Medical Coverage Policy

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Transvaginal Ultrasound, Non-Obstetrical

Table of Contents

Overview 2
Coverage Policy 2
Health Equity Considerations 2
General Background 2
Medicare Coverage Determinations 9
Coding Information 9
References 13
Revision Details 17

Related Coverage Resources

Infertility Services
Molecular and Proteomic Diagnostic Testing for Hematology and Oncology Indications
Ultrasound in Pregnancy (including 3D, 4D and 5D Ultrasound)

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will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses transvaginal ultrasound (TVUS) used in the evaluation of gynecologic disorders and cancer screening in asymptomatic women in the general population versus those who are at high risk for cancer.

Coverage Policy

For information on obstetric ultrasonography, refer to the Cigna Coverage Policy Ultrasound in Pregnancy (including 3D, 4D and 5D Ultrasound).

For information on infertility-related ultrasonography, refer to the Cigna Coverage Policy Infertility Services.

Non-obstetrical transvaginal ultrasound is considered medically necessary for the evaluation of suspected pelvic pathology or for screening or surveillance of a woman at increased risk for ovarian or endometrial cancer.

Non-obstetrical transvaginal ultrasound is not covered or reimbursable for any other indication including but not limited to screening in the general population for ANY type of cancer.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Ultrasound imaging, also known as ultrasound scanning or sonography is a method of obtaining images from inside the human body through the use of high-frequency sound waves. The echoes of the sound waves are recorded and displayed as a real-time, visual image. Pelvic ultrasound in females may be performed transabdominally or transvaginally. A transvaginal ultrasound (TVU, TVUS) also known as transvaginal sonography (TVS), involves the insertion of the transducer into the vagina. The images are obtained from different orientations to get the best views of the uterus and ovaries.

Transabdominal and transvaginal scanning are both useful in the evaluation and treatment of a number of pelvic pathologies. One of the more valuable roles of TVUS is evaluating unexplained bleeding in the postmenopausal woman. A thickened or highly echogenic endometrium in a postmenopausal patient can suggest the presence of polyps, abnormal endometrial histology such as adenomatous hyperplasia, or cancer. TVUS can provide information about the location of a pelvic mass relative to the ovary and uterus and provides higher resolution for better delineation of the internal architectural characteristics compared to a transabdominal ultrasound. TVUS also plays a role in evaluating patients with acute pelvic pain. Normal-appearing ovaries with no free intraperitoneal fluid on TVUS essentially eliminates an ovarian primary source for acute pain. The uterus can be evaluated sonographically, and pathologic causes of pelvic pain such as uterine fibroids, with or without degeneration, can be ruled out. TVUS is used in the evaluation of the infertile patient, particularly in the management of controlled ovarian hyperstimulation, which is necessary for modern assisted reproductive technology such as in vitro fertilization (IVF) (Gibbs, et al., 2008).

TVUS has also been investigated as a screening tool for cancer, primarily ovarian and endometrial, in women who are at average risk for malignancy. Screening and diagnostic methods for ovarian cancer include pelvic examination, CA-125 antigen as a tumor marker, TVUS, and potentially, multimarker panels and bioinformatic analysis of proteomic patterns. TVUS is capable of detecting small ovarian masses and may distinguish some benign masses from some malignant adnexal masses, although it poorly predicts which masses are cancers and which are due to benign diseases of the ovary. As an independent test, TVUS has shown poor performance in the detection of ovarian cancer in average-risk or high-risk women (Fishman, et al., 2005).

The risk for ovarian cancer is increased when there is a hereditary cancer syndrome (e.g., breast-ovarian cancer syndrome, Lynch syndrome [hereditary nonpolyposis colon cancer]). In these hereditary cancer syndromes, ovarian cancer typically occurred in a first- or second-degree relative at under age 50, or relatives in two or more generations had ovarian or related cancers (Carlson, 2022). Endometrial carcinoma risk factors include excess estrogen without adequate opposition by a progestin, tamoxifen therapy, obesity, and nulliparity. Additionally, women with Lynch syndrome are at a markedly increased risk of endometrial cancer (Chen and Berek, 2022a).

Chen and Berek (2022b) published data from the United States National Cancer Database Surveillance, Epidemiology, and End Results (SEER). There are approximately 1.3% of women in the United States that will be diagnosed with ovarian cancer at some point during their lifetime. The incidence rates are higher in White women (11.9 per 100,000) than in women who are Hispanic (10.3 per 100,000), Asian/Pacific Islander (9.4 per 100,000), Black (9.2 per 100,000), or American Indian/Alaska Native (8.1 per 100,000). The incidence rates have been falling: from 16.3 per 100,000 women in 1975 to 10.1 per 100,000 in 2016.

Intrauterine contraception is highly effective, safe, and generally well tolerated by most women. Intrauterine device (IUD) insertion and removal are usually relatively simple procedures that can be performed in the office setting by trained providers. The technical skills required for device insertion and removal can be obtained through hands-on training in the clinical setting and/or may be provided by the manufacturers of these devices (Bartz and Pocius, 2022). IUDs are considered appropriate for the majority of women, including nulliparous women and adolescents. Insertion can be done at any time during the menstrual cycle, immediately postpartum, within four weeks of placental delivery, and post abortion. Complications from IUD placement are relatively rare. The most common complication is IUD expulsion, which occurs in approximately 2–10% of cases. Patients should be encouraged to feel for their IUD strings on a regular basis at home to ensure correct placement. Method failure and uterine perforation are rare complications of IUD use. Severe pain or loss of resistance during IUD insertion are signs of perforation (Hagood, 2021). Ultrasound guidance is not required for IUD placement, but it can be useful in resolving difficult

IUD insertions. Specifically, ultrasound guidance has been proposed to guide dilator insertion in women with cervical stenosis or a tortuous cervical canal and to aid in identification of distorted uterine anatomy such as sharp uterine flexion (anteverted or retroverted) or fibroids (Bartz and Pocius, 2022).

U.S. Food and Drug Administration (FDA)
A number of ultrasound devices and probes have received FDA approval. The FDA notes that these devices are considered prescription devices and are to be used only with a physician's order.

Literature Review
Ovarian Cancer: Large clinical trials have evaluated the efficacy of TVUS in screening for ovarian cancer. Jacobs et al. (2016) reported results of a multicenter randomized controlled trial (RCT) (n=202,638) to evaluate the effect of early detection by screening ovarian cancer mortality. Postmenopausal women aged 50–74 years were assigned to multimodal screening (MMS) (n=50,640), annual transvaginal ultrasound screening (USS) (n=50,639), or no screening (n=101,359). Multimodal screening consisted of serum CA-125 interpreted with use of the risk of ovarian cancer algorithm. Exclusion criteria were previous bilateral oophorectomy or ovarian malignancy, increased risk of familial ovarian cancer, and active non-ovarian malignancy. The primary outcome was ovarian cancer death; secondary outcomes included death due to ovarian and primary peritoneal cancer, and complications related to screening and false-positive surgery. At a median follow-up of 11.1 years, ovarian cancer was diagnosed in 1282 (0.6%) women: 338 (0.7%) in the MMS group, 314 (0.6%) in the USS group and 630 (0.6%) in the no screening group. The overall sensitivity for detection of ovarian cancers, diagnosed within a year of a screening, was 84% in the MMS group and 73% in the USS group. Of the primary peritoneal cancers, 81% (13/16) were screen detected with MMS and 30% (3/10) were with USS. A total of 649 (0.32%) women died of ovarian cancer: 347 (0.34%) in the no screening group, 148 (0.29%) in the MMS group and 154 (0.30%) in the USS group. The relative mortality reduction was 15% in the MMS group and 11% in the USS group; these reductions were not found to be statistically significant. Post-hoc analysis suggested a significant reduction in ovarian cancer mortality in the MMS group compared to the no screening group, but not in the USS group. Women in the MMS group had a complication rate of 3.1%, and those in the USS group had a rate of 3.5%. The authors noted that although study results provide encouraging evidence of a mortality reduction, further follow-up is needed to draw firm conclusions on the effectiveness of ovarian cancer screening.

Menon et al. (2021) reported the long term results of the ovarian cancer mortality in the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS). At a median follow-up of 16.3 years ovarian cancer was diagnosed in 2055 women: 522 (1·0%) of 50,625 in the multimodal screening (MMS) group, 517 (1·0%) of 50,623 in the annual transvaginal ultrasound screening (USS group) and 1016 (1·0%) of 101,314 in the no screening group. The MMS group had a 47·2% increase in stage I and 24·5% decrease in stage IV disease incidence when compared to the no screening group. Overall the incidence of stage I or II disease was 39·2% higher in the MMS group than in the no screening group, whereas the incidence of stage III or IV disease was 10·2% lower. A total of 1206 women died of the disease: 296 (0·6%) of 50,625 in the MMS group, 291 (0·6%) of 50,623 in the USS group, and 619 (0·6%) of 101,314 in the no screening group. No significant reduction in ovarian and tubal cancer deaths was observed in the MMS (p=0·58) or USS (p=0·36) groups compared with the no screening group. The authors concluded that the reduction in stage III or IV disease incidence in the MMS group was not sufficient to translate into lives saved, which demonstrated the importance of specifying cancer mortality as the primary outcome in screening trials. The screening did not significantly reduce ovarian and tubal cancer deaths therefore general population screening cannot be recommended.

Buhling et al. (2017) performed a systematic review (n=3 RCTs/36,343 subjects). Inclusion criteria were studies that contained at least one population-based intervention screening group with annual TVUS, at least one group of postmenopausal women aged 45 years or older with no personal history or current symptoms associated with ovarian cancer, and at least three years of follow-up. Subjects with a history of bilateral oophorectomy were excluded. A change in mortality, the primary outcome, was not demonstrated by using TVUS for annual screening. It was noted that the heterogeneity in study methods, algorithms and intervention groups, which limited the ability to make comparisons. Evidence of a mortality reduction was found in years seven through 14, but the authors stated, "further follow-up is needed before firm conclusions can be reached on the efficacy and cost-effectiveness of ovarian cancer screening".

Reade et al. (2013) conducted a systematic review and meta-analysis (n=10 RCTs/thousands of subjects) to assess the risks and benefits of screening asymptomatic women for ovarian cancer. Studies were eligible if asymptomatic women were assigned to either screening for ovarian cancer or no intervention, usual care, or education regarding the signs and symptoms of ovarian cancer. All forms of screening were eligible, as were trials including women at high or low risk of ovarian cancer. Screening by TVUS alone occurred in three trials. High risk was defined as having a known BRCA 1/2 mutation or Lynch syndrome, or a strong family history of ovarian cancer. The primary outcomes for this review included all-cause and ovarian cancer specific mortality, and the number of surgeries performed to detect one case of ovarian cancer. Secondary outcomes included rates of false-positive screening tests and complications associated with unnecessary surgery. Moderate quality evidence from two trials suggested no benefit of screening for reducing ovarian cancer-specific mortality (RR=1.08, 95% CI 0.84–1.38). High quality evidence from a single trial suggested no benefit from ovarian cancer screening for reducing all-cause mortality (RR=1.0, 95% CI 0.96 to 1.06). In the eight trials that reported rates of false positive screening, 10.6% of screened women required additional testing because of abnormal results. A total of nine surgeries were needed to detect one case of ovarian cancer in the pooled estimate across screening arms of the eight trials. Screening for ovarian cancer with TVUS alone resulted in 38 surgeries to detect one case of cancer. Moderate quality evidence suggested that the risk of a severe complication while undergoing surgery where ovarian cancer was not detected was 6%. Acknowledged limitations of this review included the lack of control group information, as a better measure of harm associated with screening would be the total number of surgeries performed for suspected ovarian cancer in both the screening and control groups. Results of this study indicate that screening asymptomatic, low-risk women for ovarian cancer does not reduce mortality and is associated with unnecessary surgical procedures.

Buys et al. (2011) reported results of the Prostate, Lung, Colorectal and Ovarian Cancer Screening (PLCO) Trial, a randomized, controlled trial (n=78,216) conducted in the United States to determine the impact of screening on cause-specific mortality for several types of cancer, including ovarian cancer. Women aged 55 to 74 years were randomized to receive either annual screening with CA-125 testing for six years and TVUS for four years or usual medical care. After excluding women with a prior bilateral oophorectomy, 68,557 women remained in the analysis. Women were followed up for a maximum of 13 years, with a median follow-up of 12.4 years. Ovarian, primary peritoneal, and fallopian tube cancer were all considered ovarian cancer cases for this study. Among the 34,253 women in the intervention/screening group, 212 ovarian cancer cases and 118 ovarian cancer deaths were identified. Among the 34,304 women in the usual care group, there were 176 ovarian cancer cases and 100 ovarian cancer deaths. No reduction in ovarian cancer mortality was observed in the intervention group compared with those receiving usual care (mortality rate ratio [RR], 1.18 [95% CI, 0.82–1.71]). The trial concluded that screening women at average risk for ovarian cancer with CA 125 testing and TVUS did not reduce ovarian cancer mortality compared with usual care. In 2017, Pinsky et al. published updated PLCO mortality data for an additional three to six years, which extended the total period of follow-up to 13–19 years from randomization. A total of 187 (intervention) and 176 (usual care) deaths from

ovarian cancer were observed, for a risk-ratio of 1.06 (95% CI: 0.87–1.30). Ovarian cancer specific survival was not significantly different across trial arms (p=0.16). The authors concluded that extended follow-up of PLCO indicated no mortality benefit from screening for ovarian cancer with CA-125 and TVUS.

Other studies of average-risk populations have shown TVUS to produce a high number of false-positives (Partridge, et al 2009; Van Nagell, et al., 2007; Lacey, et al., 2006; Buys, et al., 2005). The CA–125 blood test also has a high false-positive rate. Although combining the two tests and stratifying women into risk groups based on family history does increase the positive predictive value somewhat, studies failed to demonstrate a beneficial effect of screening on mortality (Evans, et al., 2009; Van Nagell, et al., 2007; Hermsen, et al., 2007; Woodward, et al., 2007; Lacey, et al., 2006; Bosse, et al., 2006).

There is insufficient evidence in the published peer-reviewed medical literature to lend support to TVUS used as a screening tool for ovarian cancer.

Endometrial Cancer: Fewer large-scale studies have investigated TVUS as a possible screening test for endometrial cancer. Yasa et al. (2016) published the results of a retrospective cohort study (n=276) that assessed the diagnostic accuracy of endometrial thickness measurements via TVUS for the detection of endometrial malignancy. Consecutive asymptomatic postmenopausal women undergoing dilatation and curettage (D&C) and hysteroscopy for an incidental finding of thickened endometrium (≥ 4mm) were included. Different endometrial thickness cutoff values were tested on the basis of a pathologic report with carcinoma conditions (e.g., endometrial hyperplasia with atypia, endometrial carcinoma). The final pathology diagnoses included polyps (n=107) (38.8%), atrophic endometrium (n=42) (15.2%), estrogen exposure (n=39) (14.1%), and normal endometrium (n=19) (6.9%). For carcinoma conditions, nine patients (3.3%) had endometrial hyperplasia with atypia and eight patients (2.9%) had endometrial carcinoma. Endometrial samples were reported as insufficient tissue in 52 (18.8%) patients of the study group. The positive predictive values (PPVs) for carcinoma-related conditions for all given endometrial thickness cutoff values were between 6.1 and 9.6%. The negative predictive values (NPVs) of TVUS were between 94.8 and 100% at all endometrial thickness cutoff values for carcinoma-related conditions. The area under the ROC curve was 0.52 (95% CI 0.44-0.57), which indicated a poor accuracy of endometrial thickness of TVUS for carcinoma conditions. The authors noted that routine use of endometrial thickness measurement with TVUS does not seem to be an effective diagnostic tool for endometrial cancer because it has a low diagnostic performance in asymptomatic postmenopausal women. Acknowledged study limitations included the retrospective design and the very low incidence of cancer-related conditions in the cohort, which resulted in poor information about very rare occurrences. Further prospective studies are required to evaluate endometrial thickness measurement with TVUS as a screening method for endometrial malignancy.

Jacobs et al. (2011) conducted a nested case-control study of postmenopausal women (n=48,230) who underwent TVUS in the United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) trial. The primary outcome measured was endometrial cancer and atypical endometrial hyperplasia. Performance characteristics of endometrial thickness and abnormalities for detection of endometrial cancer within one year of TVUS were calculated. Median follow-up was five-11 years. A total of 136 women with endometrial cancer or atypical endometrial hyperplasia within one year of TVUS were included in the primary analysis. The optimum endometrial thickness cutoff for endometrial cancer or atypical endometrial hyperplasia was 5–15 mm, with sensitivity of 80.5% and specificity of 86.2%. For the analysis of the women with endometrial cancer or atypical endometrial hyperplasia who reported no symptoms of postmenopausal bleeding before diagnosis and had an endometrial thickness measurement available (n=96), a cutoff of 5 mm achieved a sensitivity of 77.1% and specificity of 85.8%. Study results indicate

that TVUS screening for endometrial cancer may have good sensitivity in postmenopausal women. However, the role of population screening for endometrial cancer remains uncertain.

In high-risk populations, other studies have indicated that TVUS failed to detect endometrial cancer; the efficacy of TVUS screening for endometrial cancer in high-risk women remains unproven by clinical trials (Renkonen-Sinisalo, et al., 2007; Rijcken, et al., 2003). Due to a low positive predictive value, TVUS has not been proven to be an effective screening procedure for detection of endometrial abnormality in average-risk women.

Professional Societies/Organizations
American Cancer Society (ACS): The ACS (2024) published an Ovarian Cancer Fact Sheet for health care professionals. Per the publication, the ACS does not have recommended screening guidelines for ovarian cancer. They indicate studies to identify effective screening tests are underway. In addition to a complete pelvic exam, clinicians may consider offering a transvaginal ultrasound (TVUS) and the CA-125 blood test for people who are at high risk for ovarian cancer.

The 2019 ACS cancer screening guidelines for endometrial cancer were unchanged from the 2011 publication. In 2011, the ACS concluded that there was insufficient evidence to recommend screening for endometrial cancer in women at average risk or who were at an increased risk due to a history of unopposed estrogen therapy, tamoxifen therapy, late menopause, nulliparity, infertility or failure to ovulate, obesity, diabetes, or hypertension. The ACS recommended that women at average and increased risk should be informed about the risks and symptoms (in particular, unexpected bleeding and spotting) of endometrial cancer at the onset of menopause and should be strongly encouraged to immediately report these symptoms to their physicians. Women at very high risk of endometrial cancer due to 1) known Lynch (HNPCC) genetic mutation carrier status; 2) a substantial likelihood of being a mutation carrier (i.e., a mutation is known to be present in the family); or 3) the absence of genetic testing results in families with a suspected autosomal dominant predisposition to colorectal cancer should consider beginning annual testing for early endometrial cancer detection at age 35 years. The evaluation of endometrial histology with endometrial biopsy is still the standard for determining the status of the endometrium. Women at high risk should be informed that the recommendation for screening is based on expert opinion, and they also should be informed about the potential benefits, risks, and limitations of testing for early endometrial cancer detection (Smith, et al., 2019).

American College of Gastroenterology (ACG): The ACG guideline on genetic testing and management of hereditary gastrointestinal cancer syndromes stated that screening for endometrial and ovarian cancer should be offered to women at risk for or affected with Lynch syndrome by endometrial biopsy and transvaginal ultrasound annually, starting at age 30 to 35 years before undergoing surgery or if surgery is deferred (Syngal et al., 2015).

American College of Obstetricians and Gynecologists (ACOG)/Society of Gynecologic Oncology (SGO): The ACOG and SGO published a joint committee opinion on the role of the obstetrician-gynecologist in the early detection of epithelial ovarian cancer in women at average risk (2017, reaffirmed 2021). They stated that TVUS has been evaluated as an early detection method for ovarian cancer under the premise that it may detect changes in ovarian size and morphology before signs or symptoms of cancer develop, and data show it to be ineffective. The guideline further stated that the use of transvaginal ultrasonography and tumor markers (such as CA-125) in average-risk women, alone or in combination, for the early detection of ovarian cancer have not been proved to reduce mortality. There are potential harms that exist from invasive diagnostic testing (e.g., surgery) that could result from false-positive test results. The committee recommended taking a detailed personal and family history for breast, gynecologic, and colon cancer and categorizing women based on their risk (average risk or high risk) of developing epithelial ovarian cancer. The patient and her obstetrician-gynecologist should maintain an

appropriate level of suspicion when potentially relevant signs and symptoms of ovarian cancer are present.

The ACOG and SGO joint practice bulletin on hereditary breast and ovarian cancer syndrome (2017; reaffirmed 2019) stated "available screening procedures (measurement of serum CA-125 and transvaginal ultrasonography) have not been proved to decrease the mortality rate or increase the survival rate associated with ovarian cancer in high-risk populations." However, transvaginal ultrasonography or measurement of serum CA-125 level may be reasonable for short-term surveillance in women at high risk of ovarian cancer (e.g., BRCA mutations, personal or family history of ovarian cancer) who have not had risk-reducing bilateral salpingo-oophorectomy, starting at age 30–35 years.

National Comprehensive Cancer Network® (NCCN®): The NCCN Clinical Practice Guidelines in Oncology for Ovarian Cancer (including fallopian tube and primary peritoneal cancer) states the literature does not support routine screening in the general (asymptomatic) population. While the literature suggests screening (TVUS and/or CA-125) may increase the likelihood of diagnosis at an early disease stage and may slightly lengthen survival in those diagnosed with ovarian cancer, it does not improve ovarian cancer-related mortality (NCCN, 2024a).

The NCCN Clinical Practice Guidelines in Oncology for Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic and Prostate stated that although TVUS combined with serum CA-125 for ovarian cancer screening is of uncertain benefit, it may be considered for at-risk patients who have not elected ovarian cancer risk reducing surgery starting at age 30–35 years, at the clinician's discretion (NCCN, 2023a). Routine TVUS to screen for endometrial cancer in postmenopausal individuals has not been shown to be sufficiently sensitive or specific to warrant a positive recommendation but may be considered at the clinician's discretion. However, TVUS is not recommended as a screening tool in premenopausal individuals due to the wide range of endometrial strip thickness throughout the normal menstrual cycle (NCCN, 2024b).

National Cancer Institute (NCI): The NCI stated that there is "solid evidence to indicate that screening women aged 55 to 74 years at average risk of developing ovarian cancer with the serum marker CA-125 annually for six years and TVUS for four years does not result in a decrease in ovarian cancer mortality, after a median follow-up of 17 years". According to the NCI, solid evidence indicated that screening for ovarian cancer results in false-positives with higher rates of oophorectomy (NCI, 2022c).

The NCI also stated that there is no evidence that screening by ultrasonography (e.g., endovaginal ultrasound or transvaginal ultrasound) reduces mortality from endometrial cancer. Most cases of endometrial cancer (85%) are diagnosed at low stage because of symptoms and therefore survival rates are high. "Based on solid evidence, screening asymptomatic women will result in unnecessary additional biopsies because of false-positive test results. Risks associated with false-positive tests include anxiety and complications from biopsies" (NCI, 2024a).

According to the NCI executive summary on the genetics of colorectal cancer, endometrial cancer is the most common extracolonic cancer observed in Lynch syndrome families, affecting at least one female in about 50% of Lynch syndrome families. Given the increased risk of endometrial cancer, endometrial screening for women with Lynch syndrome has been suggested. Proposed modalities for screening include transvaginal ultrasound (TVUS) and/or endometrial biopsy. TVUS continues to be widely recommended without data to support its use. Lynch syndrome patients/families are also at higher risk of ovarian cancer. However, no studies on the effectiveness of ovarian screening are currently available for women in Lynch syndrome families. TVUS used for endometrial cancer screening has been extended to include ovarian cancer

screening in clinical practice for those women who do not undergo risk-reducing surgery for gynecological cancer prevention (NCI, 2023b).

U.S. Preventive Services Task Force (USPSTF): The 2018 USPSTF recommendation statement on screening for ovarian cancer stated they do not recommend ovarian cancer screening for asymptomatic women who are without known genetic mutations that increase the risk for ovarian cancer. They do not recommend routine screening using any method. Transvaginal ultrasonography and serum CA-125 testing are both highly accessible and most commonly used to evaluate women with signs and symptoms of ovarian cancer, and both have been evaluated in screening studies. The USPSTF evaluated the evidence and concluded that screening for ovarian cancer does not reduce ovarian cancer mortality. Screening can lead to important harms, including false-positive screening test results and subsequent surgery in women who do not have cancer. The harms of screening for ovarian cancer outweigh the benefits. The report further stated that women with BRCA1 and BRCA2 genetic mutations are at increased risk for ovarian cancer. Women with an increased-risk family history should be considered for genetic counseling to further evaluate their potential risks.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Not Covered or Reimbursable:

CPT®* Codes	Description
76830	Ultrasound, transvaginal

ICD-10-CM Diagnosis Codes	Description
B37.31	Acute candidiasis of vulva and vagina
B37.32	Chronic candidiasis of vulva and vagina
D64.9	Anemia, unspecified
M81.0	Age-related osteoporosis without current pathological fracture
M81.6	Localized osteoporosis [Lequesne]
M81.8	Other osteoporosis without current pathological fracture

ICD-10-CM Diagnosis Codes	Description
M85.9	Disorder of bone density and structure, unspecified
N39.0	Urinary tract infection, site not specified
N60.01	Solitary cyst of right breast
N60.02	Solitary cyst of left breast
N60.09	Solitary cyst of unspecified breast
N60.11	Diffuse cystic mastopathy of right breast
N60.12	Diffuse cystic mastopathy of left breast
N60.19	Diffuse cystic mastopathy of unspecified breast
N60.21	Fibroadenosis of right breast
N60.22	Fibroadenosis of left breast
N60.29	Fibroadenosis of unspecified breast
N60.31	Fibrosclerosis of right breast
N60.32	Fibrosclerosis of left breast
N60.39	Fibrosclerosis of unspecified breast
N60.41	Mammary duct ectasia of right breast
N60.42	Mammary duct ectasia of left breast
N60.49	Mammary duct ectasia of unspecified breast
N60.81	Other benign mammary dysplasia of right breast
N60.82	Other benign mammary dysplasia of left breast
N60.89	Other benign mammary duct dysplasia of unspecified breast
N60.91	Unspecified benign mammary dysplasia of right breast
N60.92	Unspecified benign mammary dysplasia of left breast
N60.99	Unspecified benign mammary dysplasia of unspecified breast
N61.0	Mastitis without abscess
N61.1	Abscess of the breast and nipple
N61.20	Granulomatous mastitis, unspecified breast
N61.21	Granulomatous mastitis, right breast
N61.22	Granulomatous mastitis, left breast
N61.23	Granulomatous mastitis, bilateral breast
N62	Hypertrophy of breast
N63.0	Unspecified lump in unspecified breast
N63.10	Unspecified lump in the right breast, unspecified quadrant
N63.11	Unspecified lump in the right breast, upper outer quadrant
N63.12	Unspecified lump in the right breast, upper inner quadrant
N63.13	Unspecified lump in the right breast, lower outer quadrant
N63.14	Unspecified lump in the right breast, lower inner quadrant
N63.20	Unspecified lump in the left breast, unspecified quadrant
N63.21	Unspecified lump in the left breast, upper outer quadrant
N63.22	Unspecified lump in the left breast, upper inner quadrant
N63.23	Unspecified lump in the left breast, lower outer quadrant
N63.24	Unspecified lump in the left breast, lower inner quadrant
N63.31	Unspecified lump in axillary tail of the right breast
N63.32	Unspecified lump in axillary tail of the left breast

ICD-10-CM Diagnosis Codes	Description
N63.41	Unspecified lump in right breast, subareolar
N63.42	Unspecified lump in left breast, subareolar
N64.0	Fissure and fistula of nipple
N64.1	Fat necrosis of breast
N64.2	Atrophy of breast
N64.3	Galactorrhea not associated with childbirth
N64.4	Mastodynia
N64.51	Induration of breast
N64.52	Nipple discharge
N64.53	Retraction of nipple
N64.59	Other signs and symptoms in breast
N64.81	Ptosis of breast
N64.82	Hypoplasia of breast
N64.89	Other specified disorders of breast
N64.9	Disorder of breast, unspecified
N89.8	Other specified noninflammatory disorders of vagina
N95.1	Menopausal and female climacteric states
N95.8	Other specified menopausal and perimenopausal disorders
N95.9	Unspecified menopausal and perimenopausal disorder
R30.0	Dysuria
R30.9	Painful micturition, unspecified
R31.0	Gross hematuria
R31.1	Benign essential microscopic hematuria
R31.21	Asymptomatic microscopic hematuria
R31.29	Other microscopic hematuria
R31.9	Hematuria, unspecified
R53.81	Other malaise
R53.82	Chronic fatigue, unspecified
R53.83	Other fatigue
R92.0	Mammographic microcalcification found on diagnostic imaging of breast
R92.1	Mammographic calcification found on diagnostic imaging of breast
R92.2	Inconclusive mammogram
R92.8	Other abnormal and inconclusive findings on diagnostic imaging of breast
T85.44XA	Capsular contracture of breast implant, initial encounter
T85.44XD	Capsular contracture of breast implant, subsequent encounter
T85.44XS	Capsular contracture of breast implant, sequela
Z00.00	Encounter for general adult medical examination without abnormal findings
Z00.01	Encounter for general adult medical examination with abnormal findings
Z01.30	Encounter for examination of blood pressure without abnormal findings
Z01.31	Encounter for examination of blood pressure with abnormal findings
Z01.411	Encounter for gynecological examination (general) (routine) with abnormal findings
Z01.419	Encounter for gynecological examination (general) (routine) without abnormal findings
Z01.812	Encounter for preprocedural laboratory examination

ICD-10-CM Diagnosis Codes	Description
Z01.84	Encounter for antibody response examination
Z01.89	Encounter for other specified special examinations
Z11.0	Encounter for screening for intestinal infectious diseases
Z11.1	Encounter for screening for respiratory tuberculosis
Z11.2	Encounter for screening for other bacterial diseases
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.4	Encounter for screening for human immunodeficiency virus [HIV]
Z11.51	Encounter for screening for human papillomavirus (HPV)
Z11.59	Encounter for screening for other viral diseases
Z11.6	Encounter for screening for other protozoal diseases and helminthiases
Z11.8	Encounter for screening for other infectious and parasitic diseases
Z11.9	Encounter for screening for infectious and parasitic diseases, unspecified
Z12.0	Encounter for screening for malignant neoplasm of stomach
Z12.10	Encounter for screening for malignant neoplasm of intestinal tract, unspecified
Z12.11	Encounter for screening for malignant neoplasm of colon
Z12.12	Encounter for screening for malignant neoplasm of rectum
Z12.13	Encounter for screening for malignant neoplasm of small intestine
Z12.2	Encounter for screening for malignant neoplasm of respiratory organs
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast
Z12.39	Encounter for other screening for malignant neoplasm of breast
Z12.4	Encounter for screening for malignant neoplasm of cervix
Z12.6	Encounter for screening for malignant neoplasm of bladder
Z12.72	Encounter for screening for malignant neoplasm of vagina
Z12.81	Encounter for screening for malignant neoplasm of oral cavity
Z12.83	Encounter for screening for malignant neoplasm of skin
Z13.0	Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Z13.1	Encounter for screening for diabetes mellitus
Z13.21	Encounter for screening for nutritional disorder
Z13.22	Encounter for screening for metabolic disorder
Z13.220	Encounter for screening for lipoid disorders
Z13.228	Encounter for screening for other metabolic disorders
Z13.29	Encounter for screening for other suspected endocrine disorder
Z13.30	Encounter for screening examination for mental health and behavioral disorders, unspecified
Z13.31	Encounter for screening for depression
Z13.32	Encounter for screening for maternal depression
Z13.39	Encounter for screening examination for other mental health and behavioral disorders
Z13.40	Encounter for screening for unspecified developmental delays
Z13.41	Encounter for autism screening
Z13.42	Encounter for screening for global developmental delays (milestones)
Z13.49	Encounter for screening for other developmental delays
Z13.5	Encounter for screening for eye and ear disorders

ICD-10-CM Diagnosis Codes	Description
Z13.6	Encounter for screening for cardiovascular disorders
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status
Z13.79	Encounter for other screening for genetic and chromosomal anomalies
Z13.810	Encounter for screening for upper gastrointestinal disorder
Z13.811	Encounter for screening for lower gastrointestinal disorder
Z13.818	Encounter for screening for other digestive system disorders
Z13.820	Encounter for screening for osteoporosis
Z13.828	Encounter for screening for other musculoskeletal disorder
Z13.83	Encounter for screening for respiratory disorder, NEC
Z13.84	Encounter for screening for dental disorders
Z13.850	Encounter for screening for traumatic brain injury
Z13.858	Encounter for screening for other nervous system disorder
Z13.88	Encounter for screening for disorder due to exposure to contaminants
Z13.89	Encounter for screening for other disorder
Z13.9	Encounter for screening, unspecified
Z32.02	Encounter for pregnancy test, result negative
Z78.0	Asymptomatic menopausal state

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Revision Details

Type of Revision	Summary of Changes	Date
Focus review	• Removal of one policy statement	6/15/2025
Annual Review	• Updated to new template and formatting standards.	11/12/2023
Annual Review	• No policy statement changes.	12/15/2023
Annual Review	• No policy statement changes.	12/15/2024