



March 19, 2010

First Coast Medical Services  
Medical Policy  
532 Riverside Avenue  
ROC 19T  
Jacksonville, FL 32202

RE: DL30868 Vitamin D; 25 hydroxy, includes fraction(s), if performed

On behalf of the members of the American Clinical Laboratory Association (ACLA), I am filing the attached comments on the draft local coverage decision (LCD) for Vitamin D measurement levels. ACLA is an association representing national, regional, and local laboratories including laboratories that provide testing services primarily to ESRD patients. Many of our members provide services to Medicare beneficiaries and are located within the jurisdiction of First Coast Service Options, Inc.

We believe the draft LCD would unduly limit coverage for medically necessary diagnostic Vitamin D testing services to Medicare beneficiaries. Our submission adds additional ICD-9 codes and medical documentation to support each code.

We appreciate your consideration of this submission as you develop the final LCD.

Sincerely,

A handwritten signature in black ink, appearing to read 'JoAnne Glisson', is centered below the word 'Sincerely,'.

JoAnne Glisson  
Senior Vice President

Attachment

## **Additional ICD-9s and Supporting References for DL30868**

### **733.90 Disorder of bone and cartilage, unspecified**

1. Presse Med. 38(1):43-54 (2009) "Vitamin D: Skeletal and extra skeletal effects; recommendations for good practice"; Briot, K, et.al.
2. Nat . Clin. Pract. Rheumatol 4(11):580-588(2008), "Vitamin D and musculoskeletal health", Wolff, AE, AN Jones, and KE Hansen
3. Stone,MD, William J. and Rabin, MD, Pauline L., End-Stage Renal Disease, An Integrated Approach, Renal Physiology and Pathophysiology of Renal Failure, Academic Press, 1983: 2-25
4. Block, MD, Geoffrey, et.al., Cinacalcet for Secondary Hyperparathyroidism in Patients receiving Hemodialysis, The New England Journal of Medicine, April 8, 2004:1516-1525
5. Curhan, MD, ScD, Gary, Fooling the Parathyroid Gland – Will There Be Health Benefits? Editorial, The New England Journal of Medicine April 8, 2004: 1565-1567
6. Isselbacher, Et.al., Principles of Internal Medicine (Harrison's Vol. 2) Chapter 357, Diseases of the Parathyroid Gland and Other Hyper- and Hypocalcemic Disorders, 13<sup>th</sup> edition, McGraw-Hill, Inc.: 2160-2161
7. Tietz, PhD, Norbert W., Textbook of Clinical Chemistry,Chapter 21, Calcium and Phosphate Metabolism, 3<sup>rd</sup> Edition, WB Saunders Company, 1986: 705-716
8. Bischoff-Ferrari H, Giovannucci E, Willett W, Dietrich T, Dawson-Hughes B. Estimation of optimal serum concentrations of 25-hydroxyvitamin D for multiple health outcomes

### **275.49 Other disorders of calcium metabolism**

1. Lafferty, FW. Differential diagnosis of hypercalcemia J Bone Miner Res 1991; 6 Suppl 2:s51
2. Goltzman, D, Cole, DEC. Hypoparathyroidism. In Primer on the Metabolic Bone Diseases and Disorders of Bone Metabolism, American Society of Bone and Mineral Research 2006; 6:216
3. Fitzpatrick, LA, Arnold, A. Hypoparathyroidism, In: Endocrinology, 3<sup>rd</sup> ed, Degroot, LJ, (Ed), Saunders, Philadelphia 1995 p 1123

### **V58.69 Encounter for long-term (current) use of other medications**

1. The Journal of Clinical Endocrinology and Metabolism 90(6):3215-3224, Prevalence of Vitamin D Inadequacy among Postmenopausal North American Women Receiving Osteoporosis Therapy
2. Hahn, TH. Drug-induced disorders of Vitamin D and mineral metabolism. Clin Endocrinol Metab 1980; 9:107
3. Kovacs, CS, Jones, G, Yendt, ER. Primary hyperparathyroidism masked by antituberculous therapy-induced vitamin D deficiency. Clin Endocrinol (Oxf) 1994; 41:831.
4. Fortenberry,EJ, McDermott, MT, Duncan, WE. Effect of theophylline on calcium metabolism and circulating vitamin D metabolites. J Bone Miner Res 1990; 5:321

### **571.50 Cirrhosis of liver without mention of alcohol**

1. Compston, JE. Hepatic osteodystrophy: Vitamin D metabolism in patient with liver disease. *Gut* 1986; 27:1073
2. Dibble, JB, Sheridan, P, Losowsky, MS. A survey of Vitamin D deficiency in gastrointestinal and liver disorders *Q J Med* 1984; 53:119
3. Kumar, R. Hepatic and intestinal osteodystrophy and the hepatobiliary metabolism of vitamin D. *Ann Intern Med* 1983; 98:662
4. Bernstein, CN, Leslie, WD, Leboff, MS. AGA technical review on osteoporosis in gastrointestinal diseases. *Gastroenterology* 2003; 124:795

### **579.3 Other and unspecified postsurgical nonabsorption**

1. Bernstein, CN, Leslie, WD, Leboff, MS. AGA technical review on osteoporosis in gastrointestinal diseases. *Gastroenterology* 2003; 124:795
2. American Gastroenterological Association medical position statement: guidelines on osteoporosis in gastrointestinal diseases. *Gastroenterology* 2003; 124:791

### **588.89 Other specified disorders resulting from impaired renal function**

1. *Am. J. Kidney Dis* 50(1):59-68(2007) "Changes in serum 25-hydroxyvitamin D and plasma intact PTH levels following treatment with ergocalciferol in patients with CKD", Al Aly, Z, et al
2. Bone, (2008) "Serum 25-hydroxyvitamin D as an independent determinant of 1-84 PTH and bone mineral density in non-diabetic CKD patients," Tomida, K. et al

### **728.87 Muscle weakness (generalized)**

1. Clinician's Guide to Prevention and Treatment of Osteoporosis, National Osteoporosis Foundation
2. Ceglia, L. Vitamin D and skeletal muscle tissue and function. *Mol Aspects Med*. 2008 *De*(6):407-14. Epub 2008 Aug 8. Review
3. El-Hajj Fuleihan G, Nabulsi M, MTamim H, Maalouf J, Salamoun M, Khalife H, Choucair M, Arabi A, Veith R. Effect of vitamin D replacement on musculoskeletal parameters in school children: a randomized controlled trial. *J Clin Endocrinol Metab*. 2006 Feb; 91(2):405-12 Epub 2005 Nov 8
4. Ward KA, Das G, Berry JL, Roberts SA, Rawer R, Adams JE, Mughal Z. Vitamin D status and muscle function in post menarchal adolescent girls. *J Clin Endocrinol Metab*. 2009 Feb; 94(2):559-63. Epub 2008 Nov 25
5. Gordon PL, Sakkas GK, Doyle JW, Shubert T, Johansen KL. Relationship between vitamin D and muscle size and strength in patients on hemodialysis. *J Ren Nutr*. 2007 Nov; 17(6):397-407. PubMed PMID: 17971312

### **729.10 Myalgia and myositis, unspecified**

Clinician's Guide to Prevention and Treatment of Osteoporosis, National Osteoporosis Foundation – UpToDate Causes of vitamin D deficiency and resistance – Reference: Plotnikoff, GA, Quigley, JM Prevalence of severe hypovitaminosis D in patients with persistent, nonspecific musculoskeletal pain. Mayo Clin Proc 2003; 78:1463

### **V45.86 Bariatric surgery status**

1. Clinician's Guide to Prevention and Treatment of Osteoporosis, National Osteoporosis Foundation
2. Johnson, JM, Maher, JW, Demaria, EJ, et.al. The Long-term Effects of Gastric Bypass on Vitamin D Metabolism. Ann Surg 2006; 243:703