

MEDICAL POLICY - 2.04.73

Intracellular Micronutrient Analysis

BCBSA Ref. Policy: 2.04.73

Effective Date: Mar. 1, 2025 REL

Last Revised: Feb. 10, 2025

Replaces: N/A

RELATED MEDICAL POLICIES:

None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Micronutrients are essential vitamins and minerals. Getting enough of them is important for good health. It's rare in the United States to have medical conditions caused by lack of nutrients like vitamins A, B1, B12, C, D, and selenium. Most people get enough vitamins and minerals through their diet or over-the-counter vitamins. Blood samples are a proven way to measure the level of essential nutrients. Other tests have been created that look at nutrient levels inside cells. These tests are unproven. There are no published medical studies showing whether the cell tests are more accurate or useful than standard blood tests at measuring levels of vitamins or minerals. There are also no randomized controlled trials — studies that randomly put people in different study groups — exploring whether the cell tests are effective to screen for or diagnose nutrient deficiencies.

Note:

The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Test	Investigational
Intracellular micronutrient	Intracellular micronutrient panel testing is considered
panel testing	investigational.

Coding

Code	Description
СРТ	
82310	Calcium; total
82725	Fatty acids, nonesterified
84590	Vitamin A
84591	Vitamin, not otherwise specified
84999	Unlisted chemistry procedure
86353	Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis
88348	Electron microscopy, diagnostic

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Related Information

When reviewing intracellular micronutrient panel testing, the entire panel is to be reviewed as a whole versus the individual elements of the panel.

Benefit Application

This testing is currently only available through two reference laboratories: SpectraCell Laboratories and IntraCellular Diagnostics.



Evidence Review

Description

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 individuals with nonspecific symptoms.

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 US; 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. Also, some commercial laboratories offer panels of vitamin and mineral testing that also use serum analysis.

Diagnostic Testing

This policy evaluates 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, and 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 intracellular and extracellular levels depends 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 various micronutrients (e.g., minerals, vitamins, amino acids, fatty acids). The test offered by IntraCellular Diagnostics (EXA Test) evaluates epithelial cells from buccal swabs and assesses levels of intracellular mineral electrolyte (i.e., 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 may include SPECTROX for evaluation of the total antioxidant function and IMMUNIDEX for immune response score.

Summary of Evidence

For individuals with chronic diseases or nonspecific generalized symptoms who receive intracellular micronutrient analysis, the evidence includes an observational study. The relevant outcomes are symptoms and change in disease status. No studies were identified that evaluated 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 individuals whose health outcomes would be improved compared with alternative approaches to patient management. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in November 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

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

References

- IntraCellular Diagnostics. Mitochondria: Exploration of Intracellular Space. https://www.exatest.com/ Accessed January 13, 2025.
- 2. SpectraCell Laboratories. Micronutrient Test. https://spectracell.sitewrench.com/search-tests Accessed January 13, 2025.
- 3. 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): 165-83. PMID 20400494



History

Date	Comments
09/13/11	New Policy – Add to Pathology/Laboratory section.
07/25/12	Related Policies Update – Title to 2.01.01 has been changed to include: (i.e., Multiple Chemical Sensitivities)
09/11/12	Replace policy. Literature search through May 2012 resulted in no changes to the Description or Rationale sections. No additions to the reference list. Policy statement is unchanged.
09/18/12	Update Related Policy – Add 2.04.508.
09/27/13	Replace policy. Policy updated with literature search through June 21, 2013. No change to policy statement. Within the Policy Guidelines it was clarified that the entire panel needs to be reviewed versus the individual elements of the panel. CPT codes 82310, 82725, 84590 and 84591 as these refer to the individual elements.
05/21/14	Update Related Policies. Changed title for related policy 2.04.508.
09/23/14	Annual Review. A literature review through June 18, 2014 did not prompt the addition of new references. Policy statement unchanged.
09/08/15	Annual Review. Policy updated with literature review through June 15, 2015; no references added. No change to policy statement.
08/01/16	Annual Review, approved July 12, 2016. No references added. No change to policy statement.
06/01/17	Annual Review, approved May 2, 2017. Policy updated with literature review through January 25, 2017; no references added. Policy statement unchanged.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged.
03/01/19	Annual Review, approved February 5, 2019. Policy updated with literature review through October 2018; no references added. Policy statement unchanged.
03/01/20	Annual Review, approved February 4, 2020. Policy updated with literature review through October 2019; no references added. Policy statement unchanged.
07/02/20	Coding update. Removed 88348.
03/01/21	Annual Review, approved February 2, 2021. Policy updated with literature review through October 16, 2020; no references added. Policy statement unchanged.
03/01/22	Annual Review, approved February 7, 2022. Policy updated with literature review through October 22, 2021; no references added. Policy statement unchanged.
02/01/23	Annual Review, approved January 23, 2023. Policy updated with literature review through September 19, 2022; no references added. Policy statement unchanged.



Date	Comments
	Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/24	Annual Review, approved February 12, 2024. Policy updated with literature review through November 20, 2023; no references added. Policy statement unchanged.
03/01/25	Annual Review, approved February 10, 2025. Policy updated with literature review through November 25, 2024; no references added. Policy statement unchanged. Added HCPCS code 88348.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

