Subject: Vitamin D Screening and Testing

Background: Vitamin D is a prohormone that is inactive until converted (in the liver) to 25-hydroxyvitamin D (25(OH)D; 25-hydroxycholecalciferol), and then (in the kidney) to the active form of the vitamin, 1,25-dihydroxyvitamin D (1,25(OH)2D; 1,25-dihydroxycholecalciferol).

Currently, the best accepted measure for assessing vitamin D status is total serum 25(OH)D, expressed in ng/mL or nmol/L. The Institute of Medicine lists the following vitamin D value cutoffs:
- Deficiency—serum 25-hydroxyvitamin D values ≤12 ng/mL (30 nmol/L)
- Insufficiency—serum 25-hydroxyvitamin D values of 12-19 ng/mL (30-49 nmol/L)
- Sufficiency—serum 25-hydroxyvitamin D values of 20-50 ng/mL (50-125 nmol/L)

While these values are widely accepted, there is limited evidence as to what concentration of 25(OH)D is optimal for health.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers screening for Vitamin D deficiency (or excess) medically necessary for:
- Members under age 18; and
- Symptomatic or “high risk” members aged 18 to 65 years. Members are considered “high risk” due to certain medical conditions, including:
  - Biliary Cirrhosis
  - Biliary Tract Disorders
  - Blind Loop Syndrome
  - Calcium Metabolism Disorders (e.g., hyper/hypocalcemia)
  - Celiac Disease
  - Chronic Kidney Disease
  - Crohn’s Disease
  - Cystic Fibrosis
  - Dermatomyositis
  - Hyperparathyroidism or Hypoparathyroidism
  - Hypervitaminosis of Vitamin D
  - Individuals receiving hyperalimentation
  - Intestinal Malabsorption
  - Liver Cirrhosis
  - Long term use of medications known to lower vitamin D levels (e.g., anticonvulsants, glucocorticoids)
  - Lupus Erythematosus (any form)
  - Lymphoma
  - Malnutrition

HPHC Clinical Medical Policy

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HPHC policies are based on medical science, and written for the majority of people with a given condition.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.
• Myalgia
• Myopathy related to endocrine diseases
• Myositis
• Obesity
• Osteogenesis imperfecta
• Osteomalacia
• Osteopetrosis
• Osteoporosis
• Phosphorus metabolism disorders
• Post-Bariatric Surgery
• Premature osteopenia
• Pancreatic steatorrhea
• Primary or miliary tuberculosis
• Psoriasis
• Rheumatoid Arthritis
• Regional enteritis
• Renal, ureteral or urinary calculus (includes nephrolithiasis)
• Rickets
• Sarcoidosis
• Ulcerative Colitis
• Vitamin D deficiency

NOTE: Once testing demonstrates the member is vitamin D deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished. Thereafter, annual testing may be appropriate depending upon the indication and other mitigating factors.

Screening for Vitamin D deficiency (i.e., testing to determine if someone without signs or symptoms is vitamin D deficient) is not medically necessary in healthy adults as there is limited clinical evidence to support routine screening in this population.

• Harvard Pilgrim does not cover Vitamin D screening and testing in asymptomatic adults aged 18 to 65 years without conditions listed above.

Exclusions:
Harvard Pilgrim Health Care considers vitamin D screening and testing as not medically necessary for all other indications. In addition, HPHC does not cover:

• Screening and testing in asymptomatic adults under 65 without conditions listed above

Supporting Information:
Vitamin D is a hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol. An excess of vitamin D may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders. Vitamin D is called a "vitamin" because of its exogenous source, predominately from oily fish in the form of vitamin D2 and vitamin D3. It is really a hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol, which then acts throughout the body. In the skin, 7-dehydrocholesterol is converted to vitamin D3 in response to sunlight, a process that is inhibited by sunscreen with a skin protection factor (SPF) of 8 or greater. Once in the blood, vitamin D2 and D3 from diet or skin bind with vitamin D binding protein and are

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carried to the liver where they are hydroxylated to yield calcidiol. Calcidiol then is converted in the kidney to calcitriol by the action of 1α-hydroxylase (CYP27B1). The CYP27B1 in the kidney is regulated by nearly every hormone involved in calcium homeostasis, and its activity is stimulated by PTH, estrogen, calcitonin, prolactin, growth hormone, low calcium levels, and low phosphorus levels. Its activity is inhibited by calcitriol, thus providing the feedback loop that regulates calcitriol synthesis.

An excess of vitamin D is unusual, but may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders, the most infamous of which is rickets. Evaluating patients’ vitamin D levels is accomplished by measuring the level of 25-hydroxyvitamin D. Measurement of other metabolites is generally not medically necessary.

Clinical studies and reviews evaluating the effectiveness of vitamin D screening and testing in the general population fail to show the clinical utility of testing. Some studies show screening may be beneficial in populations at risk for vitamin D deficiency.

In 2015, the United States Preventive Services Task Force (USPSTF) released final guidance noting there is insufficient evidence to assess the balance of benefits and harms for screening asymptomatic individuals for vitamin D deficiency. This recommendation is consistent with the 2011 guideline from The Endocrine Society. A 2015 review by the Canadian Agency for Drugs and Technologies in Health evaluated the clinical effectiveness, cost-effectiveness and evidence-based guidelines for vitamin D testing in the general population. Studies did not find direct evidence on vitamin D screening versus no screening in clinical outcomes in vitamin D deficient individuals. There is limited evidence to support the cost-effectiveness of screening in the general population. Guidelines do not recommend routine screening for vitamin D. No evidence was found to support testing led to adherence to the recommended intake or supplementation.

The Agency for Healthcare Research and Quality report on Vitamin D and Calcium: a systematic review of health outcomes (2009) found that no qualified systematic reviews have evaluated the association between vitamin D intake or serum 25(OH)D concentrations and incidence of cardiovascular disease, body weight in adults, total cancer incidence and mortality, immune function-related outcomes, and pregnancy. The report noted fair evidence between low serum 25 (OH)D levels and rickets. However no threshold level has been determined when rickets will not occur. The association between low serum 25 (OH)D levels and the risk of falls, fractures or performance measures among postmenopausal women or elderly men is not consistent. There is also fair evidence of an association between serum 25(OH)D and bone mineral density or changes in bone mineral density at the femoral neck in postmenopausal women and elderly men. Yet, more recent studies show no significant effects of vitamin D supplementation on bone mineral density in children or adults.

**Coding:**

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<td>82306</td>
<td>Vitamin D; 25 hydroxy, includes fraction(s), if performed</td>
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<tr>
<td>82652</td>
<td>Dihydroxyvitamin D, 1, 25 dihydroxy, includes fraction(s), if performed</td>
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**List of medically necessary ICD-10 Codes**

**Billing Guidelines:**

**HPHC Clinical Medical Policy**

Vitamin D Screening and Testing

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Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:
1. Vitamin D. Institute of Medicine of the National Academies. Dietary Reference Intakes for Calcium and

<table>
<thead>
<tr>
<th>Date</th>
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<td>9/17</td>
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Approved by UMCPC: 9/13/17
Reviewed/Revised: 9/17