

## Corporate Medical Policy

### Intracellular Micronutrient Analysis

<b>File Name:</b>	intracellular_micronutrient_analysis
<b>Origination:</b>	6/2011
<b>Last CAP Review:</b>	n/a
<b>Next CAP Review:</b>	11/2011
<b>Last Review:</b>	8/2011

#### Description of Procedure or Service

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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 novel laboratory test that measures the intracellular levels of micronutrients. This testing is known as intracellular micronutrient analysis and is also called micronutrient testing and 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, this is not a widely accepted view, as the relationship 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 tend to 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 magnesium, calcium, potassium, phosphorous, sodium and chloride as well as ratios between various combinations of these minerals. 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: vitamins A, B1, B2, B3, B6, B12, C, D, K2; biotin, folate, panthothenate

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- Minerals: calcium, magnesium, zinc, copper
- 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

Intracellular micronutrient testing is offered by two companies which have Clinical Laboratories Improvement Amendments (CLIA) accreditation. However, neither laboratory's micronutrient panel test has been through the FDA approval process.

***\*\*\*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

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

## Benefits Application

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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

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Not Applicable

## When Intracellular Micronutrient Analysis is not covered

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Intracellular Micronutrient Analysis is not covered. It is considered investigational. There is no published scientific evidence to support the benefit or the validity of intracellular micronutrient testing.

## Policy Guidelines

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This policy was developed using a PubMed literature review from May 2010 to May 2011. There are no peer-reviewed journal articles reporting on Intracellular Micronutrient Analysis, Functional Intracellular Analysis or Essential Metabolic Analysis. There are numerous clinical trials regarding micronutrient supplementation, but none regarding Intracellular Micronutrient Analysis or any other forms of intracellular micronutrient testing.

## Billing/Coding/Physician Documentation Information

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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](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

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*Applicable service codes: There is no specific code for FIA; 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

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### **For policy titled Functional Intracellular Analysis**

Food and Drug Administration (FDA). Medical Devices/Home Use Tests search page. Retrieved on May 31, 2011 from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/default.htm>

Food and Drug Administration (FDA). Buying Medical Devices and Diagnostic Tests Online. Retrieved on May 31, 2011 from <http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/BuyingMedicalDevicesandDiagnosticTestsOnline>

Medical Director review 6/2011

### **For policy re-titled Intracellular Micronutrient Analysis**

Medical Director review 8/2011

## Policy Implementation/Update Information

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### **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)

7/19/2011 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)

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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.