10 to 20 % | < 130<br>(optional: < 100)** | > 130<br>(optional: > 100)** | > 130<br>(optional: > 100)** |
| **Moderate Risk**<br>2 + RFs with 10 year risk of < 10 % | < 130 | > 130 | > 160 |
| **Lower Risk**<br>0 or 1 RF | < 160 | > 160 | > 190<br>(optional: > 160) |

*Very high risk favors the optional LDL goal of < 70 mg/dL, and in patients with high triglycerides, non-HDL cholesterol goal of < 100 mg/dL.

**For moderately high-risk patients, when LDL is 100 to 129 mg/dL, at baseline or on lifestyle therapy, initiation of an LDL lowering drug to achieve an LDL < 100 mg/dL is a therapeutic option on the basis of available clinical trial results.

7. **Consider adding drug therapy if LDL exceeds threshold for drug therapy.**

**8. Identify metabolic syndrome and treat, if present, after 3 months of TLC.**

1 Metabolic Syndrome (Any 3 of the following)
- Abdominal obesity (male waist > 40 inches, female waist > 35 inches)
- TG ≥ 150 mg/dL
- HDL < 40 mg/dL in men, HDL < 50 mg/dL in women
- BP ≥ 130/85 mmHg
- FBG ≥ 110 mg/dL

2 Treatment of the metabolic syndrome
- Intensify weight management
- Increase physical activity
- Treat hypertension
- Use aspirin for CHD patients to reduce prothrombotic state
- Treat elevated TG and/or low HDL (see step 9).

**9. Treat elevated triglycerides and/or low HDL.**

3 If TG ≥ 500 mg/dL, the first lipid-lowering priority is TG to reduce risk of acute pancreatitis.
- Very low fat diet (≤ 15 % of calories from fat)
- Weight management and physical activity
- Fibrate or nicotinic acid
- When TG < 500 mg/dL, LDL lowering becomes the top priority.

4 If TG 200 to 499 mg/dL, the first lipid-lowering priority is LDL.
- After LDL goal is reached, consider intensifying LDL lowering or adding nicotinic acid or a fibrate to further lower VLDL.

5 If HDL < 40 mg/dL, first reach LDL goal. Then:
- Intensify weight management and increase physical activity
- If TG 200 to 499 mg/dL, achieve non-HDL goal (30 mg/dL above LDL goal).
- If TG < 200 mg/dL in patients with CHD or risk equivalents, consider nicotinic acid or a fibrate.

**Special considerations for the University Health System**

1 Statins should be used in the following order (assuming that the agent's efficacy is appropriate for the patient and the patient has no contraindications):
1. Lovastatin or pravastatin (Pravachol®)
2. Simvastatin (Zocor®) or atorvastatin (Lipitor®)

2 Fenofibrate (Tricor®) should only be used if the patient has failed gemfibrozil or has a contraindication to gemfibrozil.

| Drug | Contraindications | Efficacy | Common Side Effects | Dosing | Monitoring | MAP | Subsidy Status |
|---|---|---|---|---|---|---|---|
| HMG CoA Reductase Inhibitors | | | | | | | |
| **Atorvastatin (Lipitor®)**<br><br>**($65.28 per month for 80 mg/day)** | Active or chronic liver disease | LDL – 40 to 60 %<br>HDL + 5 %<br>TG – 15 to 35 % | Myopathy<br>Elevated LFTs | 10 to 80 mg daily | Fasting lipid profile at baseline and at 6-8 weeks;<br>Evaluate LFTs initially,12 weeks after starting, then annually or more frequently if indicated[1,2] | Yes | Subsidized per criteria |
| **Lovastatin**<br><br>**($43.05 per month for 80 mg/day)** | Active or chronic liver disease | LDL – 25 to 40 %<br>HDL + 5 %<br>TG – 10 to 15 % | Myopathy<br>Elevated LFTs | 20 to 80 mg at bedtime | Fasting lipid profile at baseline and at 6-8 weeks;<br>Evaluate LFTs initially,12 weeks after starting, then annually or more frequently if indicated [1,3] | No | Subsidized per criteria |
| **Pravastatin (Pravachol®)**<br><br>**($43.89 per month for 80 mg/day)** | Active or chronic liver disease | LDL – 20 to 40 %<br>HDL + 5 %<br>TG – 5 to 15 % | Myopathy<br>Elevated LFTs | 10 to 80 mg at bedtime | Fasting lipid profile at baseline and at 6-8 weeks;<br>Evaluate LFTs initially,12 weeks after starting, then annually or more frequently if indicated [1,4] | Yes | Subsidized per criteria |
| **Simvastatin (Zocor®)**<br><br>**($43.91 per month for 80 mg/day)** | Active or chronic liver disease | LDL – 30 to 50 %<br>HDL + 5 to 10 %<br>TG – 10 to 25 % | Myopathy<br>Elevated LFTs | 10 to 80 mg at bedtime | Fasting lipid profile at baseline and at 6-8 weeks;<br>Evaluate LFTs initially,12 weeks after starting, then annually or more frequently if indicated [1,5] | Yes | Not Subsidized |
| 2-Azetidinones | | | | | | | |
| **Ezetimibe (Zetia®)**<br><br>**($47.26 per month)** | Hypersensitivity | LDL – 15 to 20 %<br>HDL + 5 %<br>TG – 5 % | Headache<br>Arthralgia | 10 mg daily | Fasting lipid profile at baseline and at 6-8 weeks[1,6] | Yes | Not Subsidized |
| Bile Acid Sequestrants | | | | | | | |
| **Cholestyramine**<br><br>**($43.95 per month for 12 g/day)** | Dys-betalipoproteinemia<br><br>TG > 400 mg/dL | LDL – 15 to 30 %<br>HDL + 5 %<br>TG + 0 to 20 % | GI distress<br>Constipation<br>Decreased absorption of other drugs | 4 g twice to six times daily | Fasting lipid profile at baseline and at 6-8 weeks[1,7] | No | Subsidized |
| Fibrates | | | | | | | |
| **Gemfibrozil**<br><br>**($7.22 per month)** | Severe renal disease<br><br>Severe hepatic disease | LDL – 5 to 10 %<br>HDL + 10 to 20 %<br>TG – 40 to 60 % | Dyspepsia<br>Gallstones<br>Myopathy | 600 mg bid | Fasting lipid profile at baseline and at 6-8 weeks;<br>LFTs at baseline and at each follow-up visit;<br>Periodic CBC[1,8] | No | Subsidized |
| **Fenofibrate (Tricor®)**<br><br>**($42.49 per month for 160 mg/day)** | Severe renal disease<br><br>Severe hepatic disease | LDL – 20 to 25 %<br>HDL + 0 to 20 %<br>TG – 30 to 50 % | Dyspepsia<br>Gallstones<br>Myopathy | 54 to 160 mg daily | Fasting lipid profile at baseline and at 6-8 weeks;<br>LFTs at baseline and at each follow-up visit;<br>Periodic CBC[1,9] | Yes | Subsidized per criteria |
| **Nicotinic Acid**<br><br>**($6.18 per month for 2000 mg tid)** | Chronic liver disease<br><br>Severe gout | LDL – 20 to 30 %<br>HDL + 10 to 35 %<br>TG – 10 to 50 % | Flushing<br>Hyperglycemia<br>Hyperuricemia<br>Upper GI distress<br>Hepatotoxicity | 500 to 2000 mg tid* | Fasting lipid profile at baseline and at 6-8 weeks;<br>Obtain LFTs initially, 6-8 weeks after reaching a daily dose of 1,500 mg, 6-8 weeks after reaching the maximum daily dose, then annually or more frequently if indicated;<br>FBG initially, 6-8 weeks after starting therapy, then annually or more frequently if indicated[1,10] | No | OTC medications are not subsidized |

*Nicotinic acid titration example (Take aspirin 325 mg 1 hr prior to each dose to reduce flushing):

Week 1: 250 mg with evening meal.
Week 2: 250 mg bid
Week 3: 500 mg bid
Week 4: 1000 mg bid
Week 5 and thereafter: increase dose weekly to maximum tolerated dose up to 2000 mg tid

References


1. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive summary of the third report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. *JAMA*. 2001; 285:2486-97.
2. Lipitor package insert. New York, NY: Pfizer Pharmaceuticals; 2003 Sept.
3. Mevacor package insert. Whitehous Station, NJ: Merck & Co., Inc.; 2002 Sept.
4. Pravachol package insert. Princeton, NJ: Bristol-Myers Squibb Co.; 2003 Sept.
5. Zocor package insert. Whitehouse Station, NJ: 2004 Jul.
6. Zetia package insert. North Wales, PA: Merck/Schering-Plough Pharmaceuticals; 2004 Jul.
7. Questran Light package insert. Princeton, NJ: Bristol-Myers Squibb Co.; 2000 Aug.
8. Lopid package insert. Vega Baja, PR: Parke Davis Pharmaceuticals, Ltd.; 2001 Aug.
9. Tricor package insert. Chicago, IL: Abbott Laboratories; 2001 Sept.
10. Niaspan package insert. Miami, FL: Kos Pharmaceuticals, Inc.; 2003 Jan.