

# Medical Coverage Policies

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## Serum Holotranscobalamin as a Marker of Vitamin B12 (i.e., Cobalamin) Status

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| <b>EFFECTIVE DATE</b> | 03/03/2009 | <b>LAST UPDATED</b> | 03/02/2010 |
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### Description:

Vitamin B12 (i.e., cobalamin) is an essential vitamin that is required for one-carbon metabolism and cell division. Cobalamin deficiency can result from nutritional/dietary deficiencies (most common among the vegetarian and the elderly), malabsorption of vitamin B12 (seen after gastrectomy or associated with autoantibodies [i.e., pernicious anemia]), or other relatively uncommon gastrointestinal conditions (i.e., Whipple's disease, Zollinger Ellison syndrome, etc.). Clinical signs and symptoms of cobalamin deficiency include megaloblastic anemia, paresthesias and neuropathy, and psychiatric symptoms such as irritability, dementia, depression, or psychosis. While the hematologic abnormalities disappear promptly after treatment, neurologic disorders may become permanent if left untreated.

There has been interest in the direct measurement of the subset of biologically active cobalamin. Cobalamin in serum is bound to 2 proteins, transcobalamin and haptocorrin. Transcobalamin-cobalamin complex (called holo-transcobalamin, or holo-TC) functions to transport cobalamin from its site of absorption in the ileum to specific receptors throughout the body. Less than 25% of the total serum cobalamin exists as holo-TC, but this is considered the clinically relevant biologically active form. Serum levels of holo-TC can be measured using a radioimmunoassay. The Axis-Shield HoloTC RIA is an example of a radioimmunoassay for holo-TC that was cleared for marketing by the U.S. Food and Drug Administration (FDA) in 2004 with the following labeled indication for use:

"The Axis-Shield HoloTC RIA is an in vitro diagnostic assay for quantitative measurement of the fraction of cobalamin (vitamin B12) bound to the carrier protein transcobalamin in the human serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of vitamin B12 deficiency."

There are inadequate data to establish holo-TC testing as an alternative to either total serum cobalamin or levels of MMA or homocysteine.

### Medical Criteria:

Not applicable.

### Policy:

Measurement of holotranscobalamin is considered not medically necessary in the diagnosis and management of Vitamin B12 deficiency because there is insufficient evidence in the published medical literature to demonstrate its efficacy.

### Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage, subscriber agreement, or Rlte Care contract for the applicable "Services Not Medically Necessary."

### Coding:

The following CPT category III code is considered not medically necessary:

**0103T**

### Also Known As:

Axis-Shield, Holo-TC  
Holo-TC, Vitamin B12 Deficienc  
Holo transcobalamin  
Vitamin B12 Deficiency, Transcobalamin

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**References:**

Blue Cross Association, Blue Web, Medical Policy Reference Manual 2.04.39 Serum Holo-Transcobalamin as a Marker of Vitamin B12 (i.e., Cobalamin) Status. Retrieved 1/23/09 from [http://blueweb.bcbs.com/global\\_assets/special\\_content/medical\\_policy/policymanual/policy.html?pnum=20439](http://blueweb.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=20439)

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