

FEP 2.04.136 Nutrient/Nutritional Panel Testing

Effective Date: April 15, 2018

Related Policies:

2.04.23 Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease
2.04.73 Intracellular Micronutrient Analysis
2.04.100 Cardiovascular Risk Panels

Nutrient/Nutritional Panel Testing

Description

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

Genova Diagnostics offers nutritional/nutrient panel testing. Among 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).¹

Genova Diagnostics produces a report that includes test results categorized as normal, borderline, and high need, along with recommendations for supplements and dosages for items categorized as high need. NutrEval FMV patient reports can recommend supplementation or any of the nutrients listed in Table 1 if they are found to be areas of high need.

A related test, the ONE (Optimal Nutritional Evaluation) FMV also by Genova Diagnostics, limits testing to the organic acid, amino acid, and oxidative stress marker categories.

SpectraCell Laboratories offers a micronutrient test that measures functional deficiencies at the cellular level. The test assesses how well the body uses 33 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 patient's deficiencies.

Table 1 Components of the NutrEval FMV Test

Category	NutrEval	SpectraCell Nutrient Testing
B vitamins	Thiamin B ₁ , riboflavin B ₂ , niacin B ₃ , pyridoxine B ₆ , biotin B ₇ , folic acid B ₉ , cobalamin B ₁₂	Vitamin A, vitamin B ₁ , vitamin B ₂ , vitamin B ₃ , vitamin B ₆ , vitamin B ₁₂ , biotin, folate, pantothenate, vitamin C, vitamin D, vitamin K
Minerals	Magnesium, manganese, molybdenum, zinc	Calcium, magnesium, manganese, zinc, copper
Fatty acids	Omega-3-oils	Oleic acid
Digestive support	Probiotics, pancreatic enzymes	
Other vitamins	Vitamin D	
Amino acids	Arginine, asparagine, cysteine, glutamine, glycine, histidine, isoleucine, leucine, lycine, methionine, phenylalanine, serine, taurine,	Asparagine, glutamine, serine

Original Policy Date: December 2015

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threonine, tryptophan, tyrosine, valine

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. Nutrient/nutritional panel testing using urine and/or blood samples is offered (eg, NutrEval FMV® and ONE FMV® by Genova Diagnostics; micronutrient testing by SpectraCell) 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.

POLICY STATEMENT

Nutrient/nutritional panel testing is considered **investigational** for all indications including but not limited to testing for nutritional deficiencies in patients with mood disorders, fibromyalgia, unexplained fatigue, and healthy individuals.

BENEFIT APPLICATION

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

RATIONALE

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 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. There was no evidence of associations between fibromyalgia or unexplained fatigue and nutrient deficiencies. Systematic reviews have found statistically significant associations between depression and levels of several nutrients; however, there is no evidence that nutrient supplementation for patients with depression improves health outcomes. Also, 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 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

The U.S. Preventive Services Task Force has not addressed nutritional panel testing. The Task Force has made several recommendations addressing screening for individual nutrients. The Task Force concluded that there is insufficient evidence to recommend for or against screening for iron deficiency anemia in asymptomatic children and vitamin D deficiency in asymptomatic adults.^{11,12} Screening for iron deficiency anemia is recommended in pregnant women.

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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

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POLICY HISTORY

Date	Action	Description
December 2015	New Policy	Considered investigational for all indications including but not limited to testing for nutritional deficiencies in patients with mood disorders, fibromyalgia, unexplained fatigue, and healthy individuals.
March 2018	Update Policy	Policy updated with a literature search through November 7, 2017; references 5, 7, and 10 added. Policy statement unchanged.

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