

Medical Coverage Policy



Analysis of Proteomic Patterns for Early Detection of Cancer

☐ Device/Equipment ☐ Drug ☐ Medical ☐ Surgery ☒ Test ☐ Other

Effective Date:	6/15/2010	Policy Last Updated:	6/18/2013
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☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:

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.

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 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. (1) 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. (2) Other issues between studies have been the lack of uniform patient inclusion and exclusion criteria, small

patient numbers, absence of standardized sample preparations, and limited analytical reproducibility.

Of particular interest have been tests that integrate results from multiple analytes into a risk score to predict the presence of disease. Two tests based on this principle have now been cleared by FDA for use in women with adnexal masses (Ova1™ test and ROMA™ test) as an aid to further assess the likelihood that malignancy is present.

No studies have been performed that directly evaluate the impact on referral patterns, or have they evaluated the impact on health outcomes and neither test has had evaluation of performance independently confirmed by independent investigators. As a result of the evidence and clinical input, these tests are considered not medically necessary pending more information about its performance and impact on outcomes. All other uses of this test, including use as a screening tool for ovarian cancer, are also considered investigational.

Medical Criteria:

None

Policy:

All BCBSRI products

Analysis of proteomic patterns for the early detection of cancer is considered **not medically necessary** due to the lack of peer-reviewed medical literature demonstrating its efficacy.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreements, for applicable "Not Medically Necessary Services."

Coding:

There is no specific CPT code for the analysis of proteomic patterns therefore an appropriate unlisted code would be used.

Also Known as:

OvaCheck, Screening for Ovarian Cancer
Ovarian Cancer, OvaCheck Test
Prostate Cancer, Proteomics
Proteomics
ROMA test

Related topics:

Policy: Proteomics-based testing for the Evaluation of Ovarian (Adnexal) Masses

<https://www.bcbsri.com/sites/default/files/polices/Proteimics-based-testing-for-adnexa-masses.pdf>

Publications:

Provider Update, August 2013

Provider Update, June 2012

Provider Update, August 2011

Provider Update, August 2010

References:

Blue Cross and Blue Shield Association Medical Policy Reference Manual 2.04.34 Analysis of Proteomic Patterns for Early Detection of Cancer

Centers for Medicare and Medicaid Technology Assessment: Update on Horizon Scans of Genetic Tests Currently Available for Clinic Use In Cancers. Final Report, April 2011.

Review History:

06/18/2013: Annual review without changes made.

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