Medical Coverage Policy

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Transvaginal Ultrasound, Non-Obstetrical

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Infertility Services
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Overview

This Coverage Policy addresses transvaginal ultrasound (TVUS) used in the evaluation of gynecologic disorders and cancer screening.

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.

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

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
M85.9	Disorder of bone density and structure, unspecified

ICD-10-CM Diagnosis Codes	Description
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 dysplasias of right breast
N60.82	Other benign mammary dysplasias of left breast
N60.89	Other benign mammary dysplasias 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
N63.41	Unspecified lump in right breast, subareolar
N63.42	Unspecified lump in left breast, subareolar

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ICD-10-CM Diagnosis Codes	Description
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
R30.9	Painful micturition, unspecified
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
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

ICD-10-CM Diagnosis Codes	Description
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
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

ICD-10-CM Diagnosis Codes	Description
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

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, ovaries and fallopian tubes.

U.S. Food and Drug Administration (FDA)
The FDA regulates ultrasound systems and transducers as Class II devices under the 510(k) premarket notification process. In gynecology these devices are indicated for evaluating pelvic organs (ovaries, uterus, fallopian tubes) via production of high detail resolution images and are intended for use by qualified personnel (FDA, 2025).

Device or Product	Identifier	Manufacturer	Decision Date
HP Transvaginal Ultrasound Transducer	K895026	Hewlett-Packard Co.	11/06/1989
SonoTouch Diagnostic Ultrasound System	K112539	Chison Medical Imaging Co., Ltd.	1/18/2012
Voluson Expert Series (18, 20, 22)	K242168	GE Medical Systems Ultrasound and Primary care Diagnostics	12/20/2024

*FDA product codes: IYN, IYO, ITX

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference

for any specific brand or model. This list is not intended to reflect all available products or technologies.

Suspected Pelvic Pathology

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).

Professional Societies/Organizations

The **American College of Obstetricians and Gynecologists** (ACOG) committee on gynecologic practice issued a committee opinion outlining the role of transvaginal ultrasonography (TVUS) in evaluating the endometrium of women with postmenopausal bleeding in 2018 (reaffirmed in 2023). The committee recommends TVUS as an appropriate initial diagnostic tool and notes it is a reasonable alternative to endometrial sampling for women experiencing a first episode of postmenopausal bleeding. However, for women with persistent or recurrent bleeding, further evaluation such as hysteroscopy with dilation and curettage is advised if initial sampling is inconclusive. Importantly, ACOG emphasizes that TVUS should not be used as a screening tool for endometrial cancer in asymptomatic postmenopausal women.

The ACOG practice bulletin for management of symptomatic uterine leiomyomas (2021; reaffirmed 2025) notes that uterine leiomyomas (fibroids) are common and estimated to occur in up to 70% of women by menopause. The incidence of leiomyomas increases with age, with additional risk factors including premenopausal status, family history, increasing interval since last birth, hypertension, and obesity. Clinical evaluation for suspected leiomyomas begins with a complete medical history and abdominal and pelvic exam. Transvaginal ultrasonography is recommended as a first-line imaging modality to assess leiomyomas.

Cancer Screening

Transvaginal ultrasound (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).

Literature Review

Ovarian Cancer: Large clinical trials have evaluated the efficacy of TVUS in screening for ovarian cancer. 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) to assess the effectiveness of TVUS in screening for cancer. 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 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".

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.

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 (2025) published an Ovarian Cancer Fact Sheet for health care professionals. According to the publication, the ACS does not have recommended screening guidelines for ovarian cancer. Research to identify effective screening methods is ongoing. For individuals at high risk of ovarian cancer, clinicians may consider a complete pelvic exam along with a transvaginal ultrasound (TVUS) and the CA-125 blood test. However, these tests have not demonstrated a reduction in mortality and may lead to significant harms, including unnecessary surgeries resulting from false-positive findings.

The American Cancer Society's (ACS) 2019 guidelines for endometrial cancer screening remained unchanged from its 2001 recommendations. In both publications, the ACS concluded that there was insufficient evidence to support routine screening for endometrial cancer in women at average risk or those who were at an increased risk due to factors such as a history of unopposed estrogen therapy, tamoxifen use, late menopause, nulliparity, infertility or failure to ovulate, obesity, diabetes, or hypertension. Instead, the ACS recommended that women at average and increased risk be educated about the signs and symptoms of endometrial cancer at the onset of menopause, particularly unexpected bleeding or spotting, and be strongly encouraged to promptly report such symptoms to their healthcare providers. For women at very high risk, defined as those with (1) a known Lynch syndrome (hereditary nonpolyposis colorectal cancer) mutation, (2) a strong family history suggesting a mutation, or (3) no genetic testing results in families with suspected autosomal dominant colorectal cancer predisposition, the ACS advises considering annual screening for endometrial cancer beginning at age 35. Endometrial biopsy remains the standard method for evaluating endometrial histology. 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 early detection strategies (Smith, et al., 2019).

American College of Gastroenterology (ACG): The ACG guideline on genetic testing and management of hereditary gastrointestinal cancer syndromes issued a conditional recommendation, “based on very low-quality evidence,” that annual screening for endometrial and ovarian cancer should be offered to women who are either at risk for or affected by Lynch syndrome. Screening should include endometrial biopsy and transvaginal ultrasound beginning between ages 30 and 35, and is advised prior to undergoing risk-reducing surgery or if such 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 2024). The opinion concluded that transvaginal ultrasonography (TVUS), although evaluated for its potential to detect early changes in ovarian size and morphology, has proven ineffective for early detection. Furthermore, the use of TVUS and tumor markers such as CA-125, either alone or in combination, has not been shown to reduce mortality in average-risk women. The guideline emphasized the potential harms of false-positive results, including unnecessary invasive procedures like surgery. 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 their obstetrician-gynecologist should maintain an appropriate level of suspicion when potentially relevant signs and symptoms of ovarian cancer are present.

In their joint practice bulletin on hereditary breast and ovarian cancer syndrome (2017; reaffirmed in 2024), ACOG and SGO stated that current screening methods such as serum CA-125 measurement and transvaginal ultrasonography have not been proven to reduce mortality or improve survival rates in high-risk populations, therefore routine screening is not recommended. However, short-term surveillance beginning at age 30–35 may be considered reasonable for women at increased risk of ovarian cancer (e.g., those with BRCA mutations or a personal/family history of ovarian cancer) who have not undergone risk-reducing bilateral salpingo-oophorectomy.

American College of Radiology (ACR): The ACR Appropriateness Criteria® Ovarian Cancer Screening 2024 update states that transvaginal ultrasound (TVUS) of the pelvis is the most extensively studied imaging modality for ovarian cancer screening, both alone and in combination with serum CA-125 biomarker testing. However, current evidence does not support its use for screening postmenopausal patients without risk factors, as randomized controlled trials (RCTs) have not demonstrated a significant reduction in mortality as a result of screening. Additionally, there is no supporting literature for the use of TVUS in premenopausal patients without risk factors. The inclusion of high-risk individuals in RCTs, such as those with BRCA1/BRCA2 mutations, strong family history, nulliparity, or lack of breastfeeding, has been inconsistent, and data for this population remains limited. While ultrasound screening may be appropriate for select high-risk individuals, especially those who decline or defer risk-reducing salpingo-oophorectomy, the evidence is insufficient to make definitive recommendations.

National Comprehensive Cancer Network® (NCCN®): The NCCN clinical practice guidelines in oncology for ovarian cancer (including fallopian tube and primary peritoneal cancer) states that routine screening in the general, asymptomatic population is not supported by current evidence and is not recommended by any professional society. Although screening methods such as transvaginal ultrasonography (TVUS) and serum CA-125 may increase the likelihood of detecting ovarian cancer at an earlier stage and slightly extend survival among those diagnosed, they do not reduce disease-specific mortality. Additionally, these screening approaches carry risks, including false-positive results that may lead to unnecessary psychological distress and invasive procedures such as surgery (NCCN, 2025a).

The NCCN clinical practice guidelines in oncology for genetic/familial high-risk assessment: breast, ovarian, pancreatic and prostate state that there is no known effective screening method for ovarian cancer and studies assessing screening procedures have yielded mixed results. For individuals with hereditary cancer syndromes associated with uterine cancer, the benefit of screening with transvaginal ultrasound (TVUS), with or without random endometrial biopsies, remains unclear. While CA-125 and pelvic ultrasound may be used for preoperative planning in BRCA positive individuals undergoing risk-reducing surgery for ovarian, fallopian tube, peritoneal, or uterine cancers, there is no recommendation of TVUS as a routine screening or surveillance tool in this population. Additionally, for individuals with Cowden syndrome or PTEN hamartoma tumor syndrome, TVUS for endometrial cancer screening or surveillance is not recommended in postmenopausal individuals but may be considered at the clinician's discretion. In premenopausal individuals, TVUS is also not recommended due to the variability in endometrial stripe thickness throughout the menstrual cycle (NCCN, 2025b).

The NCCN clinical practice guidelines in oncology for genetic/familial high-risk assessment: colorectal, endometrial, and gastric state that routine transvaginal ultrasound (TVUS) for endometrial cancer screening in postmenopausal individuals with Lynch syndrome or other hereditary variants (e.g., MLH1, MSH2, EPCAM, MSH6, PMS2, NTHL1, POLD1, POLE) lacks sufficient sensitivity and specificity to warrant a formal recommendation, though it may be considered at the clinician's discretion. In premenopausal individuals, TVUS is not recommended due to the variability in endometrial stripe thickness throughout the menstrual cycle. Additionally, the guidelines do not support routine ovarian cancer screening with TVUS or serum CA-125 testing

in postmenopausal individuals with Lynch syndrome. Given the absence of effective screening methods for ovarian cancer, the guidelines emphasize the importance of educating patients about symptoms and encouraging prompt reporting to their healthcare provider (NCCN, 2025c).

National Cancer Institute (NCI): The NCI's physician data query (PDQ) for health professionals on screening for ovarian, fallopian tube, and primary peritoneal cancers states that solid evidence shows annual screening of women aged 55 to 74 at average risk using the serum marker CA-125 for six years and transvaginal ultrasound (TVUS) for four years does not reduce ovarian cancer mortality, based on a median follow-up of 17 years. Additionally, the NCI notes that screening can lead to false positives, which are associated with increased rates of oophorectomy. The NCI notes the U.S. Food and Drug Administration Safety Communication which advises against using currently available screening tests for ovarian cancer in any population of women. Asymptomatic women at high-risk may receive false-negative results and delay effective preventive treatments. (NCI, 2025b).

The National Cancer Institute's PDQ for health professionals on endometrial cancer screening states that there is no evidence that ultrasonographic screening methods, such as endovaginal or transvaginal ultrasound, reduce mortality from endometrial cancer. Approximately 85% of cases are diagnosed at an early stage due to symptoms, resulting in high survival rates. The NCI further affirms that, based on solid evidence, screening asymptomatic women leads to unnecessary biopsies due to false-positive results. These false positives can cause anxiety and complications from biopsy procedures. Additionally, the benefits of screening high-risk groups have not been adequately evaluated. Current published recommendations for screening certain high-risk groups are based on opinion regarding presumptive benefit (NCI, 2025c).

According to the NCI's health professional PDQ regarding 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 cases. Due to this elevated risk, screening for women with Lynch syndrome who have not undergone risk-reducing hysterectomy has been suggested. Proposed methods include transvaginal ultrasound (TVUS) and/or endometrial biopsy. Studies have shown endometrial biopsy is highly sensitive and specific and may be considered starting at age 30–35, repeated every 1–2 years. TVUS lacks sensitivity and specificity for detecting endometrial cancer and is therefore not recommended for premenopausal patients, however, it may be considered based on provider's judgement (NCI, 2025a).

U.S. Preventive Services Task Force (USPSTF): In its 2018 recommendation, the USPSTF advised against routine screening for ovarian cancer in asymptomatic women who do not have known genetic mutations associated with increased risk. This recommendation reflects moderate certainty that the harms of screening outweigh the benefits. Commonly used screening methods including transvaginal ultrasonography and serum CA-125 testing were found to be ineffective in reducing ovarian cancer mortality. Moreover, these tests can lead to significant harms, including false-positive results and unnecessary surgical procedures in women who do not have cancer. The USPSTF emphasized that women with a family history of ovarian or breast cancer may be at increased genetic risk and should be considered for genetic counseling and, if appropriate, genetic testing.

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.

The American College of Obstetricians and Gynecologists (ACOG) practice bulletin on managing symptomatic uterine leiomyomas (2021; reaffirmed 2025) reports that fibroids affect up to 70% of women by menopause, with prevalence two to three times higher among Black women compared to White women. Data for Latina and Asian populations show no significant difference, though research is limited. Black women tend to develop fibroids earlier, experience more anemia, present with clinically significant disease sooner, and have larger uteri at diagnosis. It is stated that U.S.-born Black women who self-report experiencing racism have an increased risk of uterine leiomyomas and that experiences of racism can delay women from seeking care until symptoms are severe. Racial disparities in treatment are noted, including higher rates of hysterectomy and myomectomy versus nonsurgical therapy, and more open hysterectomies versus minimally invasive approaches, even after adjusting for clinical factors. Women from diverse racial backgrounds remain underrepresented in leiomyoma research, highlighting the need for studies focused on health disparities to reduce inequities and improve care.

Atkins et al. (2025) conducted a single-center retrospective study of 3369 individuals (mean age 60 years) as part of the ongoing Performance of Ultrasound in Postmenopausal Bleeding Assessment (PUMBA) study. The objective was to determine whether race, ethnicity, language, or insurance status were associated with delayed endometrial sampling after transvaginal ultrasonography (TVUS) for postmenopausal bleeding. The study also examined whether delays affected endometrial cancer diagnosis or stage and identified common reasons for untimely follow-up. Participants were eligible if they had an intact uterus, were older than 45 years, and underwent TVUS for postmenopausal bleeding without prior TVUS for this indication. Primary outcomes included prompt follow-up (i.e., endometrial sampling within 3 months of detecting thickened or inadequately visualized endometrium), cancer diagnosis, stage at diagnosis, and tissue sampling rates. Among participants, 1671 had thickened endometrium; 307 (18.4%) did not receive timely follow-up. Of 389 with inadequately visualized endometrium, 128 (33.0%) lacked prompt follow-up. Race and ethnicity were not significantly associated with timely sampling for either thickened endometrium (OR 1.03, 95% CI 0.79–1.35 for Black vs White; OR 1.1, 95% CI 0.54–2.27 for Hispanic vs non-Hispanic) or inadequately visualized endometrium (OR 1.13, 95% CI 0.71–1.8 for Black vs White; OR 1.1, 95% CI 0.37–3.22 for Hispanic vs non-Hispanic). Endometrial cancer diagnosis rates within one year were similar (8.8% for thickened endometrium; 7.7% for inadequately visualized endometrium). The stage distribution for endometrial cancers diagnosed after prompt sampling of thickened endometrium was stage IA or IB in 107 of 133 (80.5%) and stage II–IV in 26 of 133 (19.5%), compared with stage IA in two of four (50%) and stage II–IV in two of four (50%) after delayed sampling. The stage distribution for endometrial cancers diagnosed after prompt sampling of inadequately visualized endometrium was stage IA or IB in 16 of 24 (66.7%) and stage II–IV in 8 of 24 (33.3%), with 0 of 17 (0%) cancer diagnoses occurring after delayed sampling. Clinician-related factors such as misinterpretation of ultrasound results and delays accounted for 46.1% of untimely follow-up in thickened endometrium cases and 58.4% in inadequately visualized cases. Author noted limitations include study design and incomplete data reporting.

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.

According to the National Cancer Institute's PDQ for health professionals, endometrial cancer is the most common invasive gynecologic cancer among U.S. women, with an estimated 69,120 new cases and 13,860 deaths expected in 2025. It primarily affects postmenopausal women, with a mean age at diagnosis of 60. While incidence rates are rising annually, by 0.6% in White women and 2–3% in women of other racial and ethnic groups, substantial disparities exist between Black and White women in disease stage at diagnosis and survival outcomes. Despite a lower incidence among Black women, their mortality rate is higher. Findings from the NCI's Black/White Cancer Survival Study suggest that Black women are more likely to be diagnosed with higher-grade, more aggressive tumors, contributing to advanced-stage disease. The interplay between biological factors and socioeconomic status complicates understanding these disparities. Evidence suggests lower income is linked to more advanced disease, reduced likelihood of receiving a hysterectomy, and poorer survival. However, other research indicates no racial difference in the time from symptom onset to initial medical consultation, suggesting that patient delay is not a primary factor. Further investigation is needed to clarify why Black women are disproportionately affected by aggressive disease and higher mortality, despite having a lower incidence of endometrial cancer (NCI, 2025c).

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)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Revised policy statements regarding screening for cancer. • Updated to new formatting standards.	12/15/2025
Focused review	• Removed policy statement for intrauterine device (IUD) insertion, surveillance, or removal.	6/15/2025
Annual Review	• No policy statement changes.	12/15/2024
Annual Review	• No policy statement changes. • Updated to new template and formatting standards.	12/15/2023