OVERVIEW
This policy documents the coverage determination for genetic testing using proteomics technology to detect ovarian cancer.

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial products

All uses of the OVA1 and ROMA tests are not medically necessary, including but not limited to the following, because there is insufficient clinical data to support its efficacy:

- 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.

MEDICAL CRITERIA
None

BACKGROUND
At the present time, there is no effective screening tool for ovarian cancer that can be used in the general population. Ovarian cancer is diagnosed using ultrasound, computed tomography (CT) scans, and magnetic resonance imaging (MRI). When a mass is found or cancer is suspected, then a surgical biopsy must be performed to confirm the diagnosis, the origin of the cancer and its stage. This information is then used to determine the course of treatment that will be recommended for each individual patient.

The cancer antigen 125 (CA-125) in combination with ultrasound is being used for surveillance of women at high-risk for ovarian cancer, as a treatment response indicator and to monitor the detection of recurrent disease. The disadvantages of using the CA-125 biomarker as a stand-alone screening tool are: its levels are nonspecific and can be elevated due to other non-cancerous conditions; only 50-60% of women diagnosed with stage I ovarian cancer have demonstrated an elevation in this biomarker; research has shown that it has a positive predictive value of 10%, but when used in combination with ultrasound, its positive-predictive value increases to 20%.

In an effort to develop a screening tool that can detect ovarian cancer in its earliest stages rendering it amenable to curative measures, new research in the areas of proteomics and genomics has occurred. Proteomics is the systematic study of proteins in a particular cell, tissue, or organism. Researchers are
currently applying proteomic technology in studies for the early detection of and ongoing surveillance of cancer. The application of proteomic technologies is currently limited to research purposes.

Two proteomics tests are of particular interest have been tests that integrate results from multiple analytes into a risk score to predict the presence of disease. Two tests based on this principle have now been cleared by FDA for use in women with adnexal masses (Ova1™ test and ROMA™ test) as an aid to further assess the likelihood that malignancy is present. OVA1 and ROMA tests are combinations of several separate lab tests and involve a proprietary algorithm for determining risk (i.e., they are what the American Medical Association’s CPT calls “Multianalyte Assays with Algorithmic Analyses” [MAAAs]).

Use of the ROMA and OVA1 proteomic tests in combination with clinical assessment appears to produce very modest changes in diagnostic performance for identifying adnexal masses negative for ovarian cancer. 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.

**COVERAGE**
Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable services not medically necessary coverage.

**CODING**
Effective 02/01/2014 the following CPT codes are not medically necessary for BlueCHiP for Medicare and Commercial products.

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**RELATED POLICIES**
Genetic Testing: Analysis of Proteomic Patterns for Early Detection of Cancer

**PUBLISHED**
<table>
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**REFERENCES**

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