

# Premier Health Insuring Corporation

## POLICY AND PROCEDURE MANUAL

Policy Number: MP.095.PC  
Last Review Date: 11/12/2015  
Effective Date: 01/01/2016  
Renewal Date: 01/01/2017

### MP.095.PC - OVA1™ Test

This policy applies to the following lines of business:

- ✓ Premier Commercial
- ✓ Premier Employee

Premier Health Plan considers OVA1™ Test medically necessary for the following indications:

Member must meet all of the following:

1. Women age 18 or older
2. Diagnosed with an ovarian adnexal mass for which surgery is planned
3. Have not yet been referred to an oncologist (surgical or gynecological)

#### Limitations

1. Not indicated for ovarian cancer screening or as a stand-alone test for a definitive diagnosis of ovarian cancer
2. Diagnosis of malignancy in the past five years
3. Rheumatoid factor concentration  $\geq$  250 IU/ml

#### Background

OVA1 is a Food and Drug Administration (FDA) approved biomarker panel that measures risk of ovarian cancer in women with a pelvic mass. Ovarian cancer is the fifth leading cause of death by cancer besides skin cancer in women in the United States. According to the Centers for Medicare and Medicaid (CMS), the OVA1 test can identify women who will benefit from referral to a gynecological oncologist for their surgery, despite negative results from other clinical and radiographic tests for ovarian cancer. The test works by using a blood sample to test for levels of five proteins that change due to ovarian cancer. The result is a combined numerical score between 0 and 10 which indicates likelihood of the mass being malignant prior to surgery. OVA1 is intended to be used by a primary care physician or gynecologist as an adjunctive test with other diagnostic clinical procedures.

#### Codes:

##### CPT Codes / HCPCS Codes / ICD-10 Codes

Code	Description
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##### CPT Codes

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84999	Unlisted chemistry procedure
81503	Oncology (ovarian) biochemical assays of five proteins

## References

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L35396 Biomarkers for oncology (Contractor: Novitas Solutions, Inc.), Revision Effective October 1, 2015. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35396&ContrId=324&ver=27&ContrVer=1&Date=&DocID=L35396&bc=iAAAAAgAAAAAAAA%3d%3d&>
2. Hayes GTE Report. OVA1 Ovarian Tumor Triage Test. Publication date: August 21, 2014. Annual Review date: August 27, 2015.
3. Miller RW. OVA1 test outperformed CA125 for early ovarian cancer detection. HemOnc Today (haelio.com) June 10, 2011. <http://www.healio.com/hematology-oncology/gynecologic-cancer/news/print/hemonc-today/%7B8b9ac28b-c274-4257-a1ea-7695042f8d7f%7D/ova1-test-outperformed-ca125-for-early-ovarian-cancer-detection>
4. National Comprehensive Cancer Network (NCCN): Clinical Practice Guidelines in Oncology, Genetic/Familial High-Risk Assessment: Breast and Ovarian. Version 1.2014. <https://intervalibre.files.wordpress.com/2012/06/nccn-manejo-alto-riesgo-genc3a9tico-familiar-en-cc3a1ncer-de-ovario-y-mama-2014.pdf>
5. National Comprehensive Cancer Network (NCCN): Clinical Practice Guidelines in Oncology, Ovarian Cancer- Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 3.2014. <http://www.tri-kobe.org/nccn/guideline/gynecological/english/ovarian.pdf>
6. Quest Diagnostics, U.S. Food and Drug Administration Clears Vermillion's OVA1™ Test to Determine Likelihood for Ovarian Cancer in Women with Pelvic Mass. Press Release. Sept. 11, 2011. [http://ir.questdiagnostics.com/phoenix.zhtml?c=82068&p=irol-newsArticle\\_print&ID=1331027&highlight=%20](http://ir.questdiagnostics.com/phoenix.zhtml?c=82068&p=irol-newsArticle_print&ID=1331027&highlight=%20)
7. U.S. Department of Health & Human Services (HHS). Food and Drug Administration (FDA): OVA1™ Test. Approval Letter. Issued: September 11, 2009. [http://www.accessdata.fda.gov/cdrh\\_docs/pdf8/k081754.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/k081754.pdf)
8. U.S. Department of Health & Human Services (HHS). Food and Drug Administration (FDA): OVA1™ Test. News Release. Issued: September 11, 2009. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182057.htm>

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9. U.S. Department of Health & Human Services (HHS). Food and Drug Administration (FDA): OVA1™ Test. 510(k) Decision Summary.  
[http://www.accessdata.fda.gov/cdrh\\_docs/reviews/K081754.pdf](http://www.accessdata.fda.gov/cdrh_docs/reviews/K081754.pdf)

### **Disclaimer:**

Premier Health Insuring Corporation medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of Premier Health Insuring Corporation and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

Premier Health Insuring Corporation reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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