Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Nutrient/Nutritional Panel Testing

Policy #: 613
Latest Review Date: December 2022
Category: Laboratory
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

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.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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, unexplained 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 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. The only difference between NutrEval FMV and NutrEval Plasma isthat the former uses urine (first morning void) whereas the latter uses plasma (fasting sample) to measure amino acids.

SpectraCell Laboratories offers a micronutrient test that measures functional deficiencies at the cellular level. 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 patient’s deficiencies.

Table 1: Components of the NutrEval FMV Test

Category	NutrEval	SpectraCell Nutrient Testing
Vitamins and antioxidants	Vitamin A, vitamin C, vitamin E, alpha-lipoic acid,coenzyme Q10, glutathione, plant-based antioxidants, Bvitamins (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, lycine, methionine, phenylalanine, serine, taurine, threonine, tryptophan, tyrosine, valine	Asparagine, glutamine, serine
Metabolites		Choline, inositol, carnitine

KEY POINTS:

The most recent literature update was performed through October 19, 2022.

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 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 patients 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.

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. 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, as well as vitamin D deficiency in asymptomatic, nonpregnant adults.

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

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 NutrEval Plasma® 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.

82128	Amino acids; multiple, qualitative, each specimen
82136	Amino acids, 2 to 5 amino acids, quantitative, each specimen
82746	Folic acid; serum
83735	Magnesium
83785	Manganese
84590	Vitamin A
84630	Zinc
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
Medical Policy Group, December 2021
Medical Policy Group, December 2022
Medical Policy Group, November 2023: Archived effective 11/1/2023.

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.