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Subject: Cancer Antigen 125 Testing
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Description

- This document addresses ~~the~~ tumor marker cancer antigen 125 (CA-125) testing.

Clinical Indications

Medically Necessary:

- I. CA-125 testing is considered **medically necessary** for **either** clinical scenario (A or B) **and** the following conditions (C):
 - A. As part of initial evaluation for suspected or diagnosed disease; **or**
 - B. To determine whether residual tumor exists post-surgical therapy;
 - and**
 - C. Conditions^{*}:
 1. Appendiceal adenocarcinoma; **or**
 2. Endometrial cancer; **or**
 3. Ovarian, primary peritoneal or fallopian tube cancer; **or**
 4. Pancreatic adenocarcinoma; **or**

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5. Peritoneal mesothelioma; or
6. Uterine neoplasms (endometrial cancer and uterine sarcoma).

II. CA-125 testing is considered **medically necessary** for evaluation of a pelvic or abdominal mass when malignancy is suspected.

I. CA-125 testing is considered **medically necessary** when there are signs or symptoms suggestive of ovarian cancer. (for example, ascites, abdominal distension, bloating, pelvic/abdominal pain, difficulty eating or feeling full quickly, urinary symptoms).

III.

IV. CA-125 testing is considered **medically necessary** for the *surveillance* of ovarian cancer in individuals with hereditary breast and ovarian cancer syndrome starting at age 30 years until the time they choose to pursue risk-reducing bilateral salpingo-oophorectomy.

V. Repeat CA-125 testing* is considered **medically necessary** when used to:

- A. Monitor response to therapy; or
- B. Assess for recurrence when suggested by clinical factors.

*See Discussion/General Information section below for additional information on medical society guideline recommendations regarding the clinical appropriateness of testing frequency.

CA-125 testing is considered **medically necessary** for any of the following:

- Suspected ovarian cancer:
 - Evaluation of a pelvic or abdominal mass in postmenopausal individuals; or
 - Evaluation of a pelvic or abdominal mass suspicious for an epithelial ovarian cancer or other specified malignancy in premenopausal individuals; or
 - Evaluation of an individual with signs or symptoms suggestive of ovarian cancer (for example, ascites, abdominal distention, bloating, pelvic/abdominal pain, difficulty eating or feeling full quickly, urinary symptoms); or
- I. Management of ovarian cancer:
 - a. As an aid in the monitoring of disease; or
 - a. Assessing response to treatment; or
 - a. As an aid to a surgical procedure; or

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- a. ~~Detection of recurrent disease; or~~
- 1. ~~Management of endometrial cancer:

 - ~~As an aid to a surgical procedure; or~~
 - ~~When elevated at diagnosis, to be used as an aid in the monitoring of disease, assessment of response to treatment and monitoring for recurrent disease; or~~~~
- 1. ~~Surveillance in individuals with hereditary breast and ovarian cancer syndrome starting at age 30 years until the time they choose to pursue risk-reducing bilateral salpingo-oophorectomy; or~~
- 1. ~~Evaluation or management of the following malignancies:

 - ~~Appendiceal adenocarcinoma; or~~
 - ~~Pancreatic adenocarcinoma; or~~
 - ~~Peritoneal mesothelioma; or~~
 - ~~Uterine neoplasms.~~~~

Not Medically Necessary:

CA-125 testing is considered **not medically necessary** when the above criteria are not met, including, but not limited to, as a screening test in an average risk ~~population~~ individuals.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Medically Necessary:

CPT

86304 Immunoassay for tumor antigen, quantitative; CA 125

ICD-10 Diagnosis

C18.1 Malignant neoplasm of appendix
 C25.0-C25.9 Malignant neoplasm of pancreas
 C45.1 Mesothelioma of peritoneum
 C48.0-C48.8 Malignant neoplasm of retroperitoneum and peritoneum

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C51.8	Malignant neoplasm of overlapping sites of vulva
C53.0-C55	Malignant neoplasm of cervix uteri, corpus uteri, uterus part unspecified
C56.1-C56.9	Malignant neoplasm of ovary
C57.00-C57.9	Malignant neoplasm of other and unspecified female genital organs
C7B.04	Secondary carcinoid tumors of peritoneum
C76.2-C76.3	Malignant neoplasm of abdomen, pelvis
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C79.60-C79.63	Secondary malignant neoplasm of ovary
C79.82	Secondary malignant neoplasm of genital organs
D07.0-D07.39	Carcinoma in situ of endometrium, vulva, vagina, other and unspecified female genital organs
D25.0-D26.9	Leiomyoma of uterus, other benign neoplasms of uterus
D27.0-D27.9	Benign neoplasm of ovary
D39.0-D39.9	Neoplasm of uncertain behavior of female genital organs
D48.114	Desmoid tumor, intraabdominal
D48.3-D48.4	Neoplasm of uncertain behavior of retroperitoneum, peritoneum
D49.59	Neoplasm of unspecified behavior of other genitourinary organ
G89.3	Neoplasm related pain (acute) (chronic)
N32.81	Overactive bladder
N39.41-N39.498	Other specified urinary incontinence
N73.0-N73.9	Other female pelvic inflammatory diseases
N80.00-N80.399	Endometriosis of uterus, ovary, fallopian tube, pelvic peritoneum
R10.0-R10.9	Abdominal and pelvic pain
R14.0	Abdominal distension (gaseous)
R18.0-R18.8	Ascites
R19.00-R19.09	Intra-abdominal and pelvic swelling, mass and lump
R32	Unspecified urinary incontinence
R35.0-R35.89	Polyuria
R39.15	Urgency of urination
R63.30-R63.39	Feeding difficulties
R68.81	Early satiety
R97.0-R97.1	Elevated carcinoembryonic antigen [CEA], elevated cancer antigen 125 [CA 125]
R97.8	Other abnormal tumor markers
Z15.01-Z15.02	Genetic susceptibility to malignant neoplasm of breast, ovary
Z80.3	Family history of malignant neoplasm of breast
Z80.41	Family history of malignant neoplasm of ovary
Z80.49	Family history of malignant neoplasm of other genital organs

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Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.41-Z85.44	Personal history of malignant neoplasm of cervix uteri, other parts of uterus, ovary, other female genital organs
Z85.831	Personal history of malignant neoplasm of soft tissue
Z86.002	Personal history of in-situ neoplasm of other and unspecified genital organs

When services are Not Medically Necessary:

For the procedure codes listed above for all other diagnoses not listed.

Discussion/General Information

Cancer antigen 125 (CA-125) is a type of tumor marker. It is commonly expressed by epithelial ovarian neoplasms and other tissues, such as cells lining the endometrium, fallopian tubes, pleura, peritoneum, and pericardium. High levels of tumor markers such as CA-125 in the blood may also be a sign of cancer. CA-125 testing may be used to monitor how well cancer treatments are working or if cancer has reoccurred. However, elevated levels of CA-125 may also be present in instances of endometriosis, pregnancy, pelvic inflammatory disease, and nongynecologic cancer. These instances of potential fluctuation in CA-125 levels can lead to false positive results and limited specificity.

Ovarian Cancer

[Signs and symptoms suggestive of ovarian cancer include ascites, abdominal distension, bloating, pelvic/abdominal pain, difficulty eating or feeling full quickly and urinary symptoms.](#)

The National Comprehensive Cancer Network[®] (NCCN) guidelines for Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer (NCCN, 2024) recommend CA-125 testing for those who present with a suspicious or palpable pelvic mass on abdominal/pelvic exam, and/or ascites, or abdominal distention. The NCCN also recommends CA-125 testing for those with symptoms not without source of malignancy (that is, bloating, pelvic/abdominal pain, difficulty eating or feeling full quickly, and urinary symptoms [urgency or frequency]). In addition, the NCCN guidelines recommend CA-125 testing for individuals with a new diagnosis of ovarian cancer after a recent surgical procedure and as part of a preoperative workup. This is based on data showing that CA-125 levels correlate with the extent of the disease, the clinical course of the disease which can assist in treatment planning, monitoring response to therapy, and surveillance for recurrence. The NCCN guideline also notes “Primary peritoneal and fallopian tube cancers are treated in the same manner as epithelial ovarian cancer.” The NCCN guidelines note it is appropriate to monitor for ovarian cancer with CA-125 as clinically indicated prior to

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each cycle of chemotherapy and after completion of primary therapy. Monitoring and follow-up may be appropriate after primary treatment if CA-125 was initially elevated. Testing for recurrent disease may be appropriate with a rising CA-125 if there was no previous chemotherapy, a serially rising CA-125 if there was previous chemotherapy, and for platinum-sensitive disease if there is a rising CA-125 without radiographic evidence of disease.

The 2016 American College of Obstetricians and Gynecologists (ACOG) practice bulletin for evaluation and management of adnexal masses states that using CA-125 in the evaluation of adnexal masses is most useful in those who are postmenopausal and in identifying nonmucinous epithelial cancer. For those with epithelial ovarian cancer, the CA-125 level is elevated in 80% of individuals.

Surveillance of ovarian cancer, including concurrent transvaginal ultrasound (TVUS) and testing of CA-125, may be appropriate for certain high-risk individuals (specifically, carriers of high penetrance hereditary breast and ovarian cancer syndrome-associated mutations with a strong family history of breast and ovarian cancer) who are of the age range of recommended risk-reducing salpingo-oophorectomy and opt not to pursue it. Studies of concurrent testing with CA-125 and TVUS in high-risk individuals are largely limited to observational studies and have found that most detected cancers (70 to 80 percent) are stage III or IV, with a positive predictive value of 26% for incident screening. The 2024 NCCN guidelines for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic along with the American Cancer Society and ACOG suggest that screening may be appropriate in individuals with a diagnosed genetic syndrome that increases the lifetime risk for ovarian and breast cancer and have not or not yet elected to pursue risk-reducing removal of bilateral tubes/ovaries.

Neither current literature nor the United States Preventive Services Task Force (USPSTF) support routine screening for ovarian cancer in asymptomatic individuals. The 2017 ACOG committee opinion titled “The Role of the Obstetrician–Gynecologist in the Early Detection of Epithelial Ovarian Cancer in Women at Average Risk” concludes:

The use of transvaginal ultrasonography and tumor markers (such as CA 125), alone or in combination, for the early detection of ovarian cancer in average-risk women have not been proved to reduce mortality, and harms exist from invasive diagnostic testing (eg, surgery) resulting from false-positive test results.

In 2016, Pinsky and colleagues reported an analysis of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial with extended mortality follow-up for 6 years. Those in the intervention arm were screened for ovarian cancer with annual trans-vaginal ultrasound and CA-125. There was a total of 187 deaths from ovarian cancer in the intervention arm and 176 deaths in the usual care arm, for a risk-ratio of 1.06 (95% confidence interval [CI], 0.87–1.30). The authors concluded there was no mortality benefit from screening for ovarian cancer with CA-125 and transvaginal ultrasound.

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A 1996 prospective study by Jacobs and colleagues analyzed the risk of epithelial ovarian cancer and fallopian tube cancer in asymptomatic, postmenopausal individuals with an elevated CA-125. The authors concluded that an elevated CA-125 was a predictor of ovarian cancer with a relative risk of 35.9 (95% CI, 18.3 to 70.4) during the year after a screen and 14.3 (8.5 to 24.3) during the 5 years after a screen. However, in 2009 Partridge and colleagues (as part of the PLCO Cancer Screening Trial) reported whether annual screening with transvaginal ultrasound and CA-125 reduces ovarian cancer mortality. The authors found “the surgery to detected cancer ratio was 19.5 to 1, and 72% of screen detected cancers were late stage.”

Individuals who are premenopausal have a higher likelihood of having benign gynecologic conditions. However, positive predictive value (PPV) is low even in those who are postmenopausal. In the detection of ovarian cancer in postmenopausal individuals, specificity of a single CA-125 ranged from 98.6% to 99.4% which resulted in a low PPV of 3% (Einhorn, 1992; Zurawski, 1988). PPV for invasive cancer among healthy women ages 55 to 74 years old was similarly low.

Screening for ovarian cancer can be challenging due to the low disease prevalence in those at average risk. Testing strategies should include those with high specificity and sensitivity to minimize false-positive tests. Screening for those at average risk with CA-125 has not been shown to reduce mortality.

Endometrial Cancer

Along with expert review, the 2024 NCCN guideline for Uterine Neoplasms considers CA-125 in the initial evaluation of endometrial cancer and as an aid to a surgical procedure. The NCCN guidelines note it is appropriate to test for CA-125 when there is suspected extraperitoneal disease as this may be helpful in monitoring clinical response and for surveillance if the CA-125 is initially elevated.

A single-center retrospective chart review by LyBarger and colleagues in 2022 reported the odds ratio (OR) and relative risks (RR) between preoperative levels of CA-125 and the likelihood of a positive (+) lymph node metastasis and + lymphovascular space invasion. Using preoperative levels of CA-125, risk factors for + lymph node metastasis could distinguish those who are more likely to benefit from lymphadenectomy versus those who would not. There were 890 participants included. There was an increase in the median CA-125 and for those with + lymph node metastasis and + lymphovascular space invasion. Also, as stage and grade of disease increased, CA-125 generally increased. The RR and OR tended to increase above a CA-125 threshold of 35U/ml for all participants. The participants who had a CA-125 level of 9U/ml, 10U/ml, or 12U/ml had a decrease in risk of +lymph node metastasis 87, 88, and 72% respectively. With a CA-125 level of 222U/ml or greater, the largest increase in risk for participants having stage II/III/IV disease was 52% greater than for stage I and the largest risk for those having stage III/IV disease was 66% greater. Participants with a CA-125 of 122U/ml or greater showed a significantly increased risk of +lymph node metastasis and those with a CA-125 of 199 U/ml or greater showed a

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significantly increased risk of + lymphovascular space invasion. The authors concluded an elevated preoperative CA125 is associated with an increased risk of elevated stage, + lymphovascular space invasion, +lymph node metastasis, and higher grade, which could be associated with less favorable outcomes.

Hereditary Breast and Ovarian Cancer

The 2024 NCCN guideline for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic notes that for individuals diagnosed with a genetic syndrome that increases the lifetime risk for ovarian and breast cancer and have not or not yet elected to pursue risk-reducing removal of bilateral tubes/ovaries, CA-125 results using the risk of ovarian cancer algorithm (ROCA) protocol in high-risk individuals suggest a stage shift. Conclusions were based on a study of 4348 individuals with an estimated lifetime ovarian cancer risk no less than 10% who underwent ovarian cancer screening via serum CA-125 tests every 4 months (using ROCA protocol). There were 13 participants who were diagnosed with ovarian cancer as a result of the screening protocol, with 5 of the 13 participants being diagnosed with early-stage cancer. The sensitivity, positive predictive value, and negative predictive value of the screening protocol for detecting ovarian cancer within 1 year were 94.7%, 10.8%, and 100%, respectively. The NCCN guidelines note it is appropriate to test for CA-125 for preoperative planning. The NCCN guidelines recommend testing of CA-125 for surveillance but does not provide specific recommendations for routine testing intervals.

The 2017 ACOG Practice Bulletin for Hereditary Breast and Ovarian Cancer Syndrome (ACOG, 2017) states:

In women with BRCA mutations or who have a personal or family history of ovarian cancer, routine ovarian cancer screening with measurement of serum CA 125 level or transvaginal ultrasonography generally is not recommended. Transvaginal ultrasonography or measurement of serum CA 125 level may be reasonable for short-term surveillance in women at high risk of ovarian cancer starting at age 30–35 years until the time they choose to pursue risk-reducing bilateral salpingo-oophorectomy.

Since there is an increased risk for ovarian cancer for those with BRCA mutations, Lentz and colleagues (2020) published results of prospective cohort study in which they used an algorithm which combined two biomarkers (CA-125 and HE4) for early detection of ovarian cancer in those individuals with BRCA mutations. Participants were enrolled into either a Risk of Ovarian Cancer Algorithm (ROCA) (n=149) or Standard of Care (SOC) surveillance (n=43). Surveillance in the ROCA arm was planned at every 4 months while testing in the SOC arm was planned every 6 months. In the ROCA arm, abnormal scores of CA-125 results were 24%, 16% if CA-125 or HE4 was done independently, and 8% when both markers were used. In the SOC arm, abnormal test results were found in 15% of individuals. For those without ovarian cancer, for the two-marker ROCA referral to ultrasound, the average false positive rate was 6.6% (specificity 93.4%) and the two-marker ROCA plus ultrasound for referral to surgical consultation was 1.7% (specificity 98.3%).

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Other Malignancies

Appendiceal cancer is very rare. For those with appendiceal adenocarcinoma, the 2024 NCCN guideline for Colon Cancer recommends CA-125 levels, particularly if CEA and CA 19-9 levels are normal. Also noting that normal CA-125 and CA19-9 levels correspond to an increase in survival and a decrease in recurrence of disease. The NCCN guidelines do not provide specific recommendations for routine testing intervals.

Expert review indicates CA-125 results can be clinically relevant in pancreatic adenocarcinoma, appendiceal adenocarcinoma, peritoneal mesothelioma and uterine neoplasms. The NCCN guideline for Pancreatic Adenocarcinoma notes that for resectable disease, neoadjuvant therapy, borderline resectable disease without metastases, and postoperative adjuvant treatment, CA-125 can be used in individuals who are nonsecreting or in those with normal CA 19-9 levels. The NCCN guidelines do not provide specific recommendations for routine testing intervals.

Peritoneal mesothelioma is a rare form of cancer that affects the peritoneum (the membrane that lines the abdominal cavity and organs). The use of paracentesis fluid (cytology) is not recommended for diagnosis as invasion can't be detected using cytology. The 2024 NCCN guidelines for Mesothelial: Peritoneal recommends CA-125 could be considered for the initial evaluation of peritoneal mesothelial. The NCCN guidelines do not provide specific recommendations for routine testing intervals.

In the evaluation of uterine neoplasms, the 2024 NCCN guideline recommends CA-125 in the initial preoperative evaluation for known or suspected malignancy, suspected extrauterine disease, and in surveillance of disease if the initial CA-125 was elevated. For those with extrauterine disease, CA-125 levels may be helpful to monitor clinical response. In addition, individuals with uterine serous carcinoma, clear cell carcinoma, carcinosarcoma, or undifferentiated/dedifferentiated carcinomas may present with pelvic masses, abnormal cervical cytology, or ascites in addition to postmenopausal bleeding. The NCCN also recommends CA-125 may be useful prior to surgery to assess if extrauterine disease is present. The NCCN guidelines do not provide specific recommendations for routine testing intervals.

Other Relevant Information

[There is long-standing clearance of CA-125 assays by the Food and Drug Administration \(FDA\). The Vitros CA 125 II assay \(Ortho-Clinical Diagnostics, Inc. K983875\) and the ELECSYS CA 125 II assay \(Boehringer Mannheim Corp., K972162\) were cleared in 1998 for use as an aid for monitoring response to epithelial ovarian cancer therapy. Numerous NCCN guidelines recommend CA-125 testing in specific situations \(see above for detailed discussion of these recommendations\). The ACOG practice bulletins on evaluation and management of adnexal masses, and on hereditary breast and ovarian cancer syndrome recommend CA-125 testing in specific situations; ACOG does not recommend CA-125 tests for routine screening for ovarian cancer. National guidelines](#)

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do not recommend CA-125 testing for screening or routine surveillance. The Centers for Medicare & Medicaid Services (CMS) published National Coverage Determinations (NCD) 190.28, Tumor Antigen by Immunoassay - CA 125, which was effective on January 1, 2006. This document establishes when CA-125 testing is covered for Medicare enrollees.

Definitions

Ascites: The accumulation of fluid in spaces within the abdomen.

~~**Biomarker:** A measurable indicator of a biological state or condition obtained from bodily fluids, such as blood or urine, or tissue samples. Biomarkers are used to diagnose diseases, monitor disease progression, predict disease prognosis, and track treatment response.~~

~~**Diagnostic Test:** A test conducted on individuals who exhibit signs, symptoms, or risk factors of a particular condition for the purpose of identifying the presence or absence of a specific disease or condition.~~

~~**Prognostic Test:** A test performed on individuals who have been diagnosed with a disease. Tests are used to predict the probable outcome or prognosis of the disease, provide information about the likelihood of disease progression, response to treatment, or overall survival.~~

~~**Progression:** Disease worsens or spreads without ever having gone away.~~

~~**Recurrence:** Cancer that has returned post treatment, often undetected for a certain period of time. The recurrence can happen at the same location as the initial tumor or at a different site in the body.~~

~~**Screening Test:** A test administered to individuals when there are no signs or symptoms of a specific condition.~~

~~**Surveillance:** It is used to detect early signs of recurrence in diseases, particularly cancer, or to monitor individuals at an increased risk of a disease.~~

~~**Tumor Marker:** Any element found in or generated by cancer cells or other body cells in reaction to cancer or certain noncancerous conditions. This marker gives vital information about the cancer, including its aggressiveness, whether it is treatable with specific therapy, or its responsiveness to ongoing treatment.~~

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Uterine neoplasm: A type of cancer which forms in the tissues of the uterus. Two types of uterine cancer are endometrial cancer (which begins in the cells lining the uterus) and uterine sarcoma (which begins in the muscle or other tissues in the uterus).

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4. Johnson CC, Kessel B, Riley TL, et al. The epidemiology of CA-125 in women without evidence of ovarian cancer in the prostate, lung, colorectal and ovarian cancer (PLCO) screening trial. Gynecol Oncol. 2008; 110(3):383-389.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. ACOG Committee Opinion Number 716: The role of the obstetrician–gynecologist in the early detection of epithelial ovarian cancer in women at average risk. Obstet Gynecol. 2017; 130(3):e146-e149.
2. ACOG Practice Bulletin No. 174: Evaluation and management of adnexal masses. Obstet Gynecol. 2016; 128(5):e210-e226.
3. ACOG Practice Bulletin No. 182: Hereditary breast and ovarian cancer syndrome. Obstet Gynecol. 2017; 130(3):e110-e126.

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4. [Centers for Medicare and Medicaid Services \(CMS\). National Coverage Determination 190.28 Tumor antigen by immunoassay - CA 125.](https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=130&ncdver=2) Available at: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=130&ncdver=2>. Accessed on July 11, 2024.
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 - Colon Cancer (V34.2024). Revised ~~July 3~~ May 24, 2024.
 - Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic (V3.2024) Revised February 12, 2024.
 - Mesothelial: Peritoneal (V1.2024). Revised November 21, 2023.
 - Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer (V23.2024) Revised ~~July 15~~ May 13, 2024.
 - Pancreatic Adenocarcinoma (V23.2024). Revised ~~August 2~~ April 30, 2024.
 - Uterine Neoplasms (V2.2024). Revised March 6, 2024.

Websites for Additional Information

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- 2.3. [United States Preventive Services Task Force. Recommendation: Ovarian cancer. 2018.](https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/ovarian-cancer-screening) Available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/ovarian-cancer-screening>. Accessed on May 17, 2024.

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CA-125

History

Status	Date	Action
Revised	08/08/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised criteria for suspected ovarian cancer and repeat testing, and reformatted

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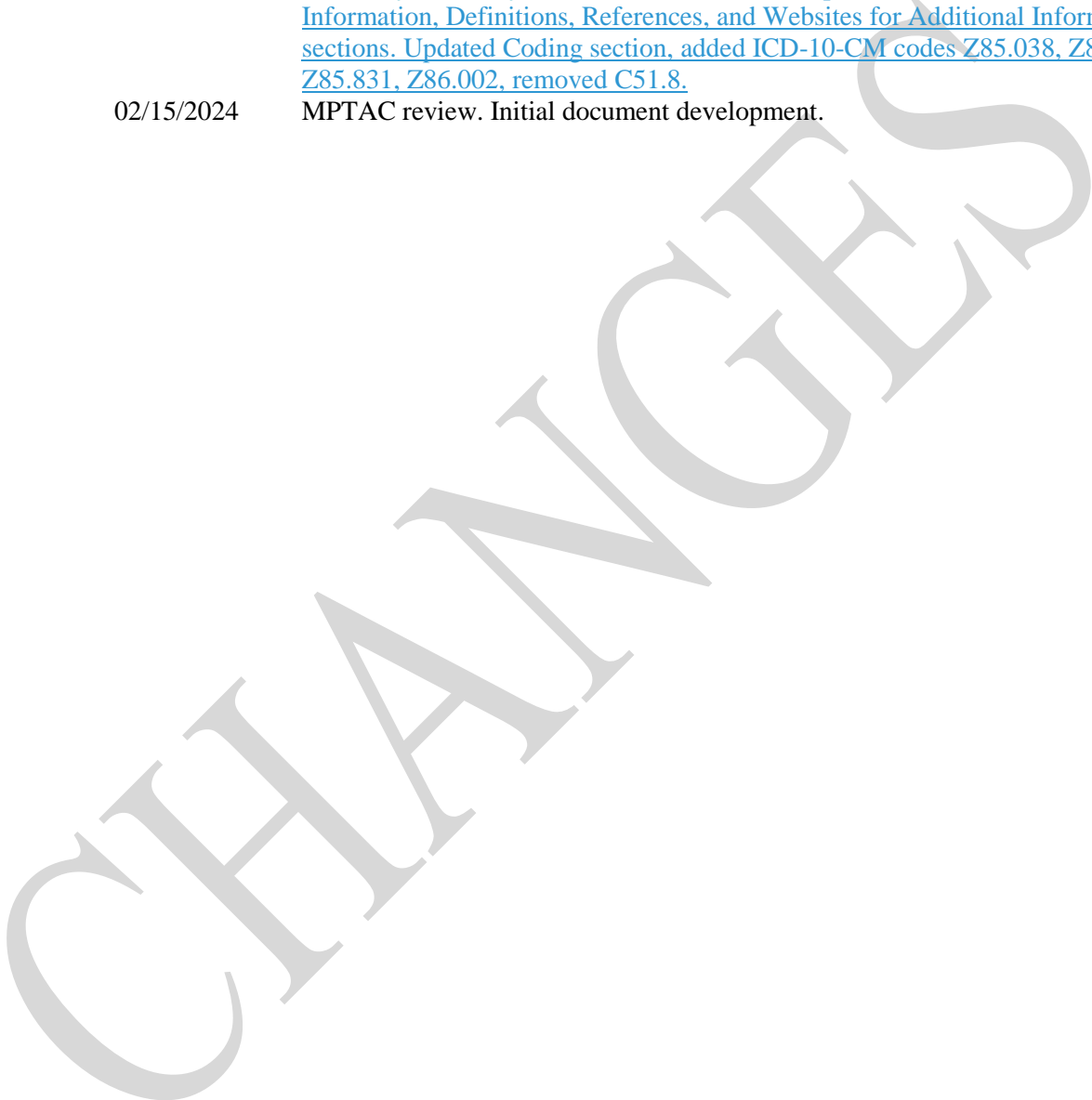
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[medically necessary statements. Revised Description, Discussion/General Information, Definitions, References, and Websites for Additional Information sections. Updated Coding section, added ICD-10-CM codes Z85.038, Z85.07, Z85.831, Z86.002, removed C51.8.](#)

New

02/15/2024

MPTAC review. Initial document development.



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