SERUM PROTEIN PATTERN ANALYSIS FOR DETECTION OF CANCER

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Proteomics (to distinguish it from genomics) is 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. Analysis of serum protein patterns has been investigated in identifying a pattern that may be consistent with cancer. The OvaCheck® is based on protein patterns detected in the serum, which are further analyzed with the use of a mass spectrometer to identify a pattern that may be consistent with ovarian cancer. OvaCheck is currently in clinical trials and is not commercially available. Other proteomic blood tests in development include MammoCheck® for the detection of colorectal and breast and ProstaCheck®, for the detection of prostate cancer.
SERUM PROTEIN PATTERN ANALYSIS FOR DETECTION OF CANCER (cont.)

Criteria:

➢ Analysis of serum protein patterns for screening and detection of cancer is considered experimental or investigational based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

SERUM PROTEIN PATTERN ANALYSIS FOR DETECTION OF CANCER (cont.)

Resources: (cont.)


