

Medical Policy Reference Manual

Medical Policy

11.01.072 Nutrient/Nutritional Panel Testing

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Description

Nutrient or nutritional panel testing is a multi-biomarker evaluation projected to provide an overall nutritional status for patients with specific chronic conditions (i.e. fibromyalgia, mood disorders, and unexplained fatigue) as well as healthy individuals seeking to optimize health and/or fitness.

Nutritional panel testing is purposed to identify nutritional deficiencies that will aide in a personalized supplement recommendation. Testing involves analyses of urine and blood specimens that provide a metabolic profile on more than 100 biomarkers including amino acids, oxidative stress components, and essential fatty acids.

The NutrEval® FMV and ONE (Optimal Nutrition Evaluation) FMV® tests are examples of nutritional panel analyses offered by Genova Diagnostics'. Both tests proffer a different high-level overview that signals key areas of concerns. ONE FMV® limits testing to key organic acids, oxidative stress, and amino acids marker classifications while NutrEval® gives a more comprehensive metabolic report categorizing the results as normal, borderline and high need along with supplement recommendations.

Policy

Nutrient/nutritional panel testing is considered **experimental / investigational** for all indications including but not limited to testing in healthy individuals seeking dietary and/or fitness recommendations as well as patients experiencing nutritional deficiencies with mood disorders, unexplained fatigue, or fibromyalgia as it does not meet TEC # 2-5.

Policy Guidelines

Rationale:

1. The technology* must have final approval from the appropriate government regulatory bodies:

Nutrient/Nutritional Panel testing using urine and blood specimens is offered per Genova Diagnostics' (i.e. NutrEval® FMV and ONE (Optimal Nutrition Evaluation) FMV®) in which is certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Food and Drug Administration (FDA) approval is not required.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes:

Analytic Validity:

The evidence search did not result in studies that directly evaluated the analytic validity of nutrient/nutritional panel testing.

Clinical Validity:

Evidence to support clinical validity were not identified. Studies that report clinical performance (i.e. sensitivity, specificity, positive predictive values, and negative predictive values) of nutrient/nutritional panel testing are needed.

Clinical Utility:

Currently, there is insufficient evidence in the published and peer-reviewed literature to establish clinical utility of the use of nutrient/nutritional panel testing for patients diagnosed with specific chronic conditions (i.e. fibromyalgia, mood disorders, and unexplained fatigue).

3. The technology must improve the net health outcome:

There is no direct evidence on the improvement of net health outcomes.

4. The technology must be as beneficial as any established alternatives:

No evidence has been identified to contribute to outcomes improvement and/or superior testing for individuals with any condition.

5. The improvement must be attainable outside the investigational settings.

No studies were identified to address health outcomes in general as it relates to nutrient/nutritional panel testing; therefore, it is not known whether there are satisfactory outcomes outside of the investigational settings.

Update 2020:

A search of the peer-reviewed literature was performed from the period of September 2018 through September 2020. Findings in the recent literature do not change the conclusions on the use of Nutrient/Nutritional Panel Testing regarding the efficacy or impact on patient outcomes as a result of this test. Therefore, the Policy statement remains experimental / investigational.

Provider Guidelines

There are no specific codes for nutrient/nutritional panel testing.

PLEASE NOTE: Claims for Nutrient/nutritional panel testing are subject to medical review.

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own, and may or may not be in agreement with those of CareFirst.

Genova Diagnostics. NutrEval. Retrieved from World Wide Web on July 18, 2018 from <https://www.gdx.net/product/nutreval-fmv-nutritional-test-blood-urine>

Gowda, U., Mutowo, M.P., Smith, B. J., Wluka, A.E., Renzaho, A. (2015, March). Vitamin D supplementation to reduce depression in adults: Meta-analysis of randomized controlled trials. *Nutrition*. doi: 10.1016/j.nut.2014.06.017.

LeFevre, M. L. (2015, January). Screening for Vitamin D Deficiency in Adults: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine*. doi:10.7326/M14-2450

Nowak, A., Boesch, L., Andres, E., Battegay, E., Hornemann, T., et al (2016, December). Effect of vitamin D3 on self-perceived fatigue: A double-blind randomized placebo-controlled trial. *Medicine Baltimore*. doi: 10.1097/MD.0000000000005353.

Petridou, E.T., Kousoulis, A. A., Michelakos, T., Papatoma, P., Dessypris, N. et al (2016, September). Folate and B12 serum levels in association with depression in the aged: a systematic review and meta-analysis. *Aging & Mental Health*. doi: 10.1080/13607863.2015.1049115.

U.S. Preventive Services Task Force. (2014, November). Vitamin D Deficiency: Screening. Retrieved from World Wide Web on July 18, 2018 from <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/vitamin-d-deficiency-screening>

This policy statement relates only to the services or supplies described herein. Coverage will vary from contract to contract and by line of business and should be verified before applying the terms of the policy.