

## Vitamin D Assay Test Testing

### Comment and Response Document

**Comment:** Providers produced literature demonstrating the dearth of evidence of the utility of Vitamin D supplementation in patients with bone loss associated with long-term steroid or anti-convulsant intake.

**Response:** Noridian agrees with the providers' conclusions and eliminates this coverage category.

**Comment:** Several commenters requested the addition of screening codes to allow for Vitamin D screening in the Medicare population.

**Response:** Neither Noridian nor CMS has authority to allow coverage of screening examinations. The Medicare law (Social Security Act 1862) prohibits payment for screening examinations. Congress must write specific emending legislation to allow payment for screening examinations, and such has been done for all currently covered screening, such as mammography, colonography.

**Comment:** Several commenters submitted literature indicating widespread prevalence of Vitamin D "deficiency" among Medicare beneficiaries and requested coverage for periodic patient examinations despite the absence of symptoms.

**Response:** Noridian will not add this coverage due to insufficient and questionable evidence of deficiency and benefits of treatment compounded by the absence of a reasonable understanding of the appropriate management of any deficiency in the face of known risks of supplementation. Since there is no consensus on the definition of normal and abnormal value ranges for Vitamin D, in general, but particularly among the poorly studied Medicare population; no standard across laboratories for either the assay or result reporting; and no evidence that supplementation beyond recommended daily doses is beneficial: coverage is denied. Noridian's conclusions are supported by the November 2010 analysis of the Institute of Medicine Dietary Reference Intakes committee, a study undertaken on behalf of the USDA, DOD, FDA, HHS and NIH.

**Comment:** Several commenters submitted supportive literature and requested coverage for Vit. D testing in a variety of medical conditions, which may be worsened by Vit. D deficiency. These conditions include: cancer (both generally and specifically), heart disease, autoimmune disorders, especially Multiple Sclerosis, glucose homeostasis, prevention of tuberculosis, Parkinson's Disease, and overall mortality.

**Response:** Coverage for testing in these conditions will not be added. Vitamin D receptor sequences have been found in over 1000 genes and the literature on Vit. D has expanded exponentially over the past few years. However, all submitted and otherwise reviewed studies have produced preliminary or suggestive results requiring further study. The best randomized clinical trials are inconsistent. All reviewed systematic reviews on the other hand, including

recent AHRQ and Cochrane analyses, conclude that evidence - at best - is intriguing but not conclusive for any of the conditions. This conclusion is supported by the November 2010 analysis of the Institute of Medicine Dietary Reference Intakes committee, a study undertaken on behalf of the USDA, DOD, FDA, HHS and NIH.

**Comment:** One commenter requested coverage of hypovitaminosis D in the absence of symptoms or signs of disease. Another commenter requested use of condition, hypovitaminosis D, only for patients under treatment for a covered condition whose last level was low.

**Response:** Coverage will not be added. There is no consensus on the definition of this condition, hypovitaminosis D, or the necessity of treatment except in specific conditions as listed in this LCD. Given the lack of consensus on the normal range for Vit. D levels, especially in the Medicare population, the emerging evidence of risks of supplementation and the recommendations of Dietary Reference Intakes report against other than routine daily intake (except in the disorders listed in our LCD), there is ample reason not to add this condition.

In the case of patients on Vit. D supplementation with a need for treatment and monitoring, the underlying condition (which management is affected by Vit. D) should be coded. If more than one LCD-listed condition contributes to Vit. D deficiency in a given patient and/or is improved by Vit. D administration, coders should use: ICD-9-CM 268.9 UNSPECIFIED VITAMIN D DEFICIENCY.

**Note:** In this LCD, the range of “normal”, for the purposes of repeat testing, was established by a consensus of Noridian providers, all experts in the fields and based on the best literature evidence currently available.

**Comment:** Two commenters requested the addition of Hypervitaminosis D.

**Response:** Noridian will add this condition. There is evidence in the literature that levels above 60 are harmful in some populations and emerging evidence of potential harm at levels lower than 60.

**Comment:** One of the commenters requesting addition of hypervitaminosis D also requested addition of several other codes related to liver and kidney disease; malnutrition states; malaise and fatigue, myalgia and Myositis; and obesity.

**Response:** Severe nutritional disorders require vitamin supplementation at higher than usual levels for repletion and Noridian will add codes for both marasmus and severe protein-calorie malnutrition. The draft LCD already includes codes that specify degrees of renal disease below which one would not expect to see Vit. D abnormalities and no additional codes will be listed. The level of evidence for addition of codes for hepatic osteodystrophy, proximal myopathy, muscle strength, weight gain and obesity is C and does not support addition of the conditions to the LCD. Noridian will add a code for chronic non-alcoholic liver disease. The addition of any of the diagnoses listed here or other diagnoses depends on the submission of literature supporting the utility of Vit. D supplementation above the daily recommended levels of the Reference Dietary Intakes.

**Comment:** One commenter objected to the restrictions of once a year testing and one test per day.

**Response:** Noridian agrees and will remove the language from the LCD. Coverage for any test will be based solely on the documentation of medical necessity.