TUMOR ANTIGEN BY IMMUNOASSAY: CA 125 TESTING

Policy Number: CMP - 017
Effective Date: January 1, 2018

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply.

UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BACKGROUND

CA 125 is a tumor marker that detects a glycoprotein produced by mesothelial cells of the peritoneum, pleura and pericardium. Elevated serum CA 125 is seen in benign gynecologic conditions including endometriosis and menstruation and other medical conditions including cirrhosis and congestive heart failure. Ovarian cancers, in addition to other nongynecologic cancers such as lymphoma and mesothelioma, cause increased levels.

After CA 125 was identified, the FDA approved its use for cancer surveillance of women with ovarian primaries. Ovarian cancer is the leading cause of gynecologic cancer and the fifth most common cause of cancer death in women. Eighty percent of epithelial ovarian cancers (EOCs) express the antigen. In cancer surveillance, clinicians follow CA 125 levels to monitor response to chemotherapy in patients with EOC. CA 125 levels have also been
followed to detect ovarian cancer recurrence before patients present with clinical evidence of recurrence. It has yet to be determined if its use in this setting will confer a survival advantage.

Because most ovarian cancers are diagnosed at late stage, methods to improve early detection are sought, and
the marker was evaluated for use as a screening test. Despite initial enthusiasm for its use as a biomarker for
ovarian cancer, CA 125, used alone, does not achieve a positive predictive value greater than 10%, and only
slightly more than half of all women with stage 1 ovarian cancer have elevated CA 125 levels. While CA 125 is no
longer viewed as a marker that could be applied to the general population for ovarian cancer screening
programs, providers utilize CA 125 and transvaginal ultrasound to follow women at high risk for ovarian cancer
(those patients with a family history of cancer or with BRCA mutations).

The National Comprehensive Cancer Network suggests biannual transvaginal ultrasound and CA 125
determination could begin at age 35, or 5-10 years earlier than the earliest age of first diagnosis of ovarian
cancer in the patient’s family, for those women who opt not to undergo a prophylactic salpingo-oophorectomy.
For diagnostic purposes, the tumor marker is used by clinicians to workup patients with ovarian malignancy
symptoms, including bloating, urinary frequency, and abdominal pain.

The FDA has recently approved the use of a clinical algorithm for following levels of CA 125 and HE4 (human
epididymis protein 4, the only other FDA-approved biomarker for ovarian cancer surveillance) in women with
pelvic masses. In this setting, women are triaged to gynecologic cancer centers for staging protocols if the test
results indicate an increased risk of EOC.

**POLICY**

BeaconLBS recommends that for the following CPT code(s) in Table 1, the patient should have a diagnosis (ICD-10-CM) code(s) listed in the attached files below.

**Table 1. HCPCS Codes (Alphanumeric, CPT® AMA)**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>86304</td>
<td>Immunoassay for tumor antigen, quantitative, CA 125</td>
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</table>

**ICD-10 Diagnosis Codes (Proven)**

CMP_017 CA 125
Testing ICD10_v2.3
REFERENCES


POLICY HISTORY/REVISION HISTORY

<table>
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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>12/07/2017</td>
<td>Annual Policy Review Completed – Updated ICD10 codes as per CMS recommendations.</td>
</tr>
<tr>
<td>01/21/2017</td>
<td>Updated ICD10 codes as per CMS recommendations. Removed ICD9 code file.</td>
</tr>
<tr>
<td>12/03/2015</td>
<td>Annual Policy Review Completed – Changes made: Added diagnosis codes related to malignancy:</td>
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<td></td>
<td>ICD9 diagnosis codes: 158.0, 197.6, V76.46</td>
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<td></td>
<td>ICD10 diagnosis codes: C48.0, C78.6, Z12.73</td>
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<tr>
<td>10/01/2015</td>
<td>Removed ICD9 table. Embedded ICD9/ICD10 PDF files.</td>
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