Medical Coverage Policy

Analysis of Proteomic Patterns for Early Detection of Cancer

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

Effective Date: 06/15/2010  Policy Last Updated: 4/3/2012

☐ 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.

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 spectometry 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.

Proteomic Tests

Correlogic Systems, Inc has developed a serum-based test using proteomics for the early detection of 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. At this time, Correlogics is conducting clinical trials on OvaCheck® at sites in the United States and abroad. Correlogics is also in the process of developing proteomic blood tests for the detection of colorectal, breast (MammoCheck®) and prostate cancer (ProstaCheck®).

At this time, the proteomic testing is not commercially available. Additionally, there are no published, large randomized controlled trials demonstrating that the use of proteomic analysis for screening or detection of disease improves clinical outcomes.

Medical Criteria:
Not applicable.

Policy:
Analysis of proteomic patterns for the early detection of cancer is considered not medically necessary as data in the peer-reviewed literature are inadequate to permit scientific conclusions regarding ovarian, prostate, or other malignancies.

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 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.

Also Known as:
OvaCheck, Screening for Ovarian Cancer
Ovarian Cancer, OvaCheck Test
Prostate Cancer, Proteomics
Proteomics

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

Publications:
Provider Update, August 2010
Provider Update, August 2011
Provider Update, June 2012
References:
Blue Cross and Blue Shield Association Medical Policy Reference Manual 2.04.34 Analysis of Proteomic Patterns for Early Detection of Cancer

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