HEPATIC ENZYME MONITORING PRIOR TO STATIN USE

Disease State: Hyperlipidemia

Indicator Category: 3º prevention

Strength of Recommendation: I

Quality of Evidence: Poor

Physician Specialties: Primary: Cardiology, Family Practice, General Practice, Internal Medicine, Mixed Specialty

Clinical Rationale

Disease Burden

- There are 232 reports of hepatitis associated with lovastatin, translating into a reporting rate of 9.7 cases/million patient-treatment years.[1]
- There are 22 reported cases of acute liver failure associated with lovastatin. This translates into a reporting rate of 1/1.14 million patient-treatment-years, approximately equal to the rate of idiopathic acute liver failure.[1]

Reason for Indicated Intervention or Treatment

- FDA recommendations indicate that liver function tests for statins should be performed for patients initiating statins and who take them regularly.[1]

Evidence supporting Intervention or Treatment

- No well designed trials have specifically evaluated if obtaining baseline liver function tests prior to initiating statin therapy is associated with better clinical outcomes — lower rates of statin induced hepatitis or acute liver failure.
- A retrospective review of statin therapy revealed that individuals with baseline elevations in LFTs on statin therapy were not at higher risk for statin-induced liver disease compared to individuals with baseline elevations in LFTs not on statin therapy.[8]

Clinical Recommendations

- The FDA recommends monitoring for potential hepatotoxicity before beginning statin treatment, 6 to 12 weeks following initiation of treatment, after a dosage change, and semiannually thereafter.[1]
- The American College of Cardiology considers the incidence of clinically important (>3 times upper limit of normal) transaminase elevations in the large statin trials to be the same for statin as for placebo. A recent meta-analysis of statin therapy supports this conclusion.[6, 7]
- The American College of Cardiology/American Heart Association/National Heart Lung Blood Institute Clinical Advisory on the Use and Safety of Statin states: "Current labeling for all statins requires baseline measurements of liver function, including alanine transferase and aspartate transferase, although this is not agreed on by many liver experts and will likely undergo review in the future."[9]

Comparative Baseline Data

First year measure developed by Health Benchmarks, Inc. No baseline data exists for this measure yet.

Denominator

Continuously enrolled members with a new prescription for a statin and 60 days or more supply during the year prior to the reporting period.
Denominator Exclusion: Members with a prescription for a statin in the year beginning two years prior to the start of the reporting period or who had an emergency or inpatient encounter in the year prior to the reporting period.

Numerator: Members who received a hepatic enzyme test in the sixty day period preceding the index prescription.

Interpretation of Score: High score implies better performance

Physician Attribution: Score any physician who saw the member 0 - 60 days prior to the index prescription.

References


1 Indicator Category (Adapted from Health Plan Employer Data Information Set (HEDIS®) technical specifications and U.S. Preventive Services Task Force (USPSTF) Methodology)

Effectiveness
Primary Prevention Measures: Those that are applicable to individuals who are asymptomatic and are designed to prevent the onset of the targeted condition (e.g. immunizations);
Secondary Prevention Measures: Those that are applicable to asymptomatic patients who have risk factors or pre-clinical disease but in whom the condition has not become clinically apparent (e.g. pap smears, screening for elevated blood pressure);
Tertiary Prevention Measures: Those that are applicable to individuals who are diagnosed with a condition and are part of the treatment or management of patients with that condition (e.g. cholesterol reduction in patients with diabetes).

2 Strength of Recommendation (Based on U.S. Preventive Services Task Force (USPSTF), 3rd Edition Criteria)
A It is strongly recommended that clinicians provide the service to eligible patients. *There is good evidence that the service improves important health outcomes and that benefits substantially outweigh harms.*

B It is recommended that clinicians provide the service to eligible patients. *There is at least fair evidence that the service improves important health outcomes and that benefits outweigh harms.*

C There is no recommendation for or against the routine provision of this service. *There is fair evidence that the service can improve health outcomes but the balance of benefits and harms is too close to justify a general recommendation.*

D It is recommended that clinicians DO NOT routinely provide the service to eligible patients. *There is at least fair evidence that the service is ineffective or that harms outweigh benefits.*

I The evidence is insufficient to recommend for or against routinely providing the service. *Evidence that the service is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined.*

3 **Quality of Evidence** (Based on U.S. Preventive Services Task Force (USPSTF), 3rd Edition Criteria)

**Good:** Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

**Fair:** Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

**Poor:** Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

**Quality of Evidence** (Based on U.S. Preventive Services Task Force (USPSTF), 3rd Edition Criteria)

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees.