

Novitas Solutions Medical Policy Department
Union Trust Building, Suite 600
501 Grant Street
Pittsburgh, PA 15219-4407

Re: DL34914

On behalf of the American Clinical Laboratory Association (ACLA), I am writing to provide input to Novitas Solutions, Inc. regarding the recent draft Local Coverage Determination that addresses the evaluation of patients with conditions placing them at high risk for vitamin D deficiency (DL34914). ACLA is an association representing national, regional and specialty laboratories several of which are located with the Novitas service area and would be affected by the draft location coverage determination.

Vitamin D deficiency is an important contributor to the development of osteoporosis; specific patient populations with specific diagnoses are at substantially increased risk for complications related to Vitamin D deficiency.

Vitamin D is a fat-soluble vitamin. The absorption of vitamin D is abnormal in many conditions that alter the normal absorption of fat-soluble compounds. This includes surgical interventions, including those done for the treatment of individuals with severe obesity with comorbidities (e.g., diabetes mellitus). Further, normal vitamin D metabolism is altered in chronic renal disease and when treating chronic conditions with certain classes of prescription medications, such as cholestyramine (to enhance cholesterol and /or bile acid excretion), select classes of anti-seizure medications, and chronic treatment with corticosteroids.

Increased recognition of the prevalence of vitamin D deficiency in these selected populations has caused professional societies to identify particularly high risk patient populations for moderate to severe vitamin D deficiency. This recognition now is codified in professional practice guidelines that identify diagnoses or conditions where a high prevalence of vitamin D deficiency is observed, recommending these patients be evaluated for vitamin D deficiency. The organizations include the Endocrine Society (1, 2), the by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery (3), American Society for Metabolic and Bariatric Surgery (4), and various kidney disease groups (the European Renal Best Practice; the Kidney Disease: Improving Global Outcomes; and Kidney Disease Outcomes Quality Initiative (5)). The specific clinical indications are summarized in Appendix 1 (taken from the Endocrine Society Practice Guidelines (1)).

Current coverage policy:

Beneficiaries covered

Current draft policy provides coverage for rickets, osteomalacia, osteoporosis, chronic kidney disease, hepatic failure, some malabsorption syndromes (i.e. IBD and Crohn's), hyperparathyroidism, some granuloma disorders (i.e. sarcoidosis and TB), older adults and with history of falls and history of non-traumatic fractures.

Summary of Recommended ICD-10 Additions to the Draft LCD

We propose that Novitas Solutions, Inc. consider further updates its LCD draft policy to cover Vitamin D testing in individuals with all known conditions or treatments that place patients at high risk. This change would bring the Novitas Solutions, Inc. coverage policies in line with the existing professional society diagnosis and treatment guidelines, including the organizations listed above and consistent with policies of some other jurisdictions. Our proposed changes are:

- 1) Include cystic fibrosis (E84.0-E84.9), bariatric surgery (e.g., Z98.0, Z98.84, K95.01, K95.09, K 95.81, K95.89, O99.840-) and radiation enteritis (K52.0) specific ICD10 codes within group 1 codes to cover this malabsorption syndrome, as recommended by Endocrine Society Guidelines.
- 2) Include histoplasmosis (B39.1-B39.9), coccidiomycosis (B38.0-B38.9), berylliosis (J63.2) and some lymphomas, particularly follicular lymphomas (C82.00-C82.99) specific ICD10 codes within group 1 codes consistent with Endocrine Society Guidelines.
- 3) Include Z68.30-Z68.45 and Z68.53-Z68.54 as covered ICD10 codes to align with Endocrine Society guidelines recommending evaluation for adults and children with BMI > 30.

As an additional consideration, the Endocrine Society recommends patients on certain medications be evaluated for Vitamin D deficiency. We appreciate Novitas Solutions, Inc. including the Chronic Drug Use ICD-10 codes in the draft LCD. We note, however, that many times clinicians will report the condition for which those drugs are used rather than the chronic drug use codes. For example, the Endocrine Society recommends evaluation for patients on anticonvulsants, antiretroviral HIV therapy, glucocorticoids, antifungals, and cholestyramine. For some of these medications (e.g., HIV therapy, anticonvulsants) there would be a very clear map to the condition for which those drugs are prescribed. We would recommend, therefore, incorporating those conditions into the LCD.

Attached is a list of references justifying the proposed additions to the policy as well as a spreadsheet listing the additional ICD-10 codes that would be added to the policy.

Thank you for the opportunity to submit these comments to Novitas Solutions, Inc. If you or your staff have any questions, please don't hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'JoAnne Glisson', with a stylized flourish at the end.

JoAnne Glisson
Senior Vice-President

Attachment

References:

1. Holick MF, Binkley NC, Bischoff-Ferrari HA, Gordon CM, Hanley DA, Heaney RP, Murad MH, Weaver CM 2011 Evaluation, Treatment, and Prevention of Vitamin D Deficiency: an Endocrine Society Clinical Practice Guideline *J Clin Endocrinol Metab* 96: 1911–1930
2. Heber D, Greenway FL, Kaplan LM, Livingston E, Salvador J, Still C 2010 Endocrine and Nutritional Management of the Post-Bariatric Surgery Patient: An Endocrine Society Clinical Practice Guideline *J Clin Endocrinol Metab* 95: 4823–4843.
3. Mechanick JI, Youdim A, Jones DB, Garvey WT, Hurley DL, McMahon MM, Heinberg LJ, Kushner R, Adams TD, Shikora S, Dixon JB, Brethauer S 2013 AACE/TOS/ASMBS Guidelines Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient—2013 Update: Cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery *Surgery for Obesity and Related Diseases* 9 (2013) 159–191
4. Aills L, Blankenship J, Buffington C, Furtado M, Parrott J 2008 ASMBS Guidelines: ASMBS Allied Health Nutritional Guidelines for the Surgical Weight Loss Patient *Surgery for Obesity and Related Diseases* 4 (2008) S73-S108
5. Kramer H, Berns JS, Choi MJ, Martin K, Rocco MV 2014 25-Hydroxyvitamin D Testing and Supplementation in CKD: An NKF-KDOQI Controversies Report *Am J Kidney Dis.* 64: 499-509