

Health Plan of Washington

# MEDICAL POLICY – 2.04.136 Nutrient/Nutritional Panel Testing

BCBSA Ref. Policy:	2.04.136		
Effective Date:	Mar. 1, 2024	RELATED	MEDICAL POLICIES:
Last Revised:	May 1, 2024	2.04.73	Intracellular Micronutrient Analysis
Replaces:	N/A	2.04.509	Cardiovascular Risk Panels

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#### Introduction

Nutrient/nutritional panel testing looks for a lack of specific nutrients in the body. Blood and urine samples are used to measure levels of vitamins, minerals, amino acids, fatty acids, antioxidants, and other markers, depending on the test. Testing can be done on healthy people and on people who have certain chronic medical conditions. This testing is intended to make personal recommendations for nutritional supplements that may help maintain health or improve certain medical conditions. Nutrient/nutritional panel testing to identify nutritional deficiencies is unproven (investigational). More studies are needed to see if this testing improves health outcomes.

**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**

Testing	Investigational
Nutrient/nutritional panel	Nutrient/nutritional panel testing is considered investigational
testing	for all indications including but not limited to testing for nutritional deficiencies in individuals with mood disorders, fibromyalgia, unexplained fatigue, and healthy individuals. (e.g., NutrEval FMV, NutrEval Plasma, Metabolomix+ [Genova Diagnostics])

# Coding

**Note:** There may not be one specific individual code for these panels, multiple individual codes may be used. The following is not an exhaustive list of what may be used in billing for these panel tests.

Code	Description
СРТ	
82746	Folic acid; serum
83735	Magnesium
83785	Manganese
84590	Vitamin A
84630	Zinc
82128	Amino acids; multiple, qualitative, each specimen
82136	Amino acids, 2 to 5 amino acids, quantitative, each specimen
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### **Related Information**

When reviewing nutrient/nutritional panel testing, the entire panel is to be reviewed as whole versus the individual elements of the panel.



# Description

Multimarker nutritional panel testing is proposed for individuals with certain chronic conditions (e.g., mood disorders, fibromyalgia, unexplained fatigue) as well as for healthy individuals seeking to optimize health and/or fitness.

### Background

Nutritional panel testing aims to identify nutritional deficiencies that will lead to personalized nutritional supplement recommendations. Testing is proposed both for healthy individuals to optimize health and for individuals with chronic conditions (e.g., mood disorders, fibromyalgia, unexplained fatigue) to specify supplements that will ameliorate symptoms.

Genova Diagnostics offers nutritional/nutrient panel testing. Among the tests this company offers is NutrEval FMV, which involves analysis of urine and blood samples and provides information on more than 100 markers including organic acids, amino acids, fatty acids, markers of oxidative stress (direct measurement of glutathione and CoQ10, and markers of oxidative injury and DNA damage) and nutrient elements (see **Table 1**).<sup>1</sup> Genova Diagnostics produces a report that includes test results categorized as minimal, moderate, or high need, along with recommendations for supplements and dosages for items categorized as high need. NutrEval FMV patient reports can recommend supplementation for any of the nutrients listed in **Table 1** if they are found to be areas of high need.

NutrEval Plasma, also by Genova Diagnostics, is a similar test.<sup>2</sup> The only difference between NutrEval FMV and NutrEval Plasma is that the former uses urine (first morning void) whereas the latter uses plasma (fasting sample) to measure amino acids. Metabolomix+ provides analysis of key nutritional biomarkers using non-invasive first morning void (FMV) urine collection with optional add-on bloodspot finger stick and buccal swab. It is similar to NutrEval, but can be collected entirely at home.

SpectraCell Laboratories offers a micronutrient test that measures functional deficiencies at the cellular level.<sup>3</sup> The test assesses how well the body uses 31 vitamins, minerals, amino and fatty acids, antioxidants, and metabolites (see **Table 1**). SpectraCell categorizes test results into



adequate, borderline, and deficient, and offers supplementation suggestions based on each individual's deficiencies.

Category	NutrEval FMV	Spectra Cell Nutrient Testing
Vitamins and antioxidants	Vitamin A, vitamin C, vitamin E, alpha- lipoic acid, coenzyme Q10, glutathione, plant-based antioxidants, B vitamins (thiamin B1, riboflavin B2, niacin B3, pyridoxine B6, biotin B7, folic acid B9, cobalamin B12)	Vitamin A, vitamin B1, vitamin B2, vitamin B3, vitamin B6, vitamin B12, biotin, folate, pantothenate, vitamin C, vitamin D, vitamin K, alpha-lipoic acid, coenzyme Q10, cysteine, glutathione, selenium, vitamin E
Minerals	Magnesium, manganese, molybdenum, zinc	Calcium, magnesium, manganese, zinc, copper
Fatty acids	Omega-3-oils	
Digestive support	Probiotics, pancreatic enzymes	
Other vitamins	Vitamin D	
Amino acids	Arginine, asparagine, cysteine, glutamine, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, serine, taurine, threonine, tryptophan, tyrosine, valine	Asparagine, glutamine, serine
Metabolites		Choline, inositol, carnitine

# Table 1. Components of the NutrEval FMV and Spectra Cell Tests

# **Summary of Evidence**

For individuals who have mood disorders, fibromyalgia, or unexplained fatigue, or healthy individuals who seek to optimize health and fitness who receive nutritional panel testing, the evidence includes several systematic reviews and randomized controlled trials (RCTs) on the association between a single condition and a single nutrient and on the treatment of specific conditions with nutritional supplements. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Systematic reviews have found statistically significant associations between depression or fibromyalgia and levels of several nutrients; however, there is little evidence that nutrient supplementation for individuals with depression improves health outcomes. An RCT has also found statistically significant associations between fatigue and levels of vitamin D. However, there is no direct evidence on the health benefits of nutritional panel testing for any condition, including testing healthy individuals, and no evidence that nutritional



panel testing is superior to testing for individual nutrients for any condition. 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 October 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

### **US Preventive Services Task Force Recommendations**

The US Preventive Services Task Force (USPSTF) has not addressed nutritional panel testing. The USPSTF has made several recommendations addressing screening for individual nutrients. The USPSTF concluded that there is insufficient evidence to recommend for or against screening for iron deficiency anemia in asymptomatic children, adolescents and pregnant women and vitamin D deficiency in asymptomatic, nonpregnant adults.<sup>13,14,15</sup>

### 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). Nutrient/nutritional panel testing using urine and/or blood samples is offered (e.g., NutrEval FMV, NutrEval Plasma, and Metabolomix+ by Genova Diagnostics; micronutrient testing by SpectraCell) 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.



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#### History

Date	Comments
02/01/21	New policy, approved January 12, 2021. Nutrient/nutritional panel testing is considered investigational for all indications.
03/01/22	Annual Review, approved February 7, 2022. Policy updated with literature review through October 19, 2021; no references added, reference to USPSTF vitamin D recommendation updated. Policy statement unchanged.
02/01/23	Annual Review, approved January 23, 2023. Policy updated with literature review through October 19, 2022; reference added. Minor editorial refinements to policy statements; intent unchanged. 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 October 23, 2023; no references added. Policy statement unchanged.
05/01/24	Minor update to related policies. 2.04.100 was replaced with 2.04.509 Cardiovascular Risk Panels.

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**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.



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