blue of california

Medical Policy

Proteomic Pattern Analysis in Serum to Identify Cancer	
Type: Investigational / Experimental	**Policy Specific Section:** Laboratory/Pathology
Original Policy Date: October 15, 2007	**Effective Date:** December 19, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Proteins are the functional units of cells and represent the end product of the interactions among the underlying genes. They perform a wide variety of functions including serving as enzymes, structural components or signaling molecules. Proteomics is the study of a set of proteins expressed by a cell and the changes in protein expressions patterns. In an effort to improve

screening and detection of cancer, research has been directed at the identification of patterns of proteins detected in a given fluid, such as serum, that is associated with an underlying malignancy. Proteomics involve the use of mass spectometry to study these differences in patterns of protein expression.

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. However, there is considerable uncertainty that the incremental increase in detection by OVA1 would result in improved health outcomes or would be as beneficial as other diagnostic strategies.

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. 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. However, commercial testing is not available at this time.

Policy

All uses of the OVA1 and ROMA tests are **investigational**, including but not limited to:

- Preoperative evaluation of adnexal masses to triage for malignancy
- Screening for ovarian cancer
- Selecting patients for surgery for an adnexal mass
- Evaluation of patients with clinical or radiologic evidence of malignancy
- Evaluation of patients with nonspecific signs or symptoms suggesting possible malignancy
- Postoperative testing and monitoring to assess surgical outcome and/or to detect recurrent malignant disease following treatment

Proteomic pattern analysis in serum is considered **investigational** for screening and detection of cancer (i.e., MammoCheck® and ProstaCheck®)

Policy Guideline

OVA1 and ROMA tests are combinations of several separate lab tests and involve a proprietary algorithm for determining risk (i.e., they are what the American Medical Association's CPT calls “Multianalyte Assays with Algorithmic Analyses” [MAAAs]).

Effective 1/1/13, there are specific CPT category I MAAA codes for these tests:

81500: Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score - is specific to the ROMA test.

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81503: Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin and pre-albumin), utilizing serum, algorithm reported as a risk score - specific to OVA1.

CPT instructs that these codes cannot be reported with the component tests (i.e., codes 86304 and 86305 cannot be reported with 81500, and codes 82172, 82232, 83695, 83700, 84134, 84466, and 86304 cannot be reported with 81503).

There are no specific CPT or HCPCS codes for serum proteomic pattern analysis for the screening and detection of cancer (e.g., MammoCheck®, ProstaCheck® tests). One of the following codes might be used to report the tests:

83788: Mass spectroscopy and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified, qualitative, each specimen

83789: Mass spectroscopy and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified, quantitative, each specimen

84999: Unlisted chemistry procedure

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review
• No records required

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the appendix for this policy

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