Multimarker Serum Testing Related to Ovarian Cancer

Introduction

When a mass of tissue is found next to the uterus (adnexal mass) it usually isn't cancer. The OVA1, ROMA, and Overa tests are a combination of several lab tests that some doctors order to try to see how likely it is that a mass is cancer. Other reasons doctors may order these tests are to try to decide if a patient should be referred to a gynecological oncologist (a doctor who specializes in women's cancers); to try to screen for ovarian cancer; to try to determine if previous surgery was successful in removing ovarian cancer; or to try to find out if ovarian cancer has come back.

The OVA1, ROMA, and Overa tests are still being studied. There is little evidence in published medical studies to show how these tests will lead to improved diagnoses or patient care. There are no studies that show how information from these tests will impact health outcomes. These tests are investigational (unproven) for all uses.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVA1®</td>
<td>All uses of the OVA1®, Overa™, and ROMA™ tests are investigational, including but not limited to:</td>
</tr>
<tr>
<td></td>
<td>• Preoperative evaluation of adnexal masses to triage for malignancy</td>
</tr>
<tr>
<td>Overa™</td>
<td>OR</td>
</tr>
<tr>
<td>ROMA™</td>
<td>• Screening for ovarian cancer</td>
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<td></td>
<td>OR</td>
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<tr>
<td></td>
<td>• Selecting patients for surgery for an adnexal mass</td>
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<tr>
<td></td>
<td>OR</td>
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<td></td>
<td>• Evaluation of patients with clinical or radiologic evidence of malignancy</td>
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<td></td>
<td>OR</td>
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<td></td>
<td>• Evaluation of patients with nonspecific signs or symptoms suggesting possible malignancy</td>
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<td></td>
<td>OR</td>
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<tr>
<td></td>
<td>• Postoperative testing and monitoring to assess surgical outcome and/or to detect recurrent malignant disease following treatment</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0003U</td>
<td>Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score – is specific to the Overa test</td>
</tr>
<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>
</tr>
<tr>
<td>81503</td>
<td>Oncology (ovarian), biochemical assays of five proteins (CA-125, apoliproprotein A1, beta-2 microglobulin, transferrin and pre-albumin), utilizing serum, algorithm reported</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td>as a risk score – is specific to OVA1 test</td>
</tr>
</tbody>
</table>

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### Related Information

OVA1, Overa, and ROMA tests are combinations of several separate lab tests and involve proprietary algorithms for determining risk (i.e., what CPT codes call multianalyte assays with algorithmic analyses [MAAAs]).

### Evidence Review

#### Description

A variety of serum biomarkers have been studied for their association with ovarian cancer. Of particular interest have been tests that integrate results from multiple analytes into a risk score to predict the presence of disease. Three tests based on this principle, OVA1, Overa (the second-generation OVA1 test), and ROMA have been cleared by the U.S. Food and Drug Administration. The intended use of OVA1 and Overa is to use them as an aid to further assess whether malignancy is present - even when the physician’s independent clinical and radiologic evaluation does not indicate malignancy. The intended use of ROMA is to use it as an aid, in conjunction with clinical assessment, to assess whether any woman who presents with an ovarian adnexal mass has a high or low likelihood of having malignancy found at surgery.

#### Background

The umbrella term “epithelial ovarian cancer” collectively includes high-grade serous epithelial ovarian, fallopian tubal, and peritoneal carcinomas due to their shared pathogenesis, clinical presentation, and treatment. We use the term “epithelial ovarian cancer” to refer to this group of malignancies in the discussion that follows. There is currently no serum biomarker that can
distinguish between these types of carcinoma. An estimated 22,440 women in the United States were diagnosed in 2017 with ovarian cancer, and approximately 14,080 will die of the disease.\(^1\) The mortality rate depends on three variables:

1. Patient characteristics
2. Tumor biology (grade, stage, type)
3. Treatment quality (nature of staging, surgery, and chemotherapy used)\(^2\)

In particular, comprehensive staging and completeness of tumor resection appear to have a positive impact on patient outcome.

In 1997, the Society of Surgical Oncology recommended that ovarian cancer surgery and follow-up treatment be performed by physicians with ovarian cancer expertise.\(^3\) Numerous articles have been published on the application of this recommendation examining long- and short-term outcomes, as well as process measures (eg, types of treatment such as complete staging or tumor debulking). At least two meta-analyses have concluded that outcomes are improved when patients with ovarian cancer are treated by gynecologic oncologists.\(^4,5\) The available data are most convincing for patients with advanced-stage disease.

Adult women presenting with an adnexal mass have an estimated 68% likelihood of having a benign lesion.\(^6\) About 6% have borderline tumors, 22% possess invasive malignant lesions, and 3% have metastatic disease. Surgery is the only way to diagnose ovarian cancer; this is because biopsy of an ovary with suspected ovarian cancer is usually not performed due to the risk of spreading cancer cells. Most clinicians agree that women with masses that have a high likelihood of malignancy should undergo surgical staging by gynecologic oncologists. However, women with clearly benign masses do not require referral to a specialist. Therefore, criteria and tests that help differentiate benign from malignant pelvic masses are desirable.

In 2005, the American College of Obstetricians and Gynecologists and the Society of Gynecologic Oncologists jointly released guidelines that address criteria for referring women with pelvic masses that are suspicious for ovarian cancer to gynecologic oncologists.\(^7\) Separate criteria were developed for premenopausal and postmenopausal women. In premenopausal women, referral criteria included at least one of the following: elevated cancer antigen 125 (CA 125; >200 U/mL), ascites, evidence of abdominal or distant metastasis, or a positive family history. The referral criteria in postmenopausal women were similar, except that a lower threshold for an elevated CA125 test was used (35 U/mL); moreover, a nodular or fixed pelvic mass was an added criterion.
Three multimarker serum-based tests specific to ovarian cancer have been cleared by the Food and Drug Administration (FDA) with the intended use of triaging patients with adnexal masses (see Regulatory Status). They are summarized in Table 1. The proposed use of the tests is to identify women with a substantial likelihood of malignant disease who may benefit from referral to a gynecologic oncology specialist. Patients with positive results may be considered candidates for referral to a gynecologic oncologist for treatment. The tests have been developed and evaluated only in patients with adnexal masses and planned surgeries. Other potential uses, such as selecting patients to have surgery, screening asymptomatic patients, and monitoring treatment, have not been investigated. Furthermore, the tests are not intended to be used as stand-alone tests, but in conjunction with clinical assessment.

Other multimarker panels and longitudinal screening algorithms are under development; however, these are not yet commercially available.8,9

Table 1. Summary of FDA-Approved Multimarker Serum-Based Tests Specific to Ovarian Cancer

<table>
<thead>
<tr>
<th>Variables</th>
<th>OVA1</th>
<th>Overa</th>
<th>ROMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>2009</td>
<td>2016</td>
<td>2011</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Quest Diagnostics</td>
<td>Vermillion</td>
<td>Roche Diagnostics</td>
</tr>
<tr>
<td><strong>Biomarkers used</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CA 125 II</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>β2-microglobulin</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Transferrin</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Transthyretin</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Apolipoprotein AI</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>HE4</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>FSH</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Score range</td>
<td>0-10</td>
<td>0-10</td>
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</tr>
<tr>
<td><strong>Risk categorization</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premenopausal</td>
<td>&lt;5.0: low</td>
<td>&lt;5.0: low</td>
<td>≥1.3: high</td>
</tr>
<tr>
<td></td>
<td>≥5.0: high</td>
<td>≥5.0: high</td>
<td></td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>&lt;4.4: low</td>
<td></td>
<td>≥2.77: high</td>
</tr>
<tr>
<td></td>
<td>≥4.4: high</td>
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</tr>
</tbody>
</table>

Summary of Evidence

For individuals with adnexal mass(es) who have multimarker serum testing with clinical assessment in order to assess their ovarian cancer risk prior to undergoing surgery, the evidence includes studies assessing the test's technical performance and diagnostic accuracy. Relevant outcomes are overall survival and test accuracy. OVA1 and Overa are intended for use in patients for whom clinical assessment does not indicate cancer. When used in this manner, OVA1’s sensitivity for ovarian malignancy was 92% and specificity was 42%; with Overa, sensitivity for malignancy was 94% and specificity was 65%. ROMA is intended for use with clinical assessment, but no specific method has been defined. One study, which used clinical assessment and ROMA results, showed a sensitivity of 90% and specificity of 67%. However, there is no direct evidence in terms of assessing patient outcomes based on the use of such testing prior to undergoing surgery. Moreover, it is uncertain whether discrimination is sufficient to alter decision making based on clinical assessment alone and offer meaningful benefit. Thus, the chain of evidence supporting improved outcomes is therefore incomplete. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in November 2017 did not identify any ongoing or unpublished trials that would likely influence this policy.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received while this policy was under review in 2012. Input was mixed in support of these tests as a tool for triaging patients with an adnexal mass. Reviewers
agreed that the evidence was insufficient to determine the impact of these tests on referral patterns. For indications other than triaging patients with an adnexal mass, there was a lack of support for use of these tests.

Practice Guidelines and Position Statements

American Congress of Obstetricians and Gynecologists

The American Congress of Obstetricians and Gynecologists (ACOG) addressed the use of the OVA1 test in its 2011 guidelines on the role of the obstetrician-gynecologist in the early detection of epithelial ovarian cancer. In 2013, the Society for Gynecologic Oncology endorsed these ACOG guidelines. This ACOG document included the following comments, which were not specific guidelines about the use of the test:

- The OVA1 test “appears to improve the predictability of ovarian cancer in women with pelvic masses.”
- “This is not a screening test, but it may be useful for evaluating women with a pelvic mass.”
- “Clinical utility is not yet established.”

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) issued guidance in 2011 on the identification and management of ovarian cancer. This guidance is currently being updated and is under review.

National Comprehensive Cancer Network

National Comprehensive Cancer Network (NCCN) guidelines on ovarian cancer (v.4.2017) include the following statement:

It has been suggested that specific biomarkers (serum HE4 [human epididymis secretory protein 4] and CA-125 [cancer antigen 125]) along with an algorithm (Risk of Ovarian Malignancy Algorithm [ROMA]) may be useful for determining whether a pelvic mass is malignant or benign. The FDA [Food and Drug Administration] has approved the use of HE4 and CA-125 for estimating the risk of ovarian cancer in
women with a pelvic mass. Currently, the NCCN Panel does not recommend the use of these biomarkers for determining the status of an undiagnosed pelvic mass.

Regarding the OVA1 test, NCCN guidelines state:

The OVA1 test uses 5 markers (including transthyretin, apolipoprotein A1, transferrin, beta-2 microglobulin, and CA-125) to assess who should undergo surgery by an experienced gynecologic oncologist and who can have surgery in the community. Based on data documenting an increased survival, NCCN Guidelines Panel Members recommend that all patients should undergo surgery by an experienced gynecologic oncologist (category 1).

U.S. Preventive Services Task Force Recommendations

In 2012, The U.S. Preventive Services Task Force recommended against screening women for ovarian cancer (D recommendation). The task force has not addressed multimarker serum testing related to ovarian cancer. The 2012 statement is currently in update.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

In July 2009, the OVA1® test (Aspira Labs [Austin, TX]) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. OVA1® was designed as a tool to further assess the likelihood that malignancy is present when the physician’s independent clinical and radiological evaluation does not indicate malignancy.

In September 2011, the Risk of Ovarian Malignancy Algorithm (ROMA™ test; Fujirebio Diagnostics [Sequin, TX]) was cleared for marketing by the FDA through the 510(k) process. The intended use of ROMA™ is as an aid, in conjunction with clinical assessment, in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low risk of having malignancy at surgery.
In March 2016, a second-generation test called Overa™ (also referred to as next-generation OVA1®), in which 2 of the 5 biomarkers in OVA1® are replaced with human epididymis secretory protein 4 (HE4) and follicle-stimulating hormone, was cleared for marketing by the FDA through the 510(k) process. Similar to OVA1®, Overa™ generates a low or high risk of malignancy on a scale from 0 to 10.

**Black Box Warning**

In December 2011, the FDA amended its regulation for classifying ovarian adnexal mass assessment score test systems. The change required that off-label risks be highlighted by a black box warning. The warning is intended to mitigate the risk to health associated with off-label use as a screening test, stand-alone diagnostic test, or as a test to determine whether or not to proceed with surgery. Considering the history and currently unmet medical needs for ovarian cancer testing, the FDA concluded that there is a risk of off-label use of this device. To address this risk, the FDA requires that manufacturers provide notice concerning the risks of off-label uses in the labeling, advertising, and promotional material of ovarian adnexal mass assessment score test systems. Manufacturers must address the following risks:

- Women without adnexal pelvic masses (ie, for cancer “screening”) are not part of the intended use population for the ovarian adnexal mass assessment score test systems. Public health risks associated with false-positive results for ovarian cancer screening tests are well described in the medical literature and include morbidity or mortality associated with unneeded testing and surgery. The risk from false-negative screening results also includes morbidity and mortality due to failure to detect and treat ovarian malignancy.

- Analogous risks, adjusted for prevalence and types of disease, arise if test results are used to determine the need for surgery in patients who are known to have ovarian adnexal masses.

- If used outside the “OR” rule that is described in this special control guidance, results from ovarian adnexal mass assessment score test systems pose a risk for morbidity and mortality due to nonreferral for oncologic evaluation and treatment.

**References**


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/13/11</td>
<td>Add to Pathology/Laboratory Section - Reviewed by OAP on May 12, 2011. New medical policy.</td>
</tr>
<tr>
<td>12/19/12</td>
<td>Replace policy. Policy updated to change the use of the OVA1™ and ROMA tests from medically necessary to investigational for all indications. Rationale updated based on a literature review through September 2012, results of TEC Assessment, and results of clinical vetting. References 7, 13, 17-28 added; others renumbered or removed. New CPT codes added. Policy statement changed as noted.</td>
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<tr>
<td>03/15/13</td>
<td>Update Related Policies. Add 2.03.501.</td>
</tr>
<tr>
<td>10/16/13</td>
<td>Update Related Policies. Add 12.04.66 and remove policy 2.04.34 as it was archived.</td>
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<tr>
<td>12/27/13</td>
<td>Replace policy. Policy updated with literature search through September 30, 2013. References 14, 15 and 20 added; other references renumbered or removed. No change to policy statement. Title changed to Proteomic-based Testing Related to Ovarian Cancer. Clarification note added that this policy is only to be used when HE4 is included in the ROMA combination test. When HE4 is billed as an individual test, it should be considered investigational and not medically necessary.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
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<tr>
<td>12/17/14</td>
<td>Annual Review. Policy updated with literature review through September 25, 2014. References 1, 14, 18 and 23 added. Policy statement unchanged. Policy title changed to “Proteomics-Based Testing Related to Ovarian Cancer”. ICD-9 and ICD-10 diagnosis and procedure codes removed; these are not utilized in adjudication of the policy.</td>
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<td>Annual Review. Policy updated with literature review through October 25, 2015; references 14 and 18 added. Policy statement unchanged.</td>
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<td>09/01/16</td>
<td>Annual Review, approved August 9, 2016. Policy statement unchanged. No new references added.</td>
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<td>03/01/17</td>
<td>Annual Review, approved February 14, 2017. Title changed to “Multimarker Serum Testing Related to Ovarian Cancer”. Policy updated with literature review through October 24, 2016; references added. New code for Overa test was added. Policy statement unchanged, this testing is considered investigational for all indications.</td>
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<tr>
<td>11/10/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>02/01/18</td>
<td>Annual Review, approved January 30, 2018. Policy update with literature through October 2017; references 1, 10, 12, 16, and 27 were added. The Overa test was added to policy statement, the intent is unchanged.</td>
</tr>
</tbody>
</table>

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Română (Romanian):

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Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує необхідність того, що Ви маєте бути відомі про ключові дати, які вказані в цьому повідомленні. Можливо, це важлива інформація для Вас. Ви маєте право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

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