

## Corporate Medical Policy

### Analysis of Proteomic Patterns for Early Detection of Cancer

**File Name:** analysis\_of\_proteomic\_patterns\_for\_early\_detection\_of\_cancer  
**Origination:** 08/2004  
**Last CAP Review:** 11/2011  
**Next CAP Review:** 11/2012  
**Last Review:** 11/2011

#### Description of Procedure or Service

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The analysis of proteomic patterns in serum for early detection of cancer has been proposed. Several of these proteomic tests are being studied, particularly in ovarian and prostate cancer.

The genetic basis of cancer has been the focus of intense research; however, 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. Research interest has been increasing in the field of proteomics (referring to the protein product of the genome), in an effort to improve on screening and detection efforts for malignancies.

##### **Serum protein biomarkers**

Current diagnostic and follow-up serum biomarkers in clinical oncology (e.g., prostate specific antigen [PSA, prostate cancer], CA-125 [ovarian cancer]), involve identifying and quantifying specific proteins, but limitations may include non-specificity and elevation in benign conditions.

Ovarian cancer is the leading cause of death from gynecologic malignancy in the United States; most patients present with advanced disease, which has a 5-year survival rate from 15%–45%. If the disease is diagnosed in Stage I, survival rates are 95%. Therefore, there is great interest in using a biomarker to detect ovarian cancer in its earliest stages, as current screening methods are inadequate.

Serum measurements of PSA are used as a screening method for detecting prostate cancer. Very low or very high serum PSA results are most reliable in determining cancer risk. However, values often fall within a range that is nonspecific, and thus many patients end up undergoing biopsy for benign disease. Proteomics has been proposed as a technique to further evaluate cancer risk in this diagnostic gray zone.

##### **Proteomics**

Proteomics involve the use of mass spectrometry to study differences in patterns of protein expression. While patterns of protein expression have been proposed to yield more biologically relevant and clinically useful information than assays of single proteins, many limitations in the use of proteomics exist. In contrast to genomics, in which amplification techniques like polymerase chain reaction (PCR) allow for the investigation of single cells, no technology is available at the protein level. Other issues between studies have been lack of uniform patient inclusion and exclusion criteria, small patient numbers, absence of standardized sample preparations, and limited analytical reproducibility.

##### **Proteomic tests**

Correlogic Systems, Inc. has developed a serum-based test using proteomics for the early detection of

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epithelial ovarian cancer called OvaCheck®. The test 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 to identify a pattern that is consistent with ovarian cancer.

## **Regulatory Status:**

Originally, the manufacturer had assumed that the test would not be subject to approval by the U.S. Food and Drug Administration (FDA), since the test would be performed exclusively at one reference laboratory and testing materials do not cross state lines (i.e., a “home brew” test). However, in 2004, the FDA determined that the software used to perform the analysis was considered a medical device and under the FDA premarket review jurisdiction. At this time, Correlogics is conducting clinical trials on OvaCheck® at sites in the United States and abroad, and it is not commercially available.

Correlogics is also in the process of developing proteomic blood tests for the detection of colorectal, breast (MammoCheck®) and prostate cancer (ProstaCheck®).

Proteomic testing is not commercially available at this time.

## **Related Policies:**

Proteomics-based Testing for the Evaluation of Ovarian (Adnexal) Masses

*\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

## **Policy**

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**Analysis of proteomic patterns in serum for screening and detection of cancer is considered investigational for all applications. BCBSNC does not provide benefits for investigational services or procedures.**

## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## **When Analysis of Proteomic Patterns for Early Detection of Cancer is covered**

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Not applicable.

## **When Analysis of Proteomic Patterns for Early Detection of Cancer is not covered**

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Analysis of proteomic patterns in serum for screening and detection of cancer is considered investigational. BCBSNC does not cover investigational services.

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## Policy Guidelines

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The use of proteomic pattern analysis for the early detection of cancer is currently in clinical trials and testing is not commercially available. There are no published prospective trials that demonstrate that the use of proteomic analysis for screening or detection of disease improves clinical outcomes

## Billing/Coding/Physician Documentation Information

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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](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: There is no specific CPT or HCPCS code available for this service.*

*There is no specific code for the OvaCheck® test. CPT code 83789 describes quantitative mass spectrometry, which might apply to the initial step of OvaCheck® test or other variants of proteomics.*

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.

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## Scientific Background and Reference Sources

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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](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](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 .

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.34, 5/14/2009.

Senior Medical Director Review 7/2010

Specialty Matched Consultant Advisory Panel – 11/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.34, 7/14/2011

Specialty Matched Consultant Advisory Panel – 11/2011

## Policy Implementation/Update Information

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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. (btw)
6/22/10	Policy number(s) removed. (amw)
8/31/10	Senior Medical Director review 7/7/2010. "Description" revised. No changes to policy statement. References added. (btw)
12/21/10	Specialty Matched Consultant Advisory Panel review 11/29/2010. No changes to policy statement. Added the following statement to the "Billing/Coding" section; There is no specific

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code for the OvaCheck® test. CPT code 83789 describes quantitative mass spectrometry, which might apply to the initial step of OvaCheck® test, or other variants of proteomics.” References added. (btw)

8/30/11 Reference added. (btw)

1/10/12 Title updated from “Analysis of Proteomic Patterns in Serum to Identify Ovarian Cancer” to “Analysis of Proteomic Patterns for Early Detection of Cancer”. “Description” section updated. The “When Not Covered” section updated to indicate; “Analysis of proteomic patterns in serum for screening and detection of cancer is not covered. It is considered investigational. BCBSNC does not cover investigational services. “Policy Guidelines” updated to indicate; “The use of proteomic pattern analysis for the early detection of cancer is currently in clinical trials and testing is not commercially available.” No change to policy intent. Specialty Matched Consultant Advisory Panel review 11/30/11. (btw)

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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.