

## Medical Coverage Policy | Intracellular Micronutrient Analysis



**EFFECTIVE DATE:** 01|01|2017

**POLICY LAST UPDATED:** 04|18|2017

### OVERVIEW

Commercial laboratories offer panels of tests evaluating intracellular levels of micronutrients (essential vitamins and minerals). Potential uses of these tests include screening for nutritional deficiencies in healthy people or those with chronic disease and aiding in the diagnosis of disease in patients with nonspecific symptoms. Classic nutritional deficiency diseases are uncommon in the United States; most people derive sufficient nutrition from their diets alone or in combination with over-the-counter multivitamins.

### MEDICAL CRITERIA

#### BlueCHiP for Medicare and Commercial

Not applicable.

### PRIOR AUTHORIZATION

#### BlueCHiP for Medicare and Commercial

Not applicable.

### POLICY STATEMENT

#### BlueCHiP for Medicare and Commercial

Intracellular micronutrient panel testing is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

### COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

### BACKGROUND

“Micronutrients” collectively refer to essential vitamins and minerals necessary in trace amounts for 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 people 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 evidence review addresses a laboratory tests that measure the intracellular levels of micronutrients. This testing, also known as intracellular micronutrient analysis, micronutrient testing, or functional intracellular analysis, is sometimes claimed to be superior to serum testing because intracellular levels reflect more stable micronutrient levels over longer time periods than serum levels, because intracellular levels 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 2 commercial laboratories (SpectraCell Laboratories (Houston, TX) and IntraCellular Diagnostics (Medford, OR) offer intracellular testing for micronutrients. Laboratories perform a panel of tests evaluating the intracellular level of various micronutrients (eg, minerals, vitamins, amino acids, fatty acids). The test offered by IntraCellular Diagnostics evaluates epithelial cells from buccal swabs and assesses levels of intracellular mineral electrolyte (ie, magnesium, calcium, potassium, phosphorous, sodium, chloride). SpectraCell Laboratories offers a panel of tests that evaluates the intracellular status of micronutrients within lymphocytes in blood samples. The micronutrients measured by the test include:

- Vitamins: A, B1, B2, B3, B6, B12, C, D, K; biotin, folate, pantothenic acid
- 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.

The SpectraCell micronutrient panel also evaluates total antioxidant function.

For individuals who have chronic diseases or nonspecific generalized symptoms who receive intracellular micronutrient analysis, the evidence includes observational studies. Relevant outcomes are test accuracy, symptoms, and change in disease status. No studies were identified that evaluated the analytic validity, clinical validity, or clinical utility of intracellular micronutrient testing compared with 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.

### **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, offered by SpectraCell and IntraCellular Diagnostics, is 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.

This testing is currently only available through 2 reference laboratories: SpectraCell Laboratories (Houston, TX) and IntraCellular Diagnostics (Medford, OR).

### **PRACTICE GUIDELINES AND POSITION STATEMENTS**

No guidelines or statements were identified.

### **ONGOING AND UNPUBLISHED CLINICAL TRIALS**

A search of ClinicalTrials.gov in January 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

## **CODING**

There is no specific CPT code for this panel of testing and claims should be filed with an unlisted code. Claims for this panel should not be reported with the specific CPT codes for each of the elements of the panel

## **RELATED POLICIES**

None

## **PUBLISHED**

Provider Update, June 2017

## **REFERENCES:**

1. Houston MC. The role of cellular micronutrient analysis, nutraceuticals, vitamins, antioxidants and minerals in the prevention and treatment of hypertension and cardiovascular disease. Ther Adv Cardiovasc Dis. Jun 2010;4(3):165-183. PMID 20400494

DRAFT

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