Memorandum

To:	LDH, MCO Policies
From:	Lesli Boudreaux, Director Compliance and Regulatory Affairs
Date:	8/6/2020
Subject:	**AmeriHealth Caritas Louisiana – Vitamin D screening Review**

AmeriHealth Caritas Louisiana submits this proposed new complex review policy specific to Vitamin D screening claims. This policy will become effective upon receipt of LDH's approval and will remain in effect until such time that revisions are submitted to LDH for review and approval.

Highlights of this policy include:

- *Verification that Vitamin D screening medical necessity criteria were met.*

This information was reviewed and approved by AmeriHealth Caritas Louisiana.

Kyle Viator
Market President

CCP.1414.04

AmeriHealth Caritas Louisiana

Vitamin D screening

Clinical Policy ID: CCP.1414.04

Recent review date: 5/2020

Next review date: 9/2021

Policy contains: Vitamin D assay testing, Vitamin D screening, Osteopenia, Bone Density; Vitamin D supplementation.

AmeriHealth Caritas Louisiana has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Louisiana's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Louisiana when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Louisiana's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Louisiana's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Louisiana will update its clinical policies as necessary. AmeriHealth Caritas Louisiana's clinical policies are not guarantees of payment.

Coverage policy

Vitamin D screening (CPT 82306 and 82652) is clinically proven and therefore medically necessary for AmeriHealth Caritas Louisiana members who exhibit signs or symptom of vitamin D deficiency (CMS 2019a; CMS 2019b; Holick 2011) and meet the billing and coding requirements outlined by the Centers for Medicare and Medicaid Services Local Coverage Determination Vitamin D Assay testing (A57736).

1. **CPT code 82306 must accompany medical necessity for one or more ICD-10-CM group one codes listed in CMS LCD A57736**
2. **CPT code 82652 must accompany medical necessity for one or more ICD-10-CM group two codes listed in CMS LCD A57736 (CMS 2019a).**

~~AmeriHealth Caritas considers annual screening for vitamin D deficiency to be clinically proven and, therefore, medically necessary for members who exhibit signs and symptoms of vitamin D deficiency (Holick, 2011), or asymptomatic members who are at risk for vitamin D deficiency, defined as one or more of the following:~~

- ~~chronic kidney disease stage III or greater~~
- ~~cirrhosis~~
- ~~hypocalcemia~~
- ~~hypercalcemia~~
- ~~hypercalciuria~~
- ~~hypervitaminosis D~~

~~• parathyroid disorders~~
~~• malabsorption states~~
~~• obstructive jaundice~~
~~• osteomalacia~~
~~• osteoporosis if:~~
~~○ T score on dual energy x-ray absorptiometry scan <-2.5 or~~
~~○ History of fragility fractures or~~
~~○ Fracture risk assessment tool > 3 percent 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture or~~
~~○ Fracture risk assessment tool > 3 percent (any fracture) with T-score <-1.5 or~~
~~○ Initiating bisphosphanate therapy (Vitamin D level and serum calcium levels should be determined and managed as necessary before bisphosphonate is initiated.)~~
~~• osteosclerosis/petrosis~~
~~• rickets~~
~~• vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment.~~
~~• unexplained hypercalcemia (suspected granulomatous disease or lymphoma)~~
~~• unexplained hypercalciuria (suspected granulomatous disease or lymphoma)~~
~~• suspected genetic childhood rickets~~
~~• suspected tumor-induced osteomalacia~~
~~• nephrolithiasis or hypercalciuria (U.S. Centers for Medicare & Medicaid Services, 2018).~~

Limitations

- **Limit one screening per year, unless the member has been shown to be vitamin D deficient, further testing (limit four per year) may be medically necessary to ensure adequate replacement has been accomplished.**
- **Screening for vitamin D deficiency is investigational, and therefore not medically necessary in asymptomatic adults age 18 years and older (U.S. Preventive Services Task Force, 2014).**
- **Testing may not be used for routine or other screening (Centers for Medicare & Medicaid Services, 2019a).**

~~AmeriHealth Caritas considers universal screening for vitamin D deficiency to be investigational, and therefore not medically necessary (U.S. Preventive Services Task Force, 2014).~~

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Vitamin D is a fat-soluble vitamin that is ingested through foods, sun exposure, and supplements. It promotes calcium absorption and normal growth of bone. Without adequate levels of vitamin D, bone can become thin, brittle, or misshapen. In addition, the vitamin helps modulate cell growth, enhance neuromuscular and immune function, and reduce inflammation. Vitamin D deficiency can lead to rickets in children and osteomalacia/osteoporosis in adults.

The Institute of Medicine considers any human with levels of less than 30 nanomoles per liter serum 25-hydroxyvitamin D to have vitamin D deficiency. The Institute also recommends daily intakes of vitamin D, which vary by age (persons over age 70 require 800 international units a day, while infants under age 1 require just 400; the remainder between ages 1 and 70 years require 600). Foods with the most vitamin D include cod liver

oil, certain fishes (sockeye salmon, swordfish, tuna), orange juice, milk, and yogurt (National Institutes of Health, 2018).

Estimates of vitamin D intake from food and supplements have been calculated to range (by age group) from 204 to 288 international units per day for males and 144 to 276 for females. A total of 37% of Americans use dietary supplements containing vitamin D.

The prevalence of vitamin D deficiency has been a concern among American public health officials for over a decade. The National Center for Environmental Health and the National Center for Health Statistics sampled Americans 12 years and older (n = 51,146) for 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3 — a measure of vitamins D2 and D3 combined — with those < 40 nanomoles per liter considered to have low levels. From 1988-1994 to 2005-2006, the percentage of deficient Americans increased. From 2005-2006 to 2009-2010, analysts observed a decrease due to the increased use of vitamin D supplements by persons over 40.

The current (2009-2010) rate of Americans over age 12 who are vitamin D deficient is 15%. Rates vary by race and ethnicity (non-Hispanic whites = 6.6%, Mexican-Americans = 23%, and non-Hispanic blacks = 46%) (Schleicher, 2016).

Vitamin D deficiency is also common among children, especially those who are overweight. The prevalence of the deficiency, defined as < 50 nanomoles per liter, for U.S. children ages 6 to 18 years was 21% (healthy weight), 29% (overweight), 34% (obese), and 49% (severely obese). Among severely obese white, Latino, and African American children, the proportions were 27%, 52%, and 87%, respectively (Turer, 2013).

Vitamin D testing has increased greatly in recent years. From 2000 to 2014, the proportion of Americans over age 70 taking a vitamin D test rose from 4/1,000 to 4/10 — a 100-fold increase (Rooney, 2017). Increases such as this have prompted a discussion about when this test is medically necessary.

Medicare paid $224 million for vitamin D assay testing in 2014, a sharp increase from just a decade earlier (Rockwell, 2014). An estimated 7.5 million outpatient visits occurred in the U.S. in the four-year period 2007-2010 with a diagnosis of vitamin D deficiency (Huang, 2014), while an estimated 10% to 16% of Medicare patients and 5% to 10% of commercially insured patients were tested for vitamin D levels in the two-year period 2009-2011 (Colla, 2017).

Findings

The American Association of Clinical Endocrinologists guideline for Vitamin D screening, which it states is similar to those of the Endocrine Society, Mayo Clinic, and U.S. Preventive Services Task Force, recommends screening for individuals with risk factors, listed in the coverage section of this policy (American Association of Clinical Endocrinologists, 2019).

Another guideline, issued by the U.S. Preventive Services Task Force, recommends against universal screening for vitamin D deficiency. The task force found no references that assessed benefits or harms of screening for the deficiency in asymptomatic adults. The Task Force noted commonly reported risk factors for low vitamin D levels, including decreased dietary vitamin D intake, absorption, or synthesis due to decreased sun exposure or darker skin pigmentation; older age; inflammatory bowel disease, malabsorptive conditions, or history of gastric

bypass; being homebound or institutionalized; routinely wearing clothing that prevents sun exposure on most of the skin; and living at high latitudes.

Finally, the group found adequate evidence that treatment of asymptomatic vitamin D deficiency has no benefit on cancer, type 2 diabetes mellitus, risk for death in community-dwelling adults, risk for fractures in persons not selected on the basis of being at high risk for fractures; and inadequate evidence on the benefit of treatment of asymptomatic vitamin D deficiency on other outcomes, including psychosocial and physical functioning (U.S. Preventive Services Task Force, 2014).

A Centers for Medicare & Medicaid Services Local Coverage Determination, in effect starting November 14, 2019, lists the conditions for which serum 25-hydroxyvitamin testing is indicated. See the Local Coverage Determination citation later in this policy, and the list of conditions for testing in the coverage section (Centers for Medicare & Medicaid Services, 2019).

Numerous systematic reviews and meta-analyses, plus other large-scale studies, have analyzed associations between vitamin D supplements and health outcomes. Below are results of these studies published in 2018. Results are mixed; some show improved outcomes, some do not, and some include both.

- Active tuberculosis (n = 1,787). Supplements could be used in conjunction with standard treatment based on significantly higher sputum smear and culture proportions, but did not impact adverse events and mortality (Wu, 2018).
- Cancer (all), 30 trials (n = 30,808). No evidence that supplementation was associated with a decrease in cancer-related incidence or mortality was found (Goulao, 2018).
- Cancer (all). A systematic review of 52 trials (n = 75,454) revealed a significant reduction between reduced risk of cancer death (RR = 0.84), but non-significant reductions for all causes (RR = 0.98) and cardiovascular disorders (RR = 0.98), and all non-cancer, non-cardiovascular causes (RR = 1.05) (Zhang, 2019).
- Cancer (colorectal), 11 trials (n = 7,718). Increased serum 25-hydroxyvitamin D concentrations improved survival in patients with colorectal cancer, and recommended supplementation be the subject of randomized trials (Maalmi, 2018).
- Cancer (prostate), 22 trials. Men taking supplements had insignificantly lower prostate cancer mortality, but 19% had at least a 50% reduction in prostate-specific antigen, which was statistically significant (Shahvazi, 2018).
- Diabetes, 28 trials. Supplements given to non-diabetics showed no effects on fasting plasma glucose levels or insulin resistance. However, significant improvements were observed for patients with diabetes for those with low body mass index or low serum 25-hydroxyvitamin D, and risk of type 2 diabetes mellitus was lower for pre-diabetic individuals (He, 2018).
- Diabetes, 20 trials (n = 2,703). Supplementation's effects on diabetes risk significantly improved .Vitamin D levels in short-term, high dose, non-obese, baseline vitamin D-deficient individuals, as well as reducing insulin resistance effectively (Li, 2018).
- Diabetes (type 2), 20 trials (n = 1,270). Supplements reduced levels of chronic low-grade inflammation, including C-reactive protein, tumor necrosis factor α, and erythrocyte sedimentation rate, in persons with diabetes, compared with placebo (Mousa, 2018).
- Diabetes (gestational), 16 trials. Six trials showed that supplements reduced the level of fasting plasma glucose and the incidence of gestational diabetes. Ten other trials found vitamin D supplements

significantly reduced the level of fasting plasma glucose and fasting insulin and improved the homeostasis model of assessment-estimated insulin resistance (Yin, 2019).

- Diabetes (type 2), 19 trials (n = 1,374). Compared with the control group, persons with type 2 diabetes given short-term vitamin D supplements had a decline in hemoglobin A1c, insulin resistance, and insulin (Hu, 2019).
- Diabetes (diabetic nephropathy), 20 trials (n = 1,464). In patients with diabetic nephropathy, vitamin D supplements significantly reduced 24-hour urine protein ($P < .00001$); urinary albumin excretion rate ($P < .0001$); high sensitivity C reactive protein ($P < .00001$), and interleukin-6 ($P < .00001$), but had no impact on other indicators (Wang, 2019).
- Diabetes, 19 trials (n = 5,214) compared pregnant women taking levels of Vitamin D above versus below the recommended amount. While children of women taking higher amounts reduced the risk of gestational diabetes, but did not reduce rates of pre-eclampsia, preterm births, and low-weight births (Palacios, 2019).
- Fall risk, seven trials (n = 7,531). Results of this study on the risk of falls after taking supplements were mixed — some found higher risk, some found lower risk (Giurgis-Blake, 2018).
- Fall risk, 30 trials (n = 10,000). No evidence existed on the ability of supplements to reduce the risk of falls, but attributed this to data quality problems, stopping short of concluding vitamin D supplementation is ineffective (Tang, 2018).
- Falls (four trials, n = 4,512). A Cochrane review showed supplementation “probably” reduced falls among the institutionalized elderly (Cameron, 2018).
- Falls and fractures, 28 trials. Supplementation was highly effective in preventing falls and fractures (Poscia, 2018).
- Falls and fractures, 81 trials (n = 53,537). Supplements had no effect on total fractures (36 studies), hip fractures (20 studies), or falls (37 studies) (Bolland, 2018).
- Fractures and falls, numerous randomized trials. Supplements reduce fractures when administered with calcium in the institutionalized elderly; reduce acute respiratory tract infections if not given as bolus monthly or annual doses; and may reduce falls in those with the lowest serum 25-hydroxyvitamin D (25OHD) levels (Ebeling, 2018).
- Fracture incidence, two trials (n = 36,727). An insignificantly lower rate of fracture incidence resulted after supplementation with vitamin D and calcium. Vitamin D alone had no significant effect on all-cause mortality (Kahwati, 2018).
- Multiple sclerosis, 12 trials (n = 933). Supplements had no apparent effect on recurrence of relapse, worsening of disability, and magnetic resonance imaging lesions, while effects on health-related quality of life and fatigue are unclear (Jaqannath, 2018).
- Outcomes, critically ill persons (six trials, n = 695). Supplementation was associated with insignificant reductions in mortality ($P = .14$). In the oral-enteral group, insignificant reductions were found in mortality ($P = .12$) and average length of hospital stay ($P = .16$) (Langlois, 2018).
- Physical activity among elderly (36 trials, n = 4,947). Supplementation of adults age 55 and older resulted in a small positive effect on physical fitness (“get up and go”), and an increased effect when the daily dose was increased to 400 – 1,000 international units (Dewansingh, 2018).
- Pregnant women, 24 trials (n = 5,405). Supplements to pregnant women were associated with a (significant) 28% reduction in small for gestational age with no risk of fetal or neonatal mortality, along with higher birth weights (Bi, 2018).

A systematic review of 84 articles assessed the association between circulating 25-hydroxyvitamin D concentration and all-cause or cause-specific mortality in generally healthy populations. The vast majority of

studies reported inverse associations between the two variables (higher vitamin D linked with lower mortality), up to a point. This association appeared to be non-linear, with progressively lower mortality with increasing 25(OH)D up to a point, beyond which there was no further decrease. There is moderate evidence of this inverse association with lung cancer mortality, and weak evidence of this inverse association of cardiovascular deaths (Heath, 2019).

Other systematic reviews and meta-analyses documented improvements in various biomarkers, and recommended that future trials of vitamin D supplementation be compared with morbidity and mortality outcomes.

A review of 175,830 persons over ager 40 documented that a significantly lower proportion of outpatient visits among African-Americans were related to Vitamin D supplements ($P < .05$). Authors suggest more focused strategies targeting blacks are needed to maintain adequate vitamin D supplements (Lee, 2016).

References

On February 10, 2020, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were Vitamin D assay testing, Vitamin D screening, and Vitamin D supplementation. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

3/2019: initial review date and clinical policy effective date: 6/2019

5/2020: Eight references were added to, and two removed from the policy.

7/2020- LCD Vitamin D Assay (A57736) billing requirements added to coverage section.