



**PROTEOMIC TESTING (OVACHECK™)
FOR THE DETECTION OF OVARIAN CANCER
HS-049**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

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HealthEase of Florida, Inc.

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**Proteomic-Based Testing
(OvaCheck™) for the
Detection of Ovarian Cancer**

Policy Number: HS-049

Original Effective Date: 9/18/2008

**Revised Date(s): 9/21/2009; 9/24/2010;
9/1/2011**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Ovarian cancer is one of the leading causes of gynecologic cancer death in women in the United States. The lifetime risk of ovarian cancer is projected to be 1.7%. When all stages of the disease are considered, the 1-year survival rate is 79%, dropping to 53% at 5 years. When diagnosis occurs at an early stage, the 5-year survival rate is 95%. Aside from prevention, early detection of cancer is one of the primary goals of cancer management. In order to develop a screening tool with the ability to detect ovarian cancer at an early stage, Correllogic Systems Inc. (Bethesda, MD) has developed a proteomic-based test called OvaCheck™. The test detects changes in serum proteins that may reflect pathological changes within the ovary. According to the manufacturer's website, once OvaCheck is made commercially available, patients' blood will be drawn at the offices of the clinicians ordering the tests or at one of 2700 specific laboratory patient service centers. The blood will be analyzed at the facilities of the Laboratory Corporation of America (LabCorp®) and Quest Diagnostics. This diagnostic test, if proven to be accurate, can serve as a tool in the screening and early diagnosis of ovarian cancer.

Some experts have raised concerns regarding OvaCheck's diagnostic capability, given the low prevalence of ovarian cancer in the general population (1 in 2500) and the risk of surgical morbidity due to false-positive results. For example, with disease prevalence of 1 in 2500, if OvaCheck has a sensitivity of 100% and a specificity of 99%, 25 women would be falsely identified for every true case of cancer found. Many experts consider this rate too high for commercial use of a diagnostic test.

There is some regulatory controversy associated with the OvaCheck test. In 2004, the Food and Drug Administration's (FDA) Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) completed a review of the information provided by Correllogic Systems Inc. As a result of this review, OIVD determined that the OvaCheck test is subject to FDA regulation under the device provisions of the Food, Drug, and Cosmetic Act. Although the FDA does not intend to regulate the activities of Correllogic's reference laboratory or its partners, the software intended for use in the OvaCheck technology is subject to FDA regulation. The Correllogic software is considered a device for which premarket approval (PMA) is required to establish safety and efficacy. In a letter dated August 2, 2004, the FDA requested the submission and review of a PMA application from Correllogic Systems Inc. As of April 2006, the results of the review of the PMA application have not been published by the FDA and OvaCheck is not yet commercially available. In addition, Centers for Medicare & Medicaid Services (CMS) has not issued a National Coverage Determination regarding the use of proteomic-based testing of serum for diagnosis or screening of ovarian cancer.

Due to the lack of published evidence, proteomic-based testing of serum is not recommended as a definitive or adjunct diagnostic tool for ovarian cancer. Clinical studies are needed to assess the accuracy of proteomic-based tests, to compare it with currently used diagnostic tests and procedures, and to determine how it would affect patient outcomes, and morbidity and mortality rates. Furthermore, the role of proteomic-based testing in the continuum of care needs to be defined (from Hayes, 2006).

Society of Gynecologic Oncologists Statement

The Society of Gynecologic Oncologists (SGO) recognizes the importance of accurate early detection biomarkers for ovarian cancer. For this reason, SGO reviewed the literature regarding OvaCheck, a serum-based diagnostic test for ovarian cancer.

In the opinion of SGO, more research is needed to validate the test's effectiveness before offering it to the public. SGO is committed to actively following and contributing to this vitally important research. As physicians who care only for women with gynecologic cancers, our hope is that these cancers can either be prevented or detected early. Because no test now exists to routinely detect ovarian cancer in its earliest and most curable stages, we will await the results of further clinical validation of OvaCheck with great interest.

American College of Obstetricians and Gynecologists

In 2005, the ACOG Committee on Gynecologic Practice states that serum-based testing for ovarian cancer requires further research to determine efficacy.

POSITION STATEMENT

Proteomic-based testing for the detection of ovarian cancer, utilizing the OvaCheck™ device, **is considered experimental and investigational and NOT a covered benefit.**

CODING

Non-Covered CPT® Codes - No specific CPT code has been designated for OvaCheck.

- 83788** Mass spectrometry and tandem mass spectrometry (MS,MS/MS) analyte not elsewhere specified; qualitative, each specimen
- 83789** Mass spectrometry and tandem mass spectrometry (MS,MS/MS) analyte not elsewhere specified; quantitative, each specimen
- 84999+** Unlisted Chemistry procedure when billed for OvaCheck
+ Requires documentation with the claim explaining the unlisted procedure(s)

ICD-9-CM Procedure Codes - No applicable codes

HCPCS Level II © Code - No applicable HCPCS codes

Non-Covered ICD-9-CM Diagnosis Codes

- 256.0 - 256.9** Ovarian Dysfunction; hyperfunction, failure, etc.
- V16.41** Family history of Ovarian Cancer
- V76.46** Special screening for malignant neoplasm of Ovary

*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Hayes Technology Assessment Brief. Proteomic-Based Testing (OvaCheck™) for the Detection of Ovarian Cancer. April, 2006.

Government Agencies, Professional and Medical Organizations

1. American College of Obstetricians and Gynecologists, Committee on Gynecologic Practice. Position regarding OvaCheck™, February 25, 2005.
2. Society of Gynecologic Oncologists (SGO). Society of Gynecologic Oncologists statement regarding OvaCheck™. Revised February 7, 2004. Accessed August 12, 2011. Available at URL address: <http://www.sgo.org/WorkArea/showcontent.aspx?id=954>



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HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
9/1/2011	<ul style="list-style-type: none">• Approved by MPC.