
FEP 2.04.73 Intracellular Micronutrient Analysis

Effective Date: July 15, 2018

Related Policies: None

Intracellular Micronutrient Analysis

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 patients with nonspecific symptoms.

FDA 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 the Clinical Laboratory Improvement Amendments. 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).

POLICY STATEMENT

Intracellular micronutrient panel testing is considered **investigational**.

BENEFIT APPLICATION

Screening (other than the preventive services listed in the brochure) is not covered. Please see Section 6 General exclusions.

Benefits are available for specialized diagnostic genetic testing when it is medically necessary to diagnose and/or manage a patient's existing medical condition. Benefits are not provided for genetic panels when some or all of the tests included in the panel are not covered, are experimental or investigational, or are not medically necessary.

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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RATIONALE

Summary of Evidence

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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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

POLICY HISTORY

Date	Action	Description
March 2012	New Policy	
December 2012	Update Policy	Policy updated with literature search; no change in policy statement.
September 2013	Update Policy	Literature search performed, no updates, No change to policy statement.
September 2014	Update Policy	Policy updated with literature review. No change to policy statement.
September 2015	Update Policy	Policy updated with literature review; no references added. No changed to policy statement.
September 2016	Update Policy	Literature search performed. No references added. No change to policy statement.
June 2018	Update Policy	Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged.

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