Medicare Local Coverage Determination Policy

Vitamin D, 25 OH
Assays for Vitamins and Metabolic Function
CPT: 82306

CMS Policy for Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas
Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Coverage Indications, Limitations, and/or Medical Necessity
Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

Medicare generally considers vitamin assay panels (more than one vitamin assay) a screening procedure and therefore, non-covered. Similarly, assays for micronutrient testing for nutritional deficiencies that include multiple tests for vitamins, minerals, antioxidants and various metabolic functions are never necessary. Medicare reimburses for covered clinical laboratory studies that are reasonable and necessary for the diagnosis or treatment of an illness. Many vitamin deficiency problems can be determined from a comprehensive history and physical examination. Any diagnostic evaluation should be targeted at the specific vitamin deficiency suspected and not a general screen. Most vitamin deficiencies are nutritional in origin and may be corrected with supplemented vitamins.

Most vitamin deficiencies are suggested by specific clinical findings. The presence of those specific clinical findings may prompt laboratory testing for evidence of a deficiency of that specific vitamin. Certain other clinical states may also lead to vitamin deficiencies (malabsorption syndromes, etc.).

Limitations
For Medicare beneficiaries, screening tests are governed by statute. Vitamin or micronutrient testing may not be used for routine screening. Once a beneficiary has been shown to be vitamin 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.

The following tests are considered non-covered services:

• Assays of selenium (84255)
• Functional intracellular analysis (84999)
• Total antioxidant function (84999)
• Assays of vitamin testing, not otherwise classified* (84591)

*Note: Assays of vitamin testing, not otherwise classified (84591) is not covered since all clinically relevant vitamins have specific assays.
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CMS Policy for Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas (continued)

Notice: This LCD imposes the following limitations to the tests addressed in this LCD. These limitations will support automated denials as follows:

- Noncovered as described above (84255, 84999, 84591)
- Diagnosis to procedure limitations only (86352)
- Frequency limitations* only (82180, 84252, 84425, 84446, 84590, 84597)
- Diagnosis to procedure and frequency limitations* (82306, 82652, 82379, 82607, 82746, 83090, 84207, 85385, 83698)

*Note: Please refer to the “Utilization Guidelines” section for an outline of the frequency limitations. Frequency limitations do not establish medical necessity for all testing but does reflect how the medical community uses the tests. Patterns of billing will be monitored for potential utilization of these tests for screening purposes, either by use of a single test or multiple tests together.

Notice: This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
  - Furnished in a setting appropriate to the patient's medical needs and condition.
  - Ordered and furnished by qualified personnel.
  - One that meets, but does not exceed, the patient's medical needs.
  - At least as beneficial as an existing and available medically appropriate alternative

Visit QuestDiagnostics.com/MLCP to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medially supportive codes, please refer to the CMS website reference www.cms.gov
CMS Policy for Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas (continued)

Utilization Guidelines
In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Medicare recognizes certain tests may exceed the stated frequencies. Should a denial occur, additional documentation can be submitted to support medical necessity. Payment for additional tests may be allowed in selected circumstances when, upon medical review, the medical necessity of additional services is demonstrated.

Following a review of utilization data at various percentiles of units billed per year, the following frequency limitations are established and are as follows:

- 82180 1 time per year
- 82306 up to 3 times per year
- 82379 up to 3 times per year
- 82607 up to 3 times per year
- 82652 up to 2 times per year
- 82746 up to 3 times per year
- 83090 1 time per year
- 83698 1 time per year
- 84207 1 time per year
- 84252 1 time per year
- 84425 1 time per year
- 84446 1 time per year
- 84590 1 time per year
- 84597 1 time per year
- 85385 up to 3 times per year
- 86352 frequencies not determined

Notice: This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximums, each patient's condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient's medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.
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The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare’s limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Note—Bolded diagnoses below have the highest utilization

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E21.0</td>
<td>Primary hyperparathyroidism</td>
</tr>
<tr>
<td>E21.1</td>
<td>Secondary hyperparathyroidism, not elsewhere classified</td>
</tr>
<tr>
<td>E21.3</td>
<td>Hyperparathyroidism, unspecified</td>
</tr>
<tr>
<td>E55.9</td>
<td>Vitamin D deficiency, unspecified</td>
</tr>
<tr>
<td>E83.30</td>
<td>Disorder of phosphorus metabolism, unspecified</td>
</tr>
<tr>
<td>E83.32</td>
<td>Hereditary vitamin D-dependent rickets (type 1) (type 2)</td>
</tr>
<tr>
<td>E83.51</td>
<td>Hypocalcemia</td>
</tr>
<tr>
<td>E83.52</td>
<td>Hypercalcemia</td>
</tr>
<tr>
<td>K90.9</td>
<td>Intestinal malabsorption, unspecified</td>
</tr>
<tr>
<td>M79.1</td>
<td>Myalgia</td>
</tr>
<tr>
<td>M79.7</td>
<td>Fibromyalgia</td>
</tr>
<tr>
<td>M81.0</td>
<td>Age-related osteoporosis without current pathological fracture</td>
</tr>
<tr>
<td>M81.8</td>
<td>Other osteoporosis without current pathological fracture</td>
</tr>
<tr>
<td>M85.9</td>
<td>Disorder of bone density and structure, unspecified</td>
</tr>
<tr>
<td>M89.9</td>
<td>Disorder of bone, unspecified</td>
</tr>
<tr>
<td>N18.3</td>
<td>Chronic kidney disease, stage 3 (moderate)</td>
</tr>
<tr>
<td>N18.4</td>
<td>Chronic kidney disease, stage 4 (severe)</td>
</tr>
<tr>
<td>N18.6</td>
<td>End stage renal disease</td>
</tr>
<tr>
<td>N25.81</td>
<td>Secondary hyperparathyroidism of renal origin</td>
</tr>
<tr>
<td>Z798.99</td>
<td>Other long term (current) drug therapy</td>
</tr>
</tbody>
</table>

There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

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