BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.04.136 Nutrient/Nutritional Panel Testing

Annual Effective Policy Date: April 1,2024

Original Policy Date: March 2024

Related Policies:

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

Nutrient/Nutritional Panel Testing

Description

Description

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

OBJECTIVE

The objective of this evidence review is to determine whether nutrient/nutritional panel testing improves the net health outcome among individuals with mood disorders, fibromyalgia, or unexplained fatigue, or among healthy individuals seeking to optimize health and fitness.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

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 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.

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 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 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.

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

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.[13,14,15,]

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.

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15. U.S. Preventive Services Task Force (USPSTF). Vitamin D Deficiency: Screening. 2021; https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/vitamin-d-deficiency-screening. Accessed October 21, 2023.

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

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	Replace policy	Policy updated with a literature search through November 7, 2017; references 5, 7, and 10 added. Policy statement unchanged.
September 2019	Replace policy	Policy updated with a literature search through October 1, 2018; no references added. Policy statement unchanged.
March 2020	Replace policy	Policy updated with a literature review through October 14, 2019; no references added. Policy statement unchanged.
March 2021	Replace policy	Policy updated with a literature review through October 20, 2020; references added. Policy statement unchanged.
March 2022	Replace policy	Policy updated with literature review through October 19, 2021; no references added, reference to USPSTF vitamin D recommendation updated. Policy statement unchanged.
March 2023	Replace policy	Policy updated with literature review through October 19, 2022; reference added. Minor editorial refinements to policy statements; intent unchanged.
March 2024	Replace policy	Policy updated with literature review through October 23, 2023; no references added. Policy statement unchanged.