



Corporate Medical Policy

Analysis of Proteomic Patterns in Serum to Identify Ovarian Cancer

File Name: analysis_of_proteomic_patterns_in_serum_to_identify_ovarian_cancer
Policy Number: MED1041
Origination: 08/2004
Last Review: 11/2008
Next Review: 11/2010

Description of Procedure or Service

While research into the genetic basis of cancer has been an intense research focus, genetic [mutations](#) do not reflect the complicated interactions between individual cells, tissue, and organs. Proteins are the functional units of cells and represent the end product of the interactions among the underlying genes. Therefore, recently there has been increasing research interest in the pattern of proteins associated with malignancies. This field may be referred to as proteomics (to distinguish it from genomics), defined as the study of all protein forms expressed within an organism as a function of time, age, state, and external factors. Within cancer research, one research application has been the identification of a pattern of proteins detected in a given fluid, such as body fluid or serum, that are associated with an underlying cancer. Essentially, the identification of patterns of proteins in the serum could function as serum tumor marker, similar in concept to the more familiar prostate specific antigen (PSA) or CA-125, which are used in the detection and monitoring of prostate and ovarian cancer, respectively.

At present, no effective screening technique exists for ovarian cancer. While CA-125 and transvaginal ultrasound have been proposed, particularly in patients at high genetic risk for ovarian cancer, to date these techniques have not resulted in a decrease in morbidity, primarily due to the disease stage at presentation and the lack of curative therapies. Use of proteomic patterns in serum to identify ovarian cancer is one of the first commercially available clinical applications of proteomics and is the result of a joint project initiated between the National Cancer Institute and the U.S. Food and Drug Administration (FDA) to develop proteomics for early detection and cancer screening. The OvaCheck (Correlogic Systems) is based on proteomic patterns detected in the serum, which are further analyzed with the use of a mass spectrometer to profile a population of proteins based on their size and electrical charge. This type of analysis contains thousands of data points, which undergo further sophisticated computer analysis using artificial intelligence based algorithms which is a logical step by step process to identify a pattern that is consistent with ovarian cancer. While the OvaCheck test is the first commercially available cancer screening test using proteomics, there are also interest in developing proteomic screening tests for prostate cancer, breast cancer, and gastrointestinal malignancies.

The OvaCheck will be offered exclusively at reference laboratories but currently it is being reviewed to determine the FDA regulatory status.

Policy

BCBSNC will not provide coverage for analysis of proteomic patterns in serum for screening and detection of ovarian cancer. It is considered investigational. BCBSNC does not provide benefits for investigational services.

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Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When Analysis of Proteomic Patterns in Serum to Identify Ovarian Cancer is covered

Not applicable.

When Analysis of Proteomic Patterns in Serum to Identify Ovarian Cancer is not covered

Analysis of proteomic patterns in serum to identify ovarian cancer is not covered. It is considered investigational. BCBSNC does not cover investigational services.

Policy Guidelines

A recent literature search found no large prospective clinical trials that demonstrated the impact on clinical outcomes for proteomic testing in the screening or detection of cancer. The U.S. Food and Drug Administration (FDA) has requested additional data to review as part of the marketing approval process.

In February 2004, the Society of Gynecologic Oncologist released the following statement: "The Society of Gynecologic Oncologist (SGO) recognizes the importance of accurate early detection biomarkers for ovarian cancer. For this reason SGO reviewed the literature regarding OvaCheck, a serum based diagnostic test for ovarian cancer. In the opinion of SGO, more research is needed to validate the test's effectiveness before offering it to the public."

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: There are no specific CPT or HCPCS available for this service.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Policy Key Words

Key Words: Proteomic Patterns, OvaCheck, MED2004

Medical Term Definitions

Mutation

a change in genetic material.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.34, 4/16/2004.

ECRI Health Technology Forecast. (2004, July). Molecular-based cancer screening. Retrieved 7/23/04 from http://www.ta.ecri.org/Forecast/Prod/summary/detail.aspx?doc_id=5093?q=molecular+based+cancer+screening&anm=wynneb.

Specialty Matched Consultant Advisory Panel 11/2004

Society of Gynecologic Oncologist (SGO). (2004, February). Society of gynecologic oncologist statement regarding ovacheck tm. Retrieved 11/30/2004 from http://www.sgo.org/images/pdfs/policy/OvaCheck_statement.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.34, 7/20/2006.

Specialty Matched Consultant Advisory Panel - 1/2007.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.34, 9/18/07.

Specialty Matched Consultant Advisory Panel - 11/2008 .

Policy Implementation/Update Information

8/26/04 New policy written. Analysis of proteomic patterns in serum to identify ovarian cancer is considered investigational. Notification given 8/26/04. Effective date 10/28/04.

12/9/04 Specialty Matched Consultant Advisory Panel meeting 11/29/2004. No change to criteria. Rationale added to Policy Guideline section. References added.

2/26/07 Specialty Matched Consultant Advisory Panel review 1/29/2007. No changes to policy statement. Updated rationale in "Policy Guidelines" section. References added.

12/22/08 Specialty Matched Consultant Advisory Panel review 11/22/08. No changes to policy statement. References added.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.