Introduction

Vitamin D is an important nutrient for maintaining good health. It is especially important for good bone health and calcium metabolism. Many studies and articles have been published in scientific journals and in lay magazines about the benefits of vitamin D. Despite all of this interest, there is very little data about optimal levels of vitamin D, and most published studies are of low quality. The endocrine society and public health experts strongly recommend against measuring vitamin D levels in healthy individuals. Vitamin D is found in some foods, has been added to other foods (cereals and milk), and is increased with exposure to the sun. The U.S. National Institutes of Health (NIH) has recommended vitamin D supplementation for Americans based on age (600 IU per day for ages 1 to 70 years of age). Testing for vitamin D levels is covered when a person has signs or symptoms of vitamin D deficiency or risk factors for vitamin D deficiency.

Claims for vitamin D tests are reviewed after submission based on the diagnosis listed. The diagnoses considered medically necessary and that are covered are listed in this medical policy.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
**Policy Coverage Criteria**

### Testing Condition | Medical Necessity
--- | ---
**Asymptomatic**  
Testing vitamin D levels is considered medically necessary for asymptomatic patients when:
- The patient has risk factors for vitamin D deficiency:
  - Chronic kidney disease, stage ≥3
  - Cirrhosis/chronic liver disease
  - Malabsorption states (e.g., cystic fibrosis, inflammatory bowel disease, Crohn’s disease, bariatric surgery, radiation enteritis, short bowel syndrome, pancreatitis, amyloidosis, celiac sprue)
  - Osteomalacia
  - Osteoporosis
  - Rickets
  - Hypo- or hyper-calcemia
  - Granulomatous diseases (e.g., sarcoidosis, tuberculosis, histoplasmosis, coccidiomycosis, berylliosis)
  - Vitamin D deficiency, on replacement
  - Obstructive jaundice/biliary tract disease
  - Osteogenesis imperfecta
  - Osteosclerosis/osteopetrosis
  - Chronic use of anticonvulsant medication or corticosteroids
  - Parathyroid disorders
  - Osteopenia
- The patient is institutionalized (see **Definition of Terms**)

Testing vitamin D levels is considered not medically necessary for asymptomatic patients when criteria in this policy are not met.

---

### Testing Condition | Medical Necessity
--- | ---
**Symptomatic = Vitamin D Deficiency**  
Testing vitamin D levels may be considered medically necessary when the patient presents with signs and symptoms of vitamin D deficiency.
### Testing Condition

<table>
<thead>
<tr>
<th>Symptomatic = Vitamin D Toxicity (hypervitaminosis D)</th>
<th>Testing vitamin D levels may be considered medically necessary when the patient presents with signs and symptoms of vitamin D toxicity (hypervitaminosis D).</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Signs and symptoms of vitamin D toxicity generally result from induced hypercalcemia.</td>
<td>• Signs and symptoms of vitamin D toxicity generally result from induced hypercalcemia.</td>
</tr>
<tr>
<td>o Acute intoxication can cause symptoms of confusion, anorexia, vomiting, weakness, polydipsia, and polyuria.</td>
<td>o Acute intoxication can cause symptoms of confusion, anorexia, vomiting, weakness, polydipsia, and polyuria.</td>
</tr>
<tr>
<td>o Chronic intoxication can cause bone demineralization, kidney stones, and bone pain.</td>
<td>o Chronic intoxication can cause bone demineralization, kidney stones, and bone pain.</td>
</tr>
</tbody>
</table>

### Repeat testing

A repeat test may be appropriate to determine whether supplementation has been successful in restoring normal serum levels when the initial test was for a medically necessary indication (as noted above).

More than 1 repeat test may be indicated in cases where supplementation has not been successful in restoring levels, documented by continued or recurrent signs and symptoms (as noted above), which may indicate ongoing deficiency, and/or inadequate absorption.
The following codes are specific to vitamin D testing and related to medically necessary diagnoses:

<table>
<thead>
<tr>
<th>Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0038U</td>
<td>Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative</td>
</tr>
<tr>
<td>82306</td>
<td>Vitamin D; 25 hydroxy, includes fraction(s), if performed</td>
</tr>
<tr>
<td>82652</td>
<td>Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed</td>
</tr>
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**ICD-10 Diagnosis Codes - Covered**

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A15.0</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>B38.0-B38.9</td>
<td>Coccidiomycosis</td>
</tr>
<tr>
<td>B39.0-B39.9</td>
<td>Histoplasmosis</td>
</tr>
<tr>
<td>D71</td>
<td>Functional disorders of polymorphonuclear neutrophils</td>
</tr>
<tr>
<td>D86.0 – D86.9</td>
<td>Sarcoïdosis</td>
</tr>
<tr>
<td>E20.0 – E20.9</td>
<td>Hypoparathyroidism, code range</td>
</tr>
<tr>
<td>E21.0 – E21.5</td>
<td>Hyperparathyroidism and other disorders of parathyroid gland</td>
</tr>
<tr>
<td>E41</td>
<td>Nutritional marasmus</td>
</tr>
<tr>
<td>E43</td>
<td>Unspecified severe protein-calorie malnutrition</td>
</tr>
<tr>
<td>E55.0; E55.9</td>
<td>Vitamin D deficiency codes</td>
</tr>
<tr>
<td>E67.3</td>
<td>Hypervitaminosis D</td>
</tr>
<tr>
<td>E72.0 – E72.09</td>
<td>Disorders of amino-acid transport, unspecified</td>
</tr>
<tr>
<td>E74.21</td>
<td>Galactosemia</td>
</tr>
<tr>
<td>E83.30 – E83.39</td>
<td>Disorder of phosphorus metabolism</td>
</tr>
<tr>
<td>E83.50 – E83.59</td>
<td>Disorder of calcium metabolism</td>
</tr>
<tr>
<td>E84.0-E84.9</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>E85.0-E85.9</td>
<td>Amyloidosis</td>
</tr>
<tr>
<td>E89.2</td>
<td>Postprocedural hypoparathyroidism</td>
</tr>
<tr>
<td>Code</td>
<td>Descriptor</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>J63.2</td>
<td>Berylliosis</td>
</tr>
<tr>
<td>K50.00-K50.919</td>
<td>Crohn disease</td>
</tr>
<tr>
<td>K51.00-K51.919</td>
<td>Inflammatory bowel disease</td>
</tr>
<tr>
<td>K52.0</td>
<td>Radiation enteritis</td>
</tr>
<tr>
<td>K70.0 – K77</td>
<td>Disorders of the liver, code range</td>
</tr>
<tr>
<td>K83.1 – K83.9</td>
<td>Other diseases of biliary tract</td>
</tr>
<tr>
<td>K86.0-K86.9</td>
<td>Pancreatitis</td>
</tr>
<tr>
<td>K90.0 – K90.9</td>
<td>Intestinal malabsorption, code range</td>
</tr>
<tr>
<td>K91.2</td>
<td>Postsurgical malabsorption, not elsewhere classified</td>
</tr>
<tr>
<td>L92.0 – L92.9</td>
<td>Granulomatous disorders of skin and subcutaneous tissue</td>
</tr>
<tr>
<td>M80.00 – M81.8</td>
<td>Osteoporosis, code range</td>
</tr>
<tr>
<td>M83.0 – M83.9</td>
<td>Osteomalacia, code range</td>
</tr>
<tr>
<td>M85.80 – M85.9</td>
<td>Other specified disorders of bone density and structure</td>
</tr>
<tr>
<td>N18.1 – N18.9</td>
<td>Chronic kidney disease (CKD), code range</td>
</tr>
<tr>
<td>N20.0 – N20.9</td>
<td>Calculus of kidney and ureter</td>
</tr>
<tr>
<td>N22</td>
<td>Calculus of urinary tract in diseases classified elsewhere</td>
</tr>
<tr>
<td>N25.81</td>
<td>Secondary hyperparathyroidism of renal origin</td>
</tr>
<tr>
<td>P71.0 – P71.9</td>
<td>Transitory neonatal disorders of calcium and magnesium metabolism</td>
</tr>
<tr>
<td>Q78.0</td>
<td>Osteogenesis imperfecta</td>
</tr>
<tr>
<td>Q78.2</td>
<td>Osteopetrosis</td>
</tr>
<tr>
<td>R17</td>
<td>Unspecified jaundice</td>
</tr>
<tr>
<td>Z79.52</td>
<td>Long term (current) use of systemic steroids</td>
</tr>
<tr>
<td>Z79.899</td>
<td>Other long term (current) drug therapy</td>
</tr>
<tr>
<td>Z98.84</td>
<td>Bariatric surgery</td>
</tr>
</tbody>
</table>

**Related Information**
Definition of Terms

**Institutionalized**: For the purposes of this policy, “institutionalized” refers to patients who live in long-term care facilities where some degree of medical care is provided. Examples include long-term hospital stays, nursing homes, assisted living facilities, and similar environments.

Benefit Application

Consistent with federal mandates, vitamin D supplements are covered as preventive care for individuals age 65 and older (without cost sharing) when the member’s contract is subject to those mandates. A written prescription is needed for coverage.

The USPSTF recommends exercise or physical therapy and vitamin D supplementation to prevent falls in community-dwelling adults aged 65 years or older who are at increased risk for falls. (Grade B recommendation)

**Note**: The USPSTF does not recommend routine testing of vitamin D levels as a preventive strategy. (See Practice Guidelines and Position Statements).

Evidence Review

Description

Vitamin D, also known as calciferol, is a fat-soluble vitamin that has a variety of physiologic effects, most prominently in calcium homeostasis and bone metabolism. In addition to the role it plays in bone metabolism, other physiologic effects include inhibition of smooth muscle proliferation, regulation of the renin-angiotensin system, a decrease in coagulation, and a decrease in inflammatory markers.¹
Background

Vitamin D Levels

Vitamin D deficiency is best assessed by measuring serum levels of 25-hydroxyvitamin D. However, there is no consensus on the minimum vitamin D level or on the optimal serum level for overall health. A 2011 Institute of Medicine (IOM) report concluded that a serum level of 20 ng/mL is sufficient for most healthy adults. Some experts, such as the National Osteoporosis Foundation and the American Geriatrics Society, recommend a higher level (30 ng/mL).

Vitamin D deficiency, as defined by suboptimal serum levels, is common in the United States. In the National Health and Nutrition Examination Survey covering the period of 2000-2004, 30% of individuals over the age of 12 had 25-hydroxyvitamin D levels less than 20 ng/mL. Vitamin D deficiency occurs most commonly as a result of inadequate dietary intake coupled with inadequate sun exposure. Evidence from the National Nutrition Monitoring System and the National Health and Nutrition Examination Survey has indicated that the average dietary consumption is below recommended levels of intake. Yetley (2008) estimated that average daily intake for U.S. adults ranged from 228 to 335 IU/d, depending on gender and ethnicity. This level is below the average daily requirement, estimated by IOM (400 IU/d for healthy adults) and well below IOM’s required daily allowance (estimated to be 600 IU for nonelderly adults and 800 IU for elderly adults).

Vitamin D deficiency may occur less commonly for other reasons. Kidney or liver disease can cause deficiency as a result of impaired conversion of inactive vitamin D to its active products. In rare situations, there is vitamin D resistance at the tissue level, which causes a functional vitamin D deficiency despite “adequate” serum levels.

The safe upper level for serum vitamin D is also not standardized. The IOM report concluded that there is potential harm associated with levels greater than 50 ng/mL and recommended that serum levels be maintained in the 20- to 40-ng/mL range. However, conclusions on this point have differed. A 2011 Agency for Healthcare Research and Quality (AHRQ) systematic review on vitamin D and bone health concluded that “There is little evidence from existing trials that vitamin D above current reference intakes is harmful.” The Women’s Health Initiative concluded that hypercalcemia and hypercalciuria in patients receiving calcium and vitamin D were not associated with adverse clinical events. The Women’s Health Initiative did find a small increase in kidney stones for women aged 50 to 79 years who received vitamin D and calcium.

Associations of vitamin D levels with various aspects of health have been noted over the last several decades, and these findings have led to the question of whether supplementation improves health outcomes. For example, a relation between vitamin D levels and overall...
mortality has been reported in most observational studies examining this association.\textsuperscript{11,12}
Mortality is lowest at vitamin D levels in the 25- to 40-nmol/L range. At lower levels of serum vitamin D, mortality increases steeply, and overall mortality in the lowest quintile was more than 3 times that in the middle quintiles. Theodoratou et al (2014) identified 107 systematic reviews of observational studies examining the association between vitamin D levels and more than 100 different outcomes.\textsuperscript{13}

**Vitamin D Replacement**

The IOM has recommended reference values for intake of vitamin D and serum levels, based on available literature and expert consensus.\textsuperscript{2} Recommended daily allowances are 600 IU/d for individuals between 1 and 70 years of age and 800 IU/d for individuals older than 70 years.

Estimates of vitamin D requirements are complicated by the many other factors that affect serum levels. Sun exposure is the most prominent factor that affects serum levels, and this is because individuals can meet their vitamin D needs entirely through adequate sun exposure. Other factors such as age, skin pigmentation, obesity, physical activity, and nutritional status also affect vitamin D levels and can result in variable dietary intake requirements to maintain adequate serum levels.

Excessive intake of vitamin D can be toxic. Toxic effects are usually due to hypercalcemia and may include confusion, weakness, polyuria, polydipsia, anorexia, and vomiting. In addition, high levels of vitamin D may promote calcium deposition and has the potential to exacerbate conditions such as calcium kidney stones and atherosclerotic vascular disease.

The IOM defined 3 parameters of nutritional needs for vitamin D, on the assumption of minimal sun exposure. These parameters were the estimated average requirement, defined as the minimum intake required to maintain adequate levels; the recommended daily allowance, defined as the optimal dose for replacement therapy; and the upper-level intake, defined as the maximum daily dose to avoid toxicity. These recommendations are summarized in Table 1.
Table 1. Institute of Medicine Recommendations for Vitamin D Dietary Intake

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Estimated Average Requirement, IU/d</th>
<th>Recommended Daily Allowance, IU/d</th>
<th>Upper Limit Intake, IU/d</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3 years old</td>
<td>400</td>
<td>600</td>
<td>2500</td>
</tr>
<tr>
<td>4-8 years old</td>
<td>400</td>
<td>600</td>
<td>3000</td>
</tr>
<tr>
<td>9-70 years old</td>
<td>400</td>
<td>600</td>
<td>4000</td>
</tr>
<tr>
<td>&gt;70 years old</td>
<td>400</td>
<td>800</td>
<td>4000</td>
</tr>
</tbody>
</table>

Adapted from Institute of Medicine (2011).²

**Analytic Framework**

Figure 1 summarizes the approach to this policy. The diagram demonstrates the framework for how vitamin D testing affects outcomes. Using this framework, the main question is whether testing individuals for vitamin D deficiency improves outcomes.

**Figure 1. Analytic Framework**
Based on this analytic framework, the most relevant studies for showing clinical utility of vitamin D testing are trials that directly compare care including testing vitamin D levels against care without testing vitamin D levels. Should vitamin D screening in nonsymptomatic, general population be shown to be effective, guidelines would then be needed to establish criteria for screening, screening intervals, and appropriate follow-up for positive tests. Indirect evidence of the utility of vitamin D testing would include evidence of the effectiveness of supplementation from trials testing supplementation to no supplementation in patients who are vitamin D deficient. Many of the existing randomized controlled trials (RCTs), including the largest trial (Women’s Health Initiative), did not test vitamin D levels prior to treatment. Rather, they treated all patients enrolled regardless of vitamin D levels. Results of some of the main systematic reviews that take this approach will be reviewed, but this evidence is indirect and must be extrapolated from treatment of all patients to treatment of patients who are vitamin D deficient.

Summary of Evidence

For individuals who are asymptomatic without conditions or risk factors for which vitamin D treatment is recommended who receive testing of vitamin D levels, the evidence includes no randomized controlled trials (RCTs) of clinical utility (ie, evidence that patient care including testing vitamin D levels vs care without testing vitamin D levels improves outcomes). Relevant outcomes are overall survival, test validity, symptoms, morbid events, and treatment-related morbidity. Indirect evidence of the potential utility of testing includes many RCTs and systematic reviews of vitamin D supplementation. There is a lack of standardized vitamin D testing strategies and cutoffs for vitamin D deficiency are not standardized or evidence-based. In addition, despite the large quantity of evidence, considerable uncertainty remains about the beneficial health effects of vitamin D supplementation. Many RCTs have included participants who were not vitamin D deficient at baseline and did not stratify results by baseline 25 hydroxyvitamin D level. Nonwhite race/ethnic groups are underrepresented in RCTs but have increased risk of vitamin D deficiency. For skeletal health, there may be a small effect of vitamin D supplementation on falls, but there does not appear to be an impact on reducing fractures for the general population. The effect on fracture reduction may be significant in elderly women, and with higher doses of vitamin D. For patients with asthma, there may be a reduction in severe exacerbations with vitamin D supplementation, but there does not appear to be an effect on other asthma outcomes. For overall mortality, there is also no benefit for the general population. RCTs evaluating extraskeletal, cancer, cardiovascular, and multiple sclerosis outcomes have not reported a statistically significant benefit for vitamin D supplementation. Although vitamin D toxicity and adverse events appear to be rare, few data on risks have been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.
Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01169259</td>
<td>Vitamin D and Omega-3 Trial (VITAL)</td>
<td>25,871</td>
<td>Nov 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT01490502</td>
<td>A Randomized Controlled Trial of Vitamin D Supplementation in Multiple Sclerosis (VIDAMS)</td>
<td>172</td>
<td>Mar 2019</td>
</tr>
<tr>
<td>NCT00920621</td>
<td>Randomized Trial: Maternal Vitamin D Supplementation to Prevent Childhood Asthma (VDAART)</td>
<td>876</td>
<td>Jun 2019</td>
</tr>
<tr>
<td>NCT02166333</td>
<td>Vitamin D Supplements to Prevent Falls in Older Adults: A Dose-Response Trial (STURDY)</td>
<td>1200</td>
<td>Mar 2020</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02750293</td>
<td>The Effect of Vitamin D Supplementation on Cardiovascular Risk Factors in Subjects with Low Serum 25-hydroxyvitamin D Levels (D-COR)</td>
<td>411</td>
<td>Sep 2017 (completed)</td>
</tr>
<tr>
<td>NCT02424552</td>
<td>EVITA Trial: Effect of Vitamin D as add-on Therapy for Vitamin D Insufficient Patients with Severe Asthma: a Randomized, Double-blind, Placebo-controlled Trial</td>
<td>54</td>
<td>Mar 2017 (terminated)</td>
</tr>
<tr>
<td>NCT01153568</td>
<td>Vitamin D and Osteoporosis Prevention in Elderly African American Women: A 4-year Randomized, Double-blind, Placebo-controlled Study to Investigate the Effect of Vitamin D Status in Elderly African American Women</td>
<td>260</td>
<td>Oct 2016 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
Practice Guidelines and Position Statements

Endocrine Society

The Endocrine Society (2011) published clinical practice guidelines on the evaluation, treatment and prevention of vitamin D deficiency. The following recommendations were made regarding testing vitamin D levels:

- 25-hydroxyvitamin D serum level testing is recommended “to evaluate vitamin D status only in patients who are at risk of deficiency.” The guideline did not recommend screening of individuals not at risk of vitamin D deficiency.
- 1,25-dihydroxyvitamin D testing is not recommended to evaluate vitamin D status. However, the guideline did recommend monitoring calcitriol levels in certain conditions.

American College of Obstetrics and Gynecology

The American College of Obstetrics and Gynecology issued a committee opinion (2011, reaffirmed 2017) on the testing of vitamin D levels and vitamin D supplementation in pregnant women. The following recommendation was made concerning testing vitamin D levels:

- “At this time there is insufficient evidence to support a recommendation for screening all pregnant women for vitamin D deficiency. For pregnant women thought to be at increased risk of vitamin D deficiency, maternal serum 25-hydroxyvitamin D levels can be considered and should be interpreted in the context of the individual clinical circumstance. When vitamin D deficiency is identified during pregnancy, most experts agree that 1,000-2,000 international units per day of vitamin D is safe.”

American Academy of Family Physicians

The American Academy of Family Physicians (2014) concluded that the current evidence was insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency.

In 2018, key recommendations for practice concluded that there was insufficient information to recommend screening the general population for vitamin D deficiency and that treating asymptomatic individuals with identified deficiency has not been shown to improve health.
U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force published a recommendation in 2014 and associated guidelines in 2015 on vitamin D screening. The Task Force concluded that the current evidence was insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic individuals (grade I [insufficient evidence]). An update of the 2014 recommendation is currently in progress.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The U.S. Food and Drug Administration has cleared a number of immunoassay in vitro diagnostic devices for the quantitative measurement of total 25-hydroxyvitamin D through the 510(k) process.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Lab tests for vitamin D are available under the auspices of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

References


13. Theodoratou E, Tzoulaki I, Zgaga L, et al. Vitamin D and multiple health outcomes: umbrella review of systematic reviews and meta-analyses of observational studies and randomised trials. BMJ. Apr 01 2014;348:g2035. PMID 24690624


20. Sanders KM, Stuart AL, Williamson EJ, et al. Annual high-dose oral vitamin D and falls and fractures in older women: a randomized controlled trial. JAMA. May 12 2010;303(18):1815-1822. PMID 20460620


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>01/12/16</td>
<td>New policy, add to Pathology/Laboratory testing section. Replaces 2.04.507; testing of vitamin D serum levels may be considered medically necessary when criteria are met.</td>
</tr>
<tr>
<td>Date</td>
<td>Event Description</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>02/04/16</td>
<td>Coding update. Added ICD10 diagnosis code E74.21.</td>
</tr>
<tr>
<td>02/19/16</td>
<td>Coding update. Minor clarifications to osteomalacia code range and correction to code K70.0.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>Interim Update, approved July 12, 2016. Policy published in new template with introduction added. Clarified institutional information. Intent remains the same.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Annual review, approved February 14, 2017. Policy updated literature review through October 10, 2016; references 14-16, 29, 31-36, 43, and 45 added. Policy statements unchanged.</td>
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<td>08/15/17</td>
<td>Minor formatting updates.</td>
</tr>
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<td>03/01/18</td>
<td>Annual Review, approved February 6, 2018. Policy updated with literature review through October 2017; references 32-34 and 36-48 added; notes 15 and 62 updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>10/01/18</td>
<td>Coding update. Updated diagnosis code range for “other diseases of biliary tract” from K83.0 – 8.39 to K83.1 – K83.9.</td>
</tr>
<tr>
<td>12/01/18</td>
<td>Interim Review, approved November 6, 2018. Clarified policy statements regarding repeat testing. Added diagnosis code range L92.0 – L92.9.</td>
</tr>
<tr>
<td>02/01/19</td>
<td>Annual Review, approved January 22, 2019. Policy updated, literature review through October 2018; reference 58 added; reference 57, 59, and 61 updated. Policy statements unchanged. Coding update, added diagnosis ranges A15.0, B38.0-B38.9, B39.0-B39.9, E84.0-E84.9, E85.0-E85.9, J63.2, K50.00-K50.919, K51.00-K51.919, K52.0, K86.0-K86.9, and Z98.84. Added code 0038U.</td>
</tr>
</tbody>
</table>

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  - Information written in other languages

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Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S9FF, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

يحتوي هذا الإشعار على معلومات مهمة، قد تحتوي هذه المعلومات على معلومات مهمة في حالات خاصة، يوجد في هذه الإشعار معلومات مهمة، قد تحتوي هذه المعلومات على معلومات مهمة في حالات خاصة.

Premera Blue Cross
800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):


Italiano (Italian):

Polskie (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Vocês tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Тагальский (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อสำคัญ ประกาศนี้มีข้อสำคัญที่เกี่ยวข้องกับการชำระเงินค่าส่งเสริมการสุขภาพของคุณ Premera Blue Cross และสามารถใช้ในการเก็บรักษาข้อมูลที่เกี่ยวข้องของคุณได้ ด้วยคุณอาจต้องตรวจสอบข้อมูลในประกาศนี้ตามที่ระบุไว้ในหน้าที่ของคุณ และไม่ต้องชำระค่าใช้จ่ายใด ๆ เพื่อทราบข้อมูลที่ระบุไว้ในประกาศนี้ หากคุณต้องการบริการที่เกี่ยวข้องกับการชำระเงินค่าส่งเสริมการสุขภาพของคุณ โปรดติดต่อ โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):