Measure Title: LIPID LEVEL MONITORING FOR PATIENTS RECEIVING ACCUTANE

Disease State: Acne

Strength of Recommendation: C

Clinical Intent: To ensure that all eligible members on Accutane medication receive the appropriate lipid level monitoring tests at a clinically appropriate frequency.

Physician Specialties: Refer to PQSR 2007 Specialty Matrix

Clinical Rationale Disease Burden:
- Acne vulgaris is the most common cutaneous disorder in the United States affecting 17 million Americans [1], accounting for over 10 percent of all PCP patient encounters, and over 4.8 million annual patient visits.[2]
- Estimates indicate that acne vulgaris affects 85 percent of the adolescent population.[3, 4]

Reason for Indicated Intervention or Treatment:
- For severe nodulocystic acne, acne that improves less than 50 percent after six months of treatment with oral antibiotics, relapsing acne, scarring acne, and acne that causes undue psychological distress, experts agree that the use of accutane is warranted as it is the only medication that alters the natural course of the disease.[5-7]
- Accutane (aka Isotretinoin or 13-cis-retinoic acid) is a powerful metabolite of vitamin A that significantly reduces sebum production after a four-five month course and thereby reduces or eliminates acne in 90% of patients.[8]
- The drug has many, potentially severe, side effects. Because of studies indicating that those taking accutane may suffer from elevated triglyceride and lipid levels, product information and opinion recommends making blood lipid determinations before accutane is given and then at intervals until the lipid response to Accutane is established, which usually occurs within 4 weeks.[9-14]
- In clinical trials, about 25% of patients had elevations of triglyceride levels above 800 mg/dL and approximately 15% and 7% had increased levels of HDL and cholesterol levels, respectively. Accutane related dyslipidemia can be reversed when Accutane usage is ceased.[9]

Evidence supporting Intervention or Treatment:
- A randomized controlled trial of 90 patients with severe acne showed that patients using isotretinoin every day for 3 months developed significant increases in cholesterol and triglyceride levels that was both dose-dependent and reversible.[10]
- Another multicenter randomized controlled trial showed that patients taking 10 mg/day isotretinoin for 3 years had significantly elevated serum triglycerides.[11]
- Another prospective randomized controlled trial of 20 men treated with oral isotretinoin showed isotretinoin-induced elevations in plasma triglycerides.
triglyceride and cholesterol levels up to 67 and 16%, respectively.[9]
- Indications for stopping therapy include severe hypertriglyceridemia (e.g., above 800 mg/dL or 9 mmol/L) because of the risk of acute pancreatitis.[12]
- In a cross-sectional comparison, Rodondi found that although hypertriglyceridemia usually resolves with cessation of accutane, persons who develop it during therapy are at increased risk for future hyperlipidemia and the metabolic syndrome.[15]
- In a study of 1,292 patients taking Isotretinoin for 5 to 9 months, no patient required their treatment to be stopped due to elevated lipid levels, and in only 1.5% of patients did serum triglyceride levels top 400 mg.[16]

Clinical Recommendations
- FDA labeling for accutane recommends making blood lipid determinations before accutane is given and then at intervals until the lipid response to accutane is established, which usually occurs within 4 weeks.[17]

Source
Health Benchmarks, Inc.

Denominator
Continuously enrolled members who were treated with accutane.

Denominator Exclusion
Members who received at least one prescription for accutane in the one year period starting one year and 45 days prior to the measurement year

Numerator
Members who had two blood lipid level tests, one during the 0-30 days prior to and a second test 1-45 days following the index prescription of accutane.

Relevant Billing Codes:
CPT-4 codes: 80061, 82465, 83700, 83701, 83704, 83715, 83716, 83721 84478

Interpretation of Score
High score implies better performance

Physician Attribution
Score only the physician who prescribed the index prescription for Accutane

References
Indicator Classification (Adapted from Health Plan Employer Data Information Set (HEDIS®) technical specifications)

Diagnosis
Measures applicable to patients receiving diagnostic workups for a symptom or condition that delineate appropriate laboratory or radiological testing to be performed (e.g. evaluation of thyroid nodule; pregnancy test in patients with vaginal bleeding or abdominal pain)

Effectiveness of Care
Prevention
Measures applicable to asymptomatic individuals that are designed to prevent the onset of the targeted condition (e.g. immunizations).

Screening
Measures 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).

Disease Management
Measures applicable to individuals diagnosed with a condition that are part of the treatment or management of the condition (e.g. cholesterol reduction in patients with diabetes; radiation therapy following breast conserving surgery; appropriate follow-up after acute event).

Medication Monitoring
Measures applicable to patients taking medications with narrow therapeutic windows and / or potential preventable significant side effects or adverse reactions (e.g. thyroid stimulating hormone (TSH) testing after levothyroxine dose change; hepatic enzyme monitoring for patients using antimycotic pharmacotherapy).

Medication Adherence
Measures applicable to patients taking medications for chronic conditions that are designed to assess patient adherence to medication (e.g. adherence to lipid lowering medication).

Utilization
Measures applicable to patients receiving treatment for a symptom or condition that advocate appropriate utilization of laboratory and pharmaceutical resources (e.g. conservative use of imaging for low back pain; inappropriate use of antibiotics for viral upper respiratory infection).
Strength of Recommendation Based on a Body of Evidence

FIGURE 2. Algorithm for determining the strength of a recommendation based on a body of evidence (applies to clinical recommendations regarding diagnosis, treatment, prevention, or screening). While this algorithm provides a general guideline, authors and editors may adjust the strength of recommendation based on the benefits, harms, and costs of the intervention being recommended. (USPSTF = U.S. Preventive Services Task Force)