KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Anti-Malignin Antibody Test for Cancer Detection

- Four Kallikrein Markers
- Kallikrein Panel

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “Anti-Malignin Antibody Test for Cancer Detection,” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A tumor marker is a biological substance or irregularity that indicates the presence of a tumor. These markers are used in clinical practice for diagnosis, anatomical localization, and monitoring a variety of malignancies. The more specific the marker is for the tumor histotype, the more useful it is as a marker; and the earlier the marker is detected, the earlier a possible diagnosis can be made.

Serum measurement of the majority of markers did not prove to be very reliable for screening purposes or for the early detection of cancer. These tests measure the tumor-associated antigens that appear on the surface of the cell membrane following the malignant transformation. Serum tests become more reliable as the tumor load increases and more antigens are released into the bloodstream. The tumor-associated antigens are recognized by the immune system of the host that in turn produces specific antibodies. Theoretically, antibodies are more readily detected than antigen early in the disease *(Abrams 1994, Botti 1997)*.

Malignin, a 10 kDa polypeptide, has been found by some researchers to be elevated in most patients with a wide range of malignancies regardless of site or cell type. Two researchers in Boston (Drs. S. Bogoch and E. Bogoch) reported that they discovered anti-malignin antibodies (AMAs) in the serum of patients with cancer. The antibodies were described as IgM produced by the patient against the oncoprotein malignin. Bogoch reported that

Back to Top

antibody concentration is reduced or eliminated in terminal cancer or in the presence of a large tumor mass present for 3 or more years *(Bogoch 1982)*. The human antimalignin antibody serum (AMAS) test was developed to measure the antibody concentrations against malignin. It is claimed that the test may potentially be useful in the early detection of cancer as well as managing and monitoring the progress of the cancer.

The AMAS test is based on the specific immunoadsorption of the antibody from serum to Target® reagent. The Target® reagent consists of malignin bound covalently to bromoacetylcellulose *(Abrams 1994, Botti, 1997)*. After washing with cold saline, the serum sample is added to the reagent, the AMA eluted with acetic acid, and the results are quantified. The test should be performed within 24 hours of serum collection to reduce the false-positive results that increase with the use of frozen stored serum.

The AMAS test does not replace the conventional screening and diagnostic procedures but, as reported, it may be performed with other routine procedures and in relation to risk factors, history, clinical signs and symptoms, and other factors.

Medical Technology Assessment Committee (MTAC)

Anti-Malignin Antibody Test

10/03/2005: MTAC Review

Evidence Conclusion: The two studies reviewed (Bogoch 1982, and Thornwaite 2000) compared the serum antimalignin antibody levels in patients with diagnosed cancer to those of healthy controls. Thornwaite studied it for patients with breast cancer, and Bogoch for patients with carcinomas in different organs. Both studies had their limitations. The test was performed on patients already diagnosed with or without cancer, there is no indication that the antibody cutoff-level used was validated, the authors did not discuss how they selected the study participants, and the patients with terminal cancers were excluded from the analysis.
Articles: The search yielded 16 articles. Three empirical studies were identified: Bogoch 1982, studied the relation of antimalignin antibody and malignin to survival, Bogoch 1991, published in an abstract form, and Thornthwaite (2000) compared AMAS testing for breast cancer with histopathology and other cancer markers. Another article identified by the search (Abrams 1994), compiled the results of the test performed in 42 practices in 11 states that performed AMAS test for the detection and monitoring of cancer.
The following articles were critically appraised: Thornthwaite JT. Anti-malignin antibody in serum and other tumor marker determinations in breast cancer. Cancer Letters. 2000; 148:39–48. See Evidence Table.

The use of Anti-Malignin Antibody does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

******To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/03/2005	10/03/2005[MDCRPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	10/25/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision	Description

Back to Top

History	
10/25/2019	Adopted Kaiser Permanente policy for MA members

Back to Top