



FEP Medical Policy Manual

FEP 2.04.136 Nutrient/Nutritional Panel Testing

Effective Policy Date: April 1, 2021

Related Policies:

2.04.100 - Cardiovascular Risk Panels

Original Policy Date: December 2015

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 patients with mood disorders, fibromyalgia, or unexplained fatigue, or among healthy individuals seeking to optimize health and fitness.

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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.

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 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.

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 that the technology results in an improvement in the net health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

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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 and vitamin D deficiency in asymptomatic adults. [12.13.14.](#)

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.

REFERENCES

1. Genova Diagnostics. NutrEval FMV; <https://www.gdx.net/product/nutreval-fmv-nutritional-test-blood-urine>. Accessed October 20, 2020.
2. SpectraCell Laboratories Micronutrient Test Panel. <https://www.spectracell.com/micronutrient-test-panel>. Accessed October 20, 2020.
3. Petridou ET, Kousoulis AA, Michelakos T, et al. Folate and B12 serum levels in association with depression in the aged: a systematic review and meta-analysis. *Aging Ment Health*. Sep 2016; 20(9): 965-73. PMID 26055921
4. Cheungpasitporn W, Thongprayoon C, Mao MA, et al. Hypomagnesaemia linked to depression: a systematic review and meta-analysis. *Intern Med J*. Apr 2015; 45(4): 436-40. PMID 25827510
5. Swardfager W, Herrmann N, Mazereeuw G, et al. Zinc in depression: a meta-analysis. *Biol Psychiatry*. Dec 15 2013; 74(12): 872-8. PMID 23806573
6. Anglin RE, Samaan Z, Walter SD, et al. Vitamin D deficiency and depression in adults: systematic review and meta-analysis. *Br J Psychiatry*. Feb 2013; 202: 100-7. PMID 23377209
7. Hsiao MY, Hung CY, Chang KV, et al. Is Serum Hypovitaminosis D Associated with Chronic Widespread Pain Including Fibromyalgia? A Meta-analysis of Observational Studies. *Pain Physician*. Sep-Oct 2015; 18(5): E877-87. PMID 26431141
8. Daniel D, Pirotta MV. Fibromyalgia--should we be testing and treating for vitamin D deficiency?. *Aust Fam Physician*. Sep 2011; 40(9): 712-6. PMID 21894281
9. Gowda U, Mutowo MP, Smith BJ, et al. Vitamin D supplementation to reduce depression in adults: meta-analysis of randomized controlled trials. *Nutrition*. Mar 2015; 31(3): 421-9. PMID 25701329
10. Taylor MJ, Carney S, Geddes J, et al. Folate for depressive disorders. *Cochrane Database Syst Rev*. 2003; (2): CD003390. PMID 12804463
11. Nowak A, Boesch L, Andres E, et al. Effect of vitamin D3 on self-perceived fatigue: A double-blind randomized placebo-controlled trial. *Medicine (Baltimore)*. Dec 2016; 95(52): e5353. PMID 28033244
12. U.S. Preventive Services Task Force (USPSTF). Iron Deficiency Anemia: Screening. 2015; <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/iron-deficiency-anemia-in-young-children-screening#fullrecommendationstart>. Accessed October 20, 2020.
13. U.S. Preventive Services Task Force (USPSTF). Iron Deficiency Anemia in Pregnant Women: Screening and Supplementation, 2015. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/iron-deficiency-anemia-in-pregnant-women-screening-and-supplementation>. Accessed October 20, 2020.
14. U.S. Preventive Services Task Force (USPSTF). Vitamin D Deficiency: Screening. 2014; <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/vitamin-d-deficiency-screening>. Accessed October 20, 2020.

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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.

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