

February 20, 2009

Gina Oliveri  
National Government Solutions, Inc.  
P.O. Box 2019  
Milwaukee, WI 53201  
VIA E-MAIL

**RE: Draft LCD (DL29510) for Vitamin D Assay Testing**

Dear Ms. Oliveri:

The Endocrine Society (Society) appreciates the opportunity to provide comments to National Government Services, Inc. (NGS) on its proposed Medicare local coverage determination (LCD) on vitamin D assay testing (DL29510). Founded in 1916, the Society represents over 14,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as osteoporosis, diabetes, thyroid disease, obesity, hypertension, and infertility.

The Endocrine Society is concerned with the changes proposed for 25-hydroxyvitamin D [25(OH)D] and 1,25 dihydroxy vitamin D testing that will immediately affect Medicare beneficiaries in ME, NH, VT, MA, CT, NY, VA, WV, OH, IN, KY, IL, MI and WI. Not only will thousands of Medicare enrollees lose access to an important test that assists endocrinologists and other physicians in screening and diagnosing debilitating diseases, but the affect of such a decision is sure to resonate among many other Medicare contractors with a deleterious affect on patients. We ask that NGS reconsider its draft LCD to include at a minimum the use of the 25-hydroxyvitamin D test for the diagnosis and ongoing management of conditions such as osteopenia, osteoporosis and primary and secondary hyperparathyroidism.

As you are no doubt aware, vitamin D testing has increased dramatically over the last few years. Much of this increase is warranted as new research has shown that vitamin D testing can indicate a variety of potential disease states and disease-related symptoms. However, in the draft LCD, NGS has eliminated using this test in ways that have historically been accepted medical protocol, including testing for osteoporosis and secondary hyperparathyroidism, two conditions for which patients seek medical care from an endocrinologist.

Significant amounts of research have been conducted on the affect of vitamin D on the body and as an indication of disease and future disease risk. For example, the serum 25(OH)D level is influenced by several factors and the measurement of this level is the only way to determine the vitamin D status of a patient. As a result, measurement of serum 25(OH)D is recommended in patients with osteoporosis.<sup>1</sup> In fact, most women with osteoporosis are vitamin D insufficient as

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<sup>1</sup> Liu, E. et al., "Plasma 25-hydroxyvitamin D is Associated with Markers of the Insulin Resistant Phenotype in Nondiabetic Adults," *Journal of Nutrition*. 139 (2): 329-334 (2009).

they are not obtaining an optimal dose of the supplement.<sup>2</sup> Patients with osteoporosis require vitamin D supplementation to help reduce bone loss and prevent bone fractures – costly conditions that can require hospitalization if not properly treated. Without vitamin D testing, patients on expensive osteoporotic medications may not benefit from the drugs, as vitamin D supplementation helps osteoporotic medications effectively work to strengthen bones. Without access to appropriate vitamin D testing, these patients and their physicians will have no ability to determine an appropriate dose of oral vitamin D supplementation. As a result, their medical care will be compromised and their health placed at risk of serious and costly complications.

Additional research has shown that in patients without diabetes, vitamin D status was inversely associated with surrogate fasting measures of insulin resistance, suggesting that vitamin D status may be an important determinant for type 2 diabetes mellitus<sup>3</sup>, a disease that accounted for over 30 percent of Medicare spending in 2004. In addition, newly released data suggests that low levels of 25 hydroxyvitamin D are associated with myocardial dysfunction, deaths due to heart failure, and sudden cardiac death.<sup>4</sup> While the frequency of vitamin D testing may have increased, there is abundant research available to suggest that ordering and performing such tests have important medical indications which in turn may ultimately help reduce long-term costs associated with many costly conditions.

The Endocrine Society strongly opposes the NGS draft LCD which would significantly restrict the important use of vitamin D testing. We thank you for the opportunity to comment on this important issue and we would be happy to discuss our concerns at your earliest convenience. If you have any questions, please feel free to contact Janet Kreizman, Senior Director of Government and Public Affairs at [jkreizman@endo-society.org](mailto:jkreizman@endo-society.org).

Thank you,



Robert M. Carey, MD, MACP  
President  
The Endocrine Society

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<sup>2</sup> Holick, M. et al., “Prevalence of Vitamin D Inadequacy among Postmenopausal North American Women Receiving Osteoporosis Therapy.” *Journal of Clinical Endocrinology and Metabolism*. 90 (6): 3215-3224.

<sup>3</sup> Knekt, P. et al., “Serum Vitamin D and Subsequent Occurrence of Type 2 Diabetes,” *Epidemiology*. 19 (5): 666-671 (2008).

<sup>4</sup> Pilz, S. et al., “Association of Vitamin D Deficiency with Heart Failure and Sudden Cardiac Death in a Large Cross-Sectional Study of Patients Referred for Coronary Angiography.” *Journal of Clinical Endocrinology and Metabolism*. 93 (10): 3927-3935 (2008c).