

Statin Therapy Assessment Guide



For each new, follow-up, or refill prescription consultation for a statin, answer the following questions with a “Yes” or “No” response. A “Yes” response to any question suggests a potential drug therapy problem exists and you should refer to the item number on the reverse side of this guide for additional information.

			Drug Therapy Problem No.
NEW RX PROFILE REVIEW			
1) Is new prescription an increase in dose for a previously-prescribed statin?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	1 or 6
2) If first prescription for statin, is prescribed statin therapy above initial recommended dose?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	2
3) Is patient also taking a beta-blocker, corticosteroid, estrogen, retinoid, anabolic steroid or progestational product?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	3
4) Is patient taking several different types of medications for chronic medical conditions?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	4
5) Is patient also taking a lipid-lowering agent in a different pharmacologic class?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	4
6) Is patient also taking cyclosporine, erythromycin, clarithromycin, itraconazole, ketoconazole, HIV protease inhibitors, nefazodone?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	4
7) Is prescribed dose equal to one-half of an available tablet size?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	5

NEW RX PATIENT INTERVIEW			
1) Have you ever been told you have cardiovascular disease, diabetes, hypothyroidism, liver or renal disease?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	6
2) Do you drink grapefruit juice on a regular basis?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	4
3) Have you found it difficult to change your diet and exercise habits?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	8
4) Has your doctor told you that your bad cholesterol (LDL) is too high?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	6
5) Has your doctor told you that your good cholesterol (HDL) is too low?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	6
6) Has your doctor told you that your triglyceride level is too high?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	6
7) Does the cost of this medication represent a financial burden to you?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	7
8) Would you be willing to split tablets of your medication if it was less expensive?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	5
9) (If female patient of child bearing age) Are you pregnant, nursing, or considering having a child?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	11

REFILL/FOLLOW-UP PROFILE REVIEW			
1) Is patient early or late for their refill based on the days supply dispensed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	9
2) Has patient recently started taking a beta-blocker, corticosteroid, estrogen, retinoid, anabolic steroid or progestational product?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	3
3) Has patient started taking a lipid-lowering agent in a different pharmacologic class since the previous prescription was filled?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	4

REFILL/FOLLOW-UP PATIENT INTERVIEW			
1) Do you sometimes forget to take your medications?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	9
2) Do you sometimes forget to take your medication at bedtime or with meals as directed?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	9
3) Have you experienced any of the following symptoms since starting to take this medication:			
a. Muscle aches or pain?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	4
b. Change in color of your skin or urine?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	4
4) Have you seen your doctor since you last had your prescription filled? If yes,	<input type="checkbox"/> Yes	<input type="checkbox"/> No	1 or 6
a. Did your doctor tell you that your bad cholesterol (LDL) is still too high?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	1 or 6
b. Did your doctor tell you that your good cholesterol (HDL) is still too low?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	1 or 6
c. Did your doctor tell you that your triglycerides are still too high?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	1 or 6
5) Do you need help finding ways to lower your dietary fat intake?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	8
6) Do you need help starting or maintaining an exercise program?.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	8
7) Has it been more than 1 year since you had a blood test to check your liver function?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	10
8) (If female patient of child bearing age) Are you pregnant, nursing, or considering having a child?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	11
9) Are you dissatisfied with your drug therapy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Potential Drug Therapy Problems:

- 1) **Needs Therapy – Combination Lipid-Lowering Regimen** Agents in this class can be expected to decrease LDL cholesterol between 16-55%, increase HDL cholesterol by 5-15% and reduce triglycerides from 7-30%. Because drugs in this class are typically very effective, patient compliance should always be verified prior to increasing the dose. Furthermore, a modest 6% reduction in LDL cholesterol can be anticipated when doubling the dose. The addition of bile acid sequestrants, niacin or fibrates may be indicated for those patients where marked reductions in LDL are needed, triglyceride or VLDL-cholesterol is elevated or if the patient cannot tolerate higher doses of statins. **Recommend:** Addition of a bile acid sequestrant, niacin or fibrate at initially lower doses, then titrated upwards. Monitor patient closely for development of myopathy.
- 2) **Excessive Dose – Statin** Patients should begin statin therapy with a low to moderate dose unless LDL cholesterol is more than 30% above desired goal. Usual initial dose is 20mg per day (except atorvastatin and rosuvastatin, which should be initiated at 10mg per day). Because a direct relationship exists between increasing statin dosages and increasing the risk of myopathy, statin dosages generally should not exceed those required to attain the goal LDL. **Recommend:** Confirm patient's current LDL cholesterol level and goal and initiate therapy with 10-20mg daily. Follow-up to ensure lipid profile is obtained in 4-6 weeks and adjust dose as indicated.
- 3) **Adverse Drug Reaction – Cholesterol-Elevating Drugs** Corticosteroids, estrogens, retinoids, and higher doses of beta blockers can elevate triglycerides. Beta blockers, anabolic steroids, and progestational agents decrease HDL. **Recommend:** If possible, discontinue or modify drug regimens that may be negatively impacting patient's lipid profile. Monitor patient lipid profile response to statin therapy and increase dosage to achieve desired goal levels.
- 4) **Adverse Drug Reaction – Myopathy** While the risk of developing severe myopathy with elevated creatine kinase is relatively small, patients who take multiple medications, have several chronic conditions, are elderly or who are also taking other lipid-lowering agents (fibrates, niacin) are at greater risk. Drugs known to reduce liver metabolism such as amiodarone, cyclosporine, erythromycin, clarithromycin, itraconazole, ketoconazole, HIV protease inhibitors, and nefazodone have the potential to increase serum statin levels and the risk for myopathy. This may also be the case with ingestion of large quantities of grapefruit juice. Small amounts of grapefruit juice present little problem as long as its use is separated from administration of the statin to minimize the potentially serious interaction. **Recommend:** Refer high risk patients for a baseline creatine kinase blood level. Instruct patients to immediately report muscle pain and weakness or brown urine. If myopathy is suspected and/or confirmed by a 10-fold increase in creatine kinase level, the statin or interacting medication should be discontinued until levels return to normal and then reinitiated at a lower dose with upward dosage adjustments as indicated and tolerated.
- 5) **Cost Efficacy Management – Tablet-Splitting More Cost-Effective** In clinical trials, tablet-splitting has been shown to have no short-term negative effects on drug therapy. Tablet-splitting has been shown to be accepted by patients, very cost effective, and capable of improving patient outcomes. **Recommend:** If patient agrees, contact prescriber for approval to dispense double strength dosage form. Educate patient on tablet-splitting technique.
- 6) **Insufficient Dose – Statin** Patients with coronary heart disease (CHD) or CHD risk equivalent morbidity such as diabetes, peripheral vascular disease, hypothyroidism, liver or renal disease will often require aggressive therapy to achieve desired LDL cholesterol levels below 100mg/dL. Less than 130 mg/dL is the recommended goal LDL cholesterol for patients with 2 or more risk factors and 160 mg/dL if 1 or fewer risk factors for CHD are present. [Risk factors include: cigarette smoking, hypertension (BP >140/90mmHg or BP controlled by anti-hypertensive medication), low HDL cholesterol (<40mg/dL), family history of premature CHD (CHD in first-degree male relative <55 years; CHD in first-degree female relative <65 years), and age (men >45 years, women >55 years). HDL >60mg/dL is considered a negative risk factor.] Patients should be monitored every 6 weeks following adjustments in dose to verify progress. **Recommend:** Verify patient's most recent lipid profile results to determine whether goal LDL has been reached and assess need to increase dose or add another agent. See Item 1) above.
- 7) **Cost Efficacy Management – Alternate Therapy Indicated** If only moderate reductions in LDL cholesterol are required, patients for whom medication cost is a factor may be willing to begin therapy with a less convenient but less expensive agent. **Recommend:** Confirm patient's current LDL cholesterol level and goal. Contact prescriber with recommendation to initiate therapy with niacin, bile acid sequestrant or fibrate and adjust dose upward based upon patient response and tolerance.
- 8) **Non-Compliance – Incorrect Administration/Technique** All patients should have attempted to lower LDL for three months using only therapeutic lifestyle changes unless necessary reduction in LDL cholesterol is too great. Even when drug therapy has been initiated, it is important for patients to continue a diet low in saturated fat and a regular exercise program to enhance drug efficacy, reduce the need for higher doses and decrease the possibility of ADR's. **Recommend:** Provide patient with written information on diet and exercise. Refer patient to registered dietitian for nutrition counseling, if necessary.
- 9) **Non-Compliance – Incorrect Administration** All statins are administered orally once daily. According to the drugs' manufacturers, atorvastatin, rosuvastatin and pravastatin may be taken without regard to time of day. Evidence suggests, though, that statins should be administered in the evening or at bedtime for optimal efficacy in lowering LDL-cholesterol since hepatic cholesterol synthesis is most prominent at night. Atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin may be administered without regard to meals. Lovastatin, however, should be given with the evening meal for optimal absorption. **Recommend:** Patient to take the statin at the same time each day, preferably in the evening.
- 10) **Adverse Drug Reaction – Elevated Liver Enzymes** While the risk is relatively small, patients started on a statin should have a liver function test performed 6-12 weeks after initiating therapy and every 6-12 months while on therapy. **Recommend:** Refer patient for liver function test if not already scheduled.
- 11) **Adverse Drug Reaction – Fetal Risk** Statins are classified by the FDA as category X medications. Category X is assigned to drugs for which animal or human studies, investigational, or postmarketing reports have shown fetal risk which clearly outweighs any possible benefit to the mother. **Recommend:** If patient is pregnant or nursing, consider alternative lipid-lowering agent only if benefits to mother outweigh risk to fetus. If patient suspects they are pregnant, contact physician immediately due to the harmful effects these drugs can have on the fetus.

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