Client: HMSC PQSR 2009

Measure Title: LIPID LEVEL MONITORING FOR PATIENTS RECEIVING ISOTRETINOIN

Disease State: Acne

Indicator Classification: Medication Monitoring

Strength of Recommendation: B

Organizations Providing Recommendation: United States Food and Drug Administration

Clinical Intent: To ensure that all members who were initiated on oral isotretinoin receive pretreatment and follow-up lipid monitoring tests.

Physician Specialties (suggested): Refer to PQSR 2009 Clinical Measures by Specialty

Background:

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 (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 is discontinued.[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 triglyceride and cholesterol levels up to 67 and 16%, respectively.[9]
- Indications for stopping therapy include severe hypertriglyceridemia (eg, 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 isotretinoin recommends making blood lipid determinations before isotretinoin is given and then at intervals until the lipid response to accutane is established: “Lipids: Pretreatment and follow-up blood lipids should be obtained under fasting conditions. After consumption of alcohol, at least 36 hours should elapse before these determinations are made. It is recommended that these tests be performed at weekly or biweekly intervals until the lipid response to Accutane is established. The incidence of hypertriglyceridemia is 1 patient in 4 on Accutane therapy.”[17]

**Source**
Health Benchmarks, Inc.

**Denominator**

<table>
<thead>
<tr>
<th>Denominator Definition</th>
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<tbody>
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<td>Continuously enrolled members who filled a prescription for at least a 90 days supply of oral isotretinoin during the 1 year period beginning 45 days prior to the start of the measurement year.</td>
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### Denominator Exclusion

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<th>Denominator Exclusion</th>
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<tr>
<td>Members who filled at least 1 prescription for isotretinoin in the 1 year period prior to the index date.</td>
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### Numerator

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<td>Members who had 2 blood lipid level tests, 1 during the 0-30 days prior to the index date and a second test during the 1-45 days after the index date.</td>
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### Physician Attribution

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<td>Score the physician who prescribed the index date prescription for isotretinoin.</td>
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### References


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