BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Measurement of Long-Chain Omega-3 Fatty Acids in Red Blood Cell Membranes as a Cardiac Risk Factor

Policy #: 239
Category: Laboratory

Latest Review Date: September 2019
Policy Grade: **Effective July 1, 2010: Active Policy but no longer scheduled for regular literature reviews and updates.**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service on or after March 24, 2020:

Blue Advantage will treat **measurement of long-chain omega-3 fatty acids in red blood cell membranes, including but not limited to its use as a cardiac risk factor,** as a **non-covered benefit** and as **investigational**.

Effective for dates for dates of service on or after February 26, 2018 and before March 24, 2020, refer to LCD L34555

Effective for dates of service on or after October 28, 2005 and prior to February 26, 2018:
Blue Advantage will treat **measurement of long-chain omega-3 fatty acids in red blood cell membranes**, including but not limited to its use as a cardiac risk factor as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Epidemiologic studies have reported that subjects who eat a diet high in fish have a reduced risk of sudden cardiac death. Fish are rich in long-chain omega-3 fatty acids, and it has been hypothesized that these fatty acids may be responsible for the beneficial effect. Long-chain omega-3 fatty acids may be detected in the red cell membrane using gas chromatography. It has been suggested this measurement may be clinically useful as a cardiac risk factor for sudden cardiac death.

KEY POINTS:

A search of the literature through September 3, 2019, identified many observational studies that have explored the association between fish consumption and risk of coronary heart disease (CHD) in different populations of patients. These studies suggest that mortality from coronary heart disease may be reduced by including fish as a regular part of the diet. However, most of them have not had sufficient statistical power to provide convincing evidence for the presence or absence of the association. There are no published articles that explored how the measurement of red blood cell membrane omega-3 fatty acids may be used to improve patient management. For example, studies establishing the diagnostic parameters of omega-3 fatty acids, i.e., the definition of normal, high, and low values were not identified. It has been suggested that the measurement of omega-3 fatty acids may be incorporated into a cardiac risk panel in patients with a prior cardiac event. No studies focused on this application of this laboratory test.

Some studies were identified that examine the association between fish consumption and risk of coronary heart disease, but lack proof of clinical utility in measurement of long chain omega-3 fatty acids in red blood cell membranes, as this measurement was not taken into consideration when recommending fish consumption. No trials were identified where prospective measurement of omega-3 fatty acids (Omega-3 Index) was used to direct treatment to prevent or treat cardiac disease.

At the present time, patients with coronary artery disease are offered the general dietary recommendation to increase fish consumption, a recommendation not based on red blood cell membrane levels of omega-3 fatty acids.

The Japan Eicosapentaenoic Acid Lipid Intervention Study (JELIS) trial compared fish oil capsules plus statins to statins alone in 18,645 patients with hypercholesterolemia. In this primary and secondary prevention study, if hypercholesterolemia remained uncontrolled, the dose of the statin could be raised by protocol. No measurements of the efficacy of fish oil treatment were performed and the dose remained constant throughout the study. The fish oil plus statin group had 18% (p=0.132) and 19% (p=0.015) fewer non-fatal (primary and secondary, respectively) cardiac events over a mean of 4.6 years compared to the statin only group.

Results of analysis of eicosapentaenoic acid (EPA) plus docosahexaenoic acid (DHA) and fish intake in relation to incident heart failure in the population-based Rotterdam Study. The analysis comprised 5,299 participants (41% men, age approximately 68 years) free from heart failure for which dietary data were available. In the 11.4 years of follow-up, 669 developed heart failure. After adjustment for lifestyle and dietary factors the relative risk (RR) of heart failure in the top vs. bottom quintile of EPA plus DHA intake was 0.89 (95% CI 0.69-1.14), after adjustment for lifestyle and dietary factors. For fish intakes > or = 20 g/day, the RR was 0.96 (0.78-1.18) compared with no fish intake. In sex-specific analysis, a high EPA plus DHA intake tended to be protective in women (RR=0.75, 0.54-1.04) but not in men (RR= 1.00, 0.73-1.36). An inverse association for EPA plus DHA was also not observed in diabetics (RR= 0.58, 0.32-1.06), which was borderline statistically significant. The authors concluded that their findings did not support a major role for fish intake in the prevention of heart failure.

No published articles have been identified that explored how the measurement of this index may be used to improve patient outcomes.

Summary of Evidence
Trials and studies are needed to demonstrate the potential impact of measuring this index on clinical outcomes. At the current time there is insufficient evidence to support the medical necessity of measurement of long-chain omega-3 fatty acids in red blood cell membranes.

KEY WORDS:

Long-chain omega-3 fatty acids, coronary heart disease, Omega-3 fatty acids, fatty acids, heart disease risk, fish oil

APPROVED BY GOVERNING BODIES:
Not applicable

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CODING:

CPT codes:

0111T	Long chain (C 20-22) omega-3 fatty acids in red blood cell membranes

REFERENCES:

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POLICY HISTORY:

Adopted for Blue Advantage, August 2005
Available for comment September 13-October 27, 2005
Medical Policy Group, July 2008
Medical Policy Group, July 2010
Policy remains active but no longer reviewed for updates effective July 1, 2010
Medical Policy Group, February 2018
Medical Policy Group, March 2020: Reinstated policy effective March 24, 2020. For dates of service before March 24, 2020, and on or after February 26, 2018, refer to LCD L34555. L34555 (Non-Covered Category III CPT Codes) retired effective March 23, 2020.