Procedure addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

<table>
<thead>
<tr>
<th>Procedure covered by this guideline</th>
<th>Procedure code</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVA1</td>
<td>81503</td>
</tr>
</tbody>
</table>

What is ovarian cancer

Definition

With an estimated 22,440 new cases a year, ovarian cancer is one of the most common gynecological cancers in women.\(^1\) In 2017, there were 14,080 deaths from ovarian cancer making it the 5\(^{th}\) most common cancer mortality.\(^1,2\)

- Signs and symptoms of ovarian cancer include the following:\(^1\)
  - "Pain, swelling, or a feeling of pressure in the abdomen or pelvis."\(^1\)
  - "Vaginal bleeding that is heavy or irregular, especially after menopause."\(^1\)
  - "Vaginal discharge that is clear, white, or colored with blood."\(^1\)
  - "A lump in the pelvic area."\(^1\)
  - "Gastrointestinal problems such as gas, bloating, or constipation."\(^1\)

- Current screening methods include gynecological assessment, vaginal ultrasound, and CA-125 assay.\(^1\) However, these screening methods have low predictive value and many times cancer is widespread by the time it is detected.\(^1\)

- As a result, there is greater interest in the discovery of better screening methods in order to identify ovarian cancer at early stages.

- One finding that may raise concern for ovarian cancer is a pelvic mass. Approximately 20% of women will have a pelvic mass during their lifetime.\(^3\) However, not all pelvic masses are cancerous.

- OVA1™ was designed by Vermillion to identify individuals with a pelvic mass who are more likely to have ovarian cancer and who should seek consultation with a gynecological surgeon.
Test information

- The OVA1 test is indicated for the pre-surgical evaluation of women with an ovarian tumor or mass, suspected of having an ovarian neoplasm, when the clinical and radiological evaluations do not suggest the presence of malignancy.\(^3\)
- This test examines the following 5 markers to assess risk:\(^2\)
  - Transthyretin, Apolipoprotein A1, Transferrin, Beta-2 microglobulin, CA-125
- OVA1 test scores range from 0-10.
  - For premenopausal women, an elevated risk is considered 5 or greater.
  - For postmenopausal women, an elevated risk score is 4.4 or greater.

Guidelines and evidence

- The National Comprehensive Cancer Network (NCCN, 2018) stated the following regarding OVA1:\(^2\)
  - “The Society of Gynecologic Oncology (SGC), the FDA, and the Mayo Clinic have stated that the OVA1 test should not be used as a screening tool to detect ovarian cancer. 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).”\(^4\)
- The American College of Obstetrics and Gynecologists (ACOG, 2016) stated the following regarding OVA1:\(^4\)
  - “Serum biomarker panels may be used as an alternative to CA 125 level alone in determining the need for referral to or consultation with a gynecologic oncologist when an adnexal mass requires surgery. These biomarker panels are not recommended for use in the initial evaluation of an adnexal mass, but may be helpful in assessing which women would benefit from referral to a gynecologic oncologist.”
  - “The multivariate index assay has demonstrated higher sensitivity and negative predictive value for ovarian malignancy when compared with clinical impression and CA 125 alone.”
- Several clinical studies in the peer-reviewed publication literature have evaluated the use of OVA1.\(^5\)\(^-\)\(^15\)
OVA1 has the potential to improve some aspects of diagnostic accuracy, particularly sensitivity and negative predictive value, beyond the current disease management strategies for ovarian tumors. When used alongside a clinician’s assessment, some studies have shown that OVA1 has the ability to increase accurate detection of ovarian malignancies, although specificity and positive predictive values suffer. However, the evidence regarding the effects of OVA1 on patient health outcomes among women undergoing surgery for ovarian tumors is not clear and at best, indirect since no studies specifically reported results on patient survival or quality of life (QOL).

Criteria

- This test is considered investigational and/or experimental.

  - Investigational and experimental (I&E) molecular and genomic (MolGen) tests refer to assays involving chromosomes, DNA, RNA, or gene products that have insufficient data to determine the net health impact, which typically means there is insufficient data to support that a test accurately assesses the outcome of interest (analytical and clinical validity), significantly improves health outcomes (clinical utility), and/or performs better than an existing standard of care medical management option. Such tests are also not generally accepted as standard of care in the evaluation or management of a particular condition.

  - In the case of MolGen testing, FDA clearance is not a reliable standard given the number of laboratory developed tests that currently fall outside of FDA oversight and FDA clearance often does not assess clinical utility.

References


3. About OVA1. OVA1 website. Available at: http://vermillion.com/providers/intro-to-ova1/


