Intracellular Micronutrient Analysis

Description of Procedure or Service

Commercial laboratories offer panels of tests evaluating intracellular levels of micronutrients (essential vitamins and minerals). Potential uses of this test including screening for nutritional deficiencies in healthy individuals or those with chronic disease, and aiding in the diagnosis of disease in patients with generalized symptoms.

Background

“Micronutrients” is a collective term used to describe essential vitamins and minerals. Adequate intake of micronutrients is important to the maintenance of health. Clinical deficiency states (states occurring after prolonged consumption of a diet lacking the nutrient that is treated by adding the nutrient to the diet) have been reported for vitamins A, B1, B12, C and D, selenium, and other micronutrients. Classic nutritional deficiency diseases are uncommon in the United States; most individuals derive sufficient nutrition from their diets alone or in combination with over-the-counter multivitamins.

Laboratory tests are available for individual micronutrients and are generally used to confirm suspected micronutrient deficiencies. Testing is performed by serum analysis using standardized values for defining normal and deficient states. In addition, some commercial laboratories offer panels of vitamin and mineral testing that also use serum analysis.

This policy addresses a laboratory test that measures the intracellular levels of micronutrients. This testing is known as intracellular micronutrient analysis, micronutrient testing or functional intracellular analysis. Advocates claim that intracellular nutrient status is superior to serum testing. This is because intracellular levels may reflect more stable micronutrient levels over longer time periods compared to serum levels since they are not influenced by recent nutrition intake. However, the relation between serum and intracellular levels of micronutrients is complex. The balance of intra- and extracellular levels depend on a number of factors, including the physiology of cellular transport mechanisms and the individual cell type.

At least two commercial laboratories offer intracellular testing for micronutrients. Laboratories perform a panel of tests evaluating the intracellular level of a variety of micronutrients e.g. minerals, vitamins, amino acids, fatty acids, etc. The test offered by one laboratory evaluates epithelial cells from buccal swabs and assesses levels of intracellular mineral electrolyte, such as magnesium, calcium, potassium, phosphorous, sodium and chloride. Another laboratory offers a panel of tests that evaluates the intracellular status of micronutrients within lymphocytes in blood samples. The micronutrients measured by the test are as follows:

- Vitamins: A, B1, B2, B3, B6, B12, C, D, K; biotin, folate, pantothenic acid
- Minerals: calcium, magnesium, zinc, copper
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- Antioxidants: alpha lipoic acid, coenzyme Q10, cysteine, glutathione, selenium, vitamin E
- Amino acids: asparagine, glutamine, serine
- Carbohydrate metabolism: chromium, fructose sensitivity, glucose-insulin metabolism
- Fatty acids: oleic acid
- Metabolites: choline, inositol, carnitine

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Intracellular micronutrient testing is offered by two companies, available under the auspices of CLIA. Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Intracellular Micronutrient Analysis is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Intracellular Micronutrient Analysis is covered

Not Applicable

When Intracellular Micronutrient Analysis is not covered

Intracellular Micronutrient Analysis is considered investigational for all applications.

Policy Guidelines

The evidence for individuals who have chronic diseases or nonspecific generalized symptoms who receive intracellular micronutrient analysis includes, observational studies. Relevant outcomes are test accuracy, symptoms and change in disease status. No studies were identified that evaluated the analytic validity, clinical utility, or clinical validity of intracellular micronutrient testing compared to standard testing for vitamin or mineral levels. Limited data from observational studies are available on correlations between serum and intracellular micronutrient levels. No randomized controlled trials or other comparative studies were identified evaluating the direct health impact of intracellular micronutrient testing. Moreover, there are insufficient data to construct a chain of evidence that intracellular micronutrient testing would likely lead to identifying patients whose health outcomes would be improved compared with alternative approaches to patient management. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information
Intracellular Micronutrient Analysis

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: There is no specific code for micronutrient analysis; however, the following series of codes may be used: 82136, 82307, 82310, 82607, 82725, 82746, 82978, 83735, 84207, 84252, 84255, 84425, 84446, 84591, 84630, 86353, 84999*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

**Scientific Background and Reference Sources**

*For policy titled Functional Intracellular Analysis*


Medical Director review 6/2011

*For policy re-titled Intracellular Micronutrient Analysis*

Medical Director review 8/2011


Medical Director review 8/2012

Specialty Matched Consultant Advisory Panel review 1/2013


Specialty Matched Consultant Advisory Panel review 1/2014


Specialty Matched Consultant Advisory Panel review 4/2015

Medical Director review 4/2015


Medical Director review 3/2016

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Specialty Matched Consultant Advisory Panel review 3/2017
Medical Director review 3/2017

Policy Implementation/Update Information

For policy titled Functional Intracellular Analysis

6/21/11 New policy implemented. Functional Intracellular Analysis is not covered. It is considered investigational. There is no published scientific evidence to support the benefit or the validity of micronutrient testing. Medical Director review 6/2011. (mco)

7/19/11 Removed specific laboratory name from policy. (mco)

For policy re-titled Intracellular Micronutrient Analysis

8/16/11 Policy re-titled from “Functional Intracellular Analysis” to “Intracellular Micronutrient Analysis.” Description section extensively revised. No changes to policy statement. Medical Director review 8/2011. (mco)

9/18/12 Policy Guidelines and References updated. No changes to Policy Statements. Medical Director review 8/2012. (mco)

2/12/13 Specialty Matched Consultant Advisory Panel review 1/2013. No changes to Policy Statements. (mco)

8/27/13 References updated. No changes to Policy Statement. (mco)


8/26/14 References updated. No changes to Policy Statement. (mco)


9/1/15 Policy Guidelines updated. References updated. Policy statement remains unchanged. (td)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.