Medical Policy
Proteomics-based Testing for the Evaluation of Ovarian Masses

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Policy Number: 249
BCBSA Reference Number: 2.04.62

Related Policies
- Analysis of Proteomic Patterns for Early Detection of Cancer, #536

Policy
Commercial Members: Managed Care (HMO and POS), and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members
All uses of the OVA1 and ROMA tests are INVESTIGATIONAL, including but not limited to
- Preoperative evaluation of adnexal masses to triage for malignancy, or
- Screening for ovarian cancer, or
- Selecting patients for surgery for an adnexal mass, or
- Evaluation of patients with clinical or radiologic evidence of malignancy, or
- Evaluation of patients with nonspecific signs or symptoms suggesting possible malignancy, or
- Postoperative testing and monitoring to assess surgical outcome and/or to detect recurrent malignant disease following treatment.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO BlueSM
This is NOT a covered service.

Medicare Members: PPO BlueSM
This is NOT a covered service.
CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>81500</td>
<td>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.</td>
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<tr>
<td>81503</td>
<td>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 – is specific to OVA1.</td>
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<tr>
<td>81504</td>
<td>Oncology (tissue of origin), microarray gene expression profiling of &gt; 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores</td>
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ICD-9 Diagnosis Codes
Investigational for all diagnoses.

Description
The OVA1™ test is a qualitative serum test that combines immunoassay results for 5 analytes (CA 125, prealbumin, apolipoprotein A-1, beta2 microglobulin, and transferrin) into a single numerical score. It is intended to be used in women with adnexal masses who are planning to have surgery by a non-gynecologic oncologist for disease considered benign using routine clinical and radiologic evaluation. In this patient subset, the test serves as an aid to further assess the likelihood that malignancy is present. Patients with positive results should be considered candidates for referral to a gynecologic oncologist for treatment. This treatment is likely to produce improved patient outcomes.

The OVA1™ test from Vermillion, Inc. is considered medically necessary for the further evaluation of ovarian (adnexal) masses when independent clinical and radiologic preoperative evaluations do not indicate malignancy. All other uses of the OVA1™ test are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except as noted in the policy statement.

Summary
The OVA1 test has been analytically validated and clinical performance has been established in a prospective multi-center clinical trial. The plan for this trial (although not the trial itself) has been described in the peer-reviewed literature, and a brief summary of results has appeared in a single abstract.

Extensive information about the trial is available through the posting of an FDA decision summary resulting from FDA clearance of the product in 2009. Use of the OVA1 test clearly improves the diagnostic sensitivity and the preoperative detection of ovarian cancers. This increase in the identification of malignancies should result in more early referrals to gynecological oncologists with resulting improvement in clinical outcomes. Thus, use of the OVA 1 test is considered medically necessary as part of the preoperative evaluation of patients with ovarian masses by non-gynecologic oncologists whose initial evaluation does not indicate the mass is malignant.

All other uses of this test, including use as a screening tool for ovarian cancer, are considered investigational.
Policy History

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<tr>
<th>Date</th>
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<tr>
<td>2/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>1/2014</td>
<td>Updated to add new CPT code 81504.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References

15. Kajiser J, Van Gorp T, Van Hoorde K et al. A comparison between an ultrasound based prediction model (LR2) and the risk of ovarian malignancy algorithm (ROMA) to assess the risk of malignancy in women with an adnexal mass. Gynecol Oncol 2013; 129(2):377-83.
17. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Multi-analyte testing for the evaluation of adnexal masses. TEC Assessments 2012; Volume 27, Tab C.