Medical Policy
**Serum Holotranscobalamin as a Marker of Vitamin B12 - Cobalamin Status**

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**Policy Number:** 561
BCBSA Reference Number: 2.04.39

**Related Policies**
None

**Policy**

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity**

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**
Measurement of holo-transcobalamin in the diagnosis and management of Vitamin B12 deficiency is **INVESTIGATIONAL.**

**Prior Authorization Information**

**Commercial Members: Managed Care (HMO and POS)**
This is **NOT** a covered service.

**Commercial Members: PPO, and Indemnity**
This is **NOT** a covered service.

**Medicare Members: HMO BlueSM**
This is **NOT** a covered service.

**Medicare Members: PPO BlueSM**
This is **NOT** a covered service.

**CPT Codes / HCPCS Codes / ICD-9 Codes**
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

### CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>0103T</td>
<td>Holo-transcobalamin, quantitative</td>
</tr>
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</table>

### ICD-9 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>266.2</td>
<td>B-complex deficiency</td>
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### ICD-10-CM Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM diagnosis codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>D51.0</td>
<td>Vitamin B12 deficiency anemia due to intrinsic factor deficiency</td>
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<tr>
<td>D51.1</td>
<td>Vitamin B12 deficiency anemia due to selective vitamin B12 malabsorption with proteinuria</td>
</tr>
<tr>
<td>D51.3</td>
<td>Other dietary vitamin B12 deficiency anemia</td>
</tr>
<tr>
<td>D51.8</td>
<td>Other vitamin B12 deficiency anemia</td>
</tr>
<tr>
<td>D51.9</td>
<td>Vitamin B12 deficiency anemia, unspecified</td>
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### Description

Vitamin B12 (cobalamin) is an essential vitamin that is required for DNA synthesis affecting red blood cell formation and methionine synthesis affecting neurologic functioning. Cobalamin deficiency can result from nutritional deficiencies or malabsorption. Clinical signs and symptoms of cobalamin deficiency include megaloblastic anemia, paresthesias and neuropathy, and psychiatric symptoms, such as irritability, dementia, depression, and psychosis. Hematologic abnormalities promptly disappear after treatment, while neurologic disorders may become permanent if treatment is delayed.

The diagnosis of cobalamin deficiency has traditionally been based on low levels of total serum cobalamin, in conjunction with clinical evidence of disease. However, this laboratory test has been found to be poorly sensitive and specific. Therefore, attention has turned to measuring metabolites of cobalamin as a surrogate marker. Holotranscobalamin (holo-TC) is a transcobalamin-vitamin B12 complex which has been investigated as a diagnostic test for vitamin B12 deficiency in symptomatic and at-risk populations, as well as an assay for monitoring response to therapy. Serum levels of holo-TC can be measured using a radioimmunoassay or enzyme immunoassay.

Examples of testing devices include HoloTC RIA and Axis-Shield HoloTC Assay from Axis-Shield. All devices used in the measurement of holotranscobalamin in the diagnosis and management of Vitamin B12 deficiency are considered investigational regardless of the commercial name, FDA status or the manufacturer.

### Summary

There are inadequate data to establish holotranscobalamin testing as an alternative to either total serum cobalamin, or levels of methylmalonic acid or homocysteine in the diagnosis of vitamin B12 deficiency. While technically feasible, and likely to have diagnostic performance that approaches that of currently utilized tests, no evidence of clinical utility has been demonstrated. Since evidence of the clinical utility of the test is currently lacking, the test remains investigational.
Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>12/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
<tr>
<td>11/2011-</td>
<td>Medical policy ICD 10 remediation: Formatting, editing and coding updates. 4/2012</td>
</tr>
<tr>
<td></td>
<td>No changes to policy statements.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References


