



**BlueCross BlueShield
of Alabama**

Name of Policy:

Nutrient/Nutritional Panel Testing

Policy #: 613
Category: Laboratory

Latest Review Date: December 2020
Policy Grade: C

BACKGROUND:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

POLICY:

Blue Advantage will treat **nutrient/nutritional panel testing** as a **non-covered benefit** and as **investigational** for all indications including but not limited to testing for nutritional deficiencies in patients with mood disorders, fibromyalgia, unexplained fatigue and healthy individuals and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

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 patients with chronic conditions (e.g., mood disorders, fibromyalgia, chronic fatigue) to specify supplements that will ameliorate symptoms.

Genova Diagnostics offers nutritional/nutrient panel testing. Among tests offered by this company is the NutrEval® FMV test, 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).

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.

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 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
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, threonine, tryptophan, tyrosine, valine	Asparagine, glutamine, serine

KEY POINTS:

The most recent literature update was performed through October 20, 2020.

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 improve 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.

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 (USPSTF) has not addressed nutritional panel testing. USPSTF 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.

KEY WORDS:

Genova Diagnostics, NutrEval® FMV, Nutrient panel testing, nutritional panel testing, ONE FMV™, Optimal Nutritional Evaluation, Metabolomix+

APPROVED BY GOVERNING BODIES:

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. Nutrient/nutritional panel testing using urine and/or blood samples is offered (e.g., 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

There are no specific codes for these panels of tests. Tests in the panel that have specific CPT codes would be reported using those codes such as folic acid (82746), magnesium (83735), manganese (83785), vitamin A (84590), zinc (84630). There are codes for testing multiple amino acids – 82128 for qualitative testing and 82136 for quantitative testing. The unlisted chemistry code 84999 would be used once for the other tests in the panel that do not have specific codes (or are used incorrectly with multiple units).

84999	Unlisted chemistry code
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POLICY HISTORY:

Medical Policy Panel, August 2015

Medical Policy Group, September 2015 **(3)**: Newly adopted policy.

Medical Policy Administration Committee, October 2015

Available for comment September 29 through November 12, 2015

Medical Policy Panel, December 2017

Medical Policy Group, January 2018 **(3)**: 2017 Updates to Description, Key Points, Approved by Governing Bodies & References; no change to policy statement

Medical Policy Group, December 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.