BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.04.73 Intracellular Micronutrient Analysis

Annual Effective Policy Date: April 1, 2024

Original Policy Date: December 2023

Related Policies:

None

Intracellular Micronutrient Analysis

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether intracellular micronutrient analysis to detect vitamin and mineral deficiencies improves the net health outcome in patients with chronic diseases or nonspecific generalized symptoms.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

This testing is currently only available through 2 reference laboratories: SpectraCell Laboratories and IntraCellular Diagnostics.

FDA 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. Intracellular micronutrient panel testing is offered by SpectraCell Laboratories and IntraCellular Diagnostics under the auspices of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

RATIONALE

Summary of Evidence

For individuals who have chronic diseases or nonspecific generalized symptoms who receive intracellular micronutrient analysis, the evidence includes an observational study. Relevant outcomes are 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 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

REFERENCES

1. IntraCellular Diagnostics. Mitochondria: Exploration of Intracellular Space. Accessed November 20, 2022. https://www.exatest.com/
2. SpectraCell Laboratories. Micronutrient Test. Accessed November 20, 2022. https://spectracell.sitewrench.com/search-tests
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

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2023	New policy	Policy updated with literature review through September 19, 2022; no references added. Policy statement unchanged. FEP Benefit change. FEP New Policy