Effective November 1, 2023, refer to <u>CMS</u>
<u>Manual 100-02, Chapter</u>
<u>16-General Exclusions</u>
<u>from Coverage</u> for services included in this policy.



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

Latest Review Date: September 2023

Category: Laboratory

ARCHIVED EFFECTIVE 11/1/2023

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:

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. 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 that this measurement may be clinically useful as a cardiac risk factor for sudden cardiac death. In addition to the Omega-3 Index (OI) as a proposed marker of coronary artery disease risk, it is also a proposed predictor of accelerated cognitive and structural brain aging.

KEY POINTS:

This policy has been updated with literature review performed through September 21, 2023.

Summary of Evidence

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. There are no published articles identified that explore how the measurement of red blood cell membrane omega-3 fatty acids may be used to improve patient management, treat, or prevent cardiac disease.

A study was identified that examined the association of red blood cell omega-3 fatty acid levels and markers of accelerated brain aging, however, the population of this study only included one ethnic group, thus limiting the generalizability of these findings. The association between lower RBC omega-3 fatty acid levels and markers of accelerated cognitive and structural brain aging observed here should be confirmed in other populations and extended in the future to include dementia outcomes.

Well-designed trials and studies are needed to demonstrate the potential impact of this technology on clinical outcomes. There is insufficient evidence to support the clinical utility of

measurement of long-chain omega-3 fatty acids in red blood cell membranes. This technology does not demonstrate improvement in net health outcomes.

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.

CURRENT CODING:

CPT codes:

For dates of service 1/1/21 and after, there are no specific codes related to this test. An unlisted code would be submitted, such as:

84999

Unlisted chemistry procedure

PREVIOUS CODING:

CPT codes:

0111T

Long chain (C 20-22) omega-3 fatty acids in red blood cell membranes (Deleted 12/31/2020)

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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.

Medial Policy Group, December 2020: 2021 annual coding update. Deleted code 0111T. Medical Policy Group, August 2021

Medical Policy Group, October 2021: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, July 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, September 2023: No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, predeterminations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.