EFFECTIVE DATE: 00|00|0000
POLICY LAST UPDATED: 00|00|0000

OVERVIEW

Hypovitaminosis D may result from inadequate intake, insufficient sunlight, malabsorption, liver, kidney and genetic disease. It results in the inadequate mineralization of bone. Vitamin D; 25 hydroxy and Vitamin D; 1, 25 dihydroxy laboratory assays are used in the medical management of patients with hypovitaminosis D.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Vitamin D; 25 hydroxy laboratory testing is medically necessary as a treatment of:

- chronic kidney disease stage III or greater
- cirrhosis
- hypocalcemia
- hypercalcemia
- hypercalciuria
- hypervitaminosis D
- parathyroid disorders
- malabsorption states
- obstructive jaundice
- osteomalacia
- osteosclerosis/petrosis
- rickets
- vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment.

Vitamin D; 1, 25 dihydroxy laboratory testing is medically necessary as a treatment of:

- 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

Vitamin D; 25 hydroxy and Vitamin D; 1, 25 dihydroxy laboratory testing is not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products for all other indications, including routine or other screening, as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable laboratory testing or not medically necessary/not covered benefits/coverage.

BACKGROUND

Routine use of laboratory assays to document Vitamin D deficiency remains controversial. The current United States Preventive Health Service Task Force recommendations consider current medical evidence insufficient to assess the balance of benefits and harms of screening for Vitamin D deficiency in asymptomatic adults. However, one major meta-analysis (one with five pooled randomized controlled trials including 1237 patients) concluded that Vitamin D supplementation reduced the risk of falls among ambulatory and institutionalized older individuals with stable health by more than 20%.

A second meta-analysis pooled 12 randomized controlled trials, all using cholecalciferol supplementation therapy between 700-800 IU/d. The results demonstrated a reduction in fractures of the hip of 26%, and non-vertebral fractures of 23%, in both ambulatory and institutionalized elderly persons.

There is also controversy as to the definition of vitamin D sufficiency, although many authors accept a level of 25(OH)D of at least 30 ng/ml. Accepting this metric, 25-50% of nursing home or homebound patients, greater than 50% of hospitalized patients and 30% of women with osteoporosis may still have Vitamin D deficiency despite a growing societal awareness of that deficiency as a contributing factor.

In 2009, the Agency for Healthcare Research and Quality, through the Tufts Evidenced Based Practice Center, conducted a systematic review of the scientific literature on Vitamin D and calcium intake as related to status indicators and health outcomes. This original report summarized 165 articles and 11 systematic reviews that incorporated 200 additional primary articles. In 2013, in preparation for a project in conjunction with the NIH Office of Dietary Supplements, the report was updated to include 154 new articles. Despite this effort, disagreement exists regarding Vitamin D optimum dosing, target 25 (OH) vitamin D levels and the reported associations with health outcomes. Associations with cardiovascular disease, major cancers breast, prostate, colorectal and pancreatic were mixed and inconclusive.

A pragmatic approach for patients and their physicians was developed by the ABIM Foundation in its Choosing Wisely initiative. The patient friendly literature reassures individuals that healthy diet and exercise maintain most persons in an adequate range of Vitamin D level. It raises the possible justification of empiric vitamin D supplementation without testing for those patients without risk factors but may be thought to have inadequate sun exposure or dietary intake, while outlining those clinical risk factors that warrant baseline diagnostic assays.

It is established that 25-hydroxyvitamin D is more reflective of total body stores of vitamin D than the shorter lived, activemetabolite, 1,25 dihydroxyvitamin D. Although lack of laboratory standardization is commonly noted in most papers, it is the preferred initial assay in the evaluation of most patients with hypovitaminosis D. The 25-hydroxyvitamin D undergoes additional hydroxylation in the kidney by 1-alphahydroxylase under the influence of parathyroid hormone to produce the active metabolite. The 1,25 dihydroxyvitamin D assay is reserved for those patients where a contributory medical illness generally related to kidney disease, but also possibly related to liver, parathyroid or genetic diseases that may influence this normal metabolism.

The benefits of treatment of Vitamin D supplementation may be modest, and those benefits made difficult to quantify by general health, habits such as exercise and smoking, and other contributory factors such as ethnicity and medication treatment regimens.

However, the prevalence of osteoporosis, fall risk and skeletal fractures, and the general tolerance of the current recommended daily requirements mitigate for early supplementation in any individual uncertain regarding adequate dietary intake and sunlight exposure.

Once a patient has been shown to be Vitamin D deficient, by assay or clinical findings, the correctly chosen assay (25 hydroxyvitamin D, or 1,25 di-hydroxyvitamin D) may be used to assure correct supplementation to attain the serum levels outlined above.

CODING

BlueCHIP for Medicare and Commercial Products

The following code is considered medically necessary when filed with the one of the diagnosis codes in the attachment below:
82306 Vitamin D; 25 hydroxy, includes fraction(s), if performed
ICD-10 Codes for 82306

The following code is considered medically necessary when filed with the one of the diagnosis codes in the attachment below:
82652 Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed
ICD-10 Codes for 82652

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations

PUBLISHED

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