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# Medicare

## **Comments and Responses Regarding Draft Local Coverage Determination: Vitamin D Assay Testing**

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the Draft LCD for Vitamin D Assay Testing. The official notice period for the final LCD begins on April 15, 2009 and the final determination will become effective on July 1, 2009.

*Comment:* Many commenters requested the addition of testing to determine one's level of vitamin D as prudent preventive care.

*Response:* As noted in the LCD, except for certain preventive tests specifically covered by amendment to the Social Security Act, screening tests are excluded from the Medicare program.

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*Comment:* Commenters stated that the policy does not acknowledge the measurement of vitamin D levels as an important measure in the evaluation and treatment of patients with osteoporosis and osteoporotic fractures.

*Response:* Osteoporosis will be added to the LCD.

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*Comment:* A commenter asked that the LCD clearly define "Vitamin D metabolites."

*Response:* Other forms of vitamin D that can be measured in the blood, e.g., 1, 25-Dihydroxyvitamin D.



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*Comment:* Commenters suggested adding ICD-9-CM codes indicating non-traumatic fractures.

*Response:* If a non-traumatic fracture results in a diagnosis of osteoporosis, vitamin D testing may then be done.

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*Comment:* A commenter suggested adding the indication of Vitamin D therapy follow-up.

*Response:* This indication will be added to the LCD.

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*Comment:* Commenters stated that recent literature has indicated “substantially reduced levels of serum 25-OH vitamin D were identified among patients with inflammatory arthritis and chronic pain.” Hence, vitamin D deficiency may play a role in other rheumatologic disorders as well.

*Response:* The literature has thus far shown only an association between reduced levels of vitamin D and disorders of this nature. There is no data supporting vitamin D supplementation as treatment for these conditions. Therefore, without an effect on the treatment course, there is no medical necessity for testing.

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*Comment:* Commenters noted that many epidemiologic and laboratory data argue for a role in the prevention of several diseases or anomalies (cancer, auto-immune diseases, cardiovascular events, diabetes, multiple sclerosis, tuberculosis and others) by assessing Vitamin D levels.

*Response:* The literature suggests that deficiency in vitamin D may be associated with many conditions. There is no strong evidence to support that vitamin D supplementation will prevent or treat most of these conditions. As such, there is no medical necessity for such testing.

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*Comment:* A commenter noted that Vitamin D levels are often obtained when patients develop arthralgias and musculoskeletal discomfort while receiving aromatase inhibitors. Patients with low levels of vitamin D are given supplements.

*Response:* The scientific literature does not support the medical necessity of such testing.

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*Comment:* A commenter noted that for renal patients both Vitamin D3 and 125-Hydroxy Vitamin D are important hormones in the body and they are not necessarily linked to serum levels. One may be deficient. Labs sometimes report D3 and sometimes D2 and other tests. For renal patients, 125-Hydroxy Vitamin D measurement should be allowed at the same time as Vitamin D3. The results of the tests will affect the treatment of patients. The 125-Hydroxy Vitamin D test is more expensive.

*Response:* The restriction regarding testing for other vitamin D metabolites has been removed. Testing for other forms of vitamin D will be left to the discretion of the treating physician, and subject to review upon request. The KDOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease suggest only the use of 25-OH vitamin D.

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*Comment:* : A commenter stated that the most common reason for Vitamin D testing in his practice is for hypocalcemia and this indication should be included in the LCD.

*Response:* This indication will be added to the LCD.

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*Comment:* A commenter recommended that malabsorption syndromes, including those caused by surgery, be added to the LCD.

*Response:* While malabsorption may cause reduced levels of vitamin D, without signs or symptoms of a condition known to be caused by such levels, testing is not medically necessary.

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*Comment:* A commenter indicated that some ICD-9-CM codes are too liberal and questioned the inclusion of Chronic Kidney Disease Stage I and II. Vitamin D deficiency usually doesn't occur before advanced Chronic Kidney Disease Stages III, IV and V.

*Response:* Per the KDOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease, such testing is needed only for patients with stage III or greater chronic kidney disease. The LCD indications will be changed to reflect this.

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