Anthem

Clinical UM Guideline

Subject: Non-Obstetrical Transvaginal Ultrasonography
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Description

This document addresses the use of non-obstetrical transvaginal ultrasonography for the evaluation of conditions of the pelvis and surrounding tissues.

Note: This document does *not* address the use of transvaginal ultrasonography for infertility-related conditions and treatments.

Clinical Indications

Medically Necessary:

A. Non-obstetrical transvaginal ultrasonography is considered **medically necessary** to evaluate or guide treatment for **any** of the following conditions:
   1. Abnormal uterine or vaginal bleeding; **or**
   2. Amenorrhea, delayed menses, or dysmenorrhea; **or**
   3. Congenital uterine or lower genital tract anomalies; **or**
   4. Endometriomas or endometriosis, including deeply infiltrating endometriosis of the rectum or rectovaginal septum; **or**
   5. Excessive bleeding, pain, or signs of infection after pelvic surgery; **or**
   6. Follow-up of a previously detected abnormality of the pelvis or surrounding tissues; **or**
   7. Incontinence or pelvic organ prolapse; **or**
   8. New onset of symptoms such as abdominal or pelvic pain, bloating, early satiety, or urinary frequency and urgency, **and** an abnormal abdominal or pelvic examination is suspicious for gynecologic cancers; **or**
   9. Pelvic infection or pelvic inflammatory disease (such as, tubo-ovarian abscess, hydrosalpinx, or pyosalpinx); **or**
   10. Pelvic masses, benign or malignant (such as, adenomyosis, fibroids, cancers of the ovaries, vagina, uterus, or other pelvic structures); **or**
   11. Polycystic ovarian syndrome.

B. Non-obstetrical transvaginal ultrasonography is considered **medically necessary** to monitor for endometrial or ovarian cancer in individuals with hereditary breast and ovarian cancer syndromes (HBOC), Lynch syndrome, **or** Peutz-Jeghers syndrome.

C. Non-obstetrical transvaginal ultrasonography is considered **medically necessary** to confirm the position of an intrauterine contraceptive device if the device string is not visible **or** there is a suspicion that the device is incorrectly positioned within the uterus.

Not Medically Necessary:

Transvaginal ultrasonography is considered **not medically necessary** when criteria are not met and for **all** other indications, including routine screening for gynecologic cancers (such as, endometrial or ovarian cancer).

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 may be Medically Necessary when criteria are met:

CPT

76830	Transvaginal ultrasound [non-obstetrical]

ICD-10 Diagnosis

	All diagnoses

When services are Not Medically Necessary:
For the procedure code listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Transvaginal ultrasonography (TVU), also referred to as endovaginal ultrasonography, is a pelvic and lower abdominal imaging procedure and type of pelvic ultrasound technique which uses a thin transducer (endocavitary ultrasound probe) covered with acoustic conducting gel and a protective sheath (often plastic or latex) that produces diagnostic anatomic images when introduced through the vaginal canal. While probe placement and manipulation can cause transient discomfort, TVU is typically a painless procedure. TVU allows rapid visualization and detailed images of the pelvic organs including the cervix, fallopian tubes, ovaries, uterus, and vagina and surrounding structures such as the rectum and bladder. No ionizing radiation (x-ray) is involved in TVU imaging. TVU is a widely accepted procedure used in the evaluation of pelvic abnormalities, allowing for medical evaluation of conditions without the need for invasive surgery or techniques that expose individuals to radiation.

In 2014, the American Institute of Ultrasound in Medicine (AIUM) in collaboration with the American College of Radiology (ACR), American College of Obstetricians and Gynecologists (ACOG), the Society of Pediatric Radiology (SPR), and the Society of Radiologists in Ultrasound (SRU) published a revised *Practice Parameter for the Performance of Ultrasound of the Female Pelvis* (AIUM, 2014). This practice parameter provides indications for pelvic ultrasonography, including the transvaginal approach and transabdominal approach. Non-obstetrical indications for TVU include, but are not limited to, evaluation of the following conditions: 1)

pelvic pain, pelvic masses, or signs or symptoms of pelvic infection; 2) endocrine abnormalities (including polycystic ovaries); 3) amenorrhea, delayed menses, or dysmenorrhea (painful menses); 4) abnormal vaginal bleeding; 5) congenital uterine and lower genital tract anomalies; 6) postoperative pelvic surgery complications (such as excessive bleeding, pain, or signs of infection); or 7) incontinence or pelvic organ prolapse. Other recommendations for non-obstetrical TVU of the pelvis include: 1) follow-up of a previously detected abnormality; 2) further characterization of a pelvic abnormality noted on another imaging study; 3) guidance for interventional or surgical procedures; 4) localization of an intrauterine contraceptive device; 5) preoperative and postoperative evaluation of pelvic structures; and, 6) screening for malignancy in high-risk individuals.

Screening for Endometrial Cancer with TVU

TVU is used as a diagnostic tool to evaluate symptomatic vaginal bleeding by measuring endometrial thickness (ET). In an early systematic review and meta-analysis, Smith-Bindman and colleagues (1998) evaluated 35 studies including 5892 women to determine the accuracy of TVU in detecting endometrial disease in postmenopausal individuals with vaginal bleeding according to hormone replacement use. TVU was found to have a high sensitivity for detecting endometrial cancer and other endometrial disease. Among individuals with postmenopausal uterine bleeding and cancer, 96% (95% confidence interval [CI], 94%-98%) with cancer were found to have an abnormal ET (> 5 millimeters [mm]) on TVU, while 92% (95% CI, 90%-93%) with endometrial disease (that is, cancer, polyp, or atypical hyperplasia) had an abnormal result. In individuals not using hormone replacement therapy, 593 (8%) with normal histological finding had an abnormal TVU result (specificity, 92%; 95% CI, 90%-94%), while 1544 (23%) using hormone replacement therapy had an abnormal TVU result (specificity, 77%; 95% CI, 75%-79%). The probability of cancer in a postmenopausal individual with vaginal bleeding with a 10% pretest probability of endometrial cancer was 1% following a normal TVU result.

Gull and colleagues (2003) used dilation and curettage as a “gold standard” to evaluate TVU measurement of ET as a predictor of endometrial cancer in individuals reporting postmenopausal bleeding (estrogen-progestin therapy [hormone therapy] and no hormone therapy users). A total of 339 participants were evaluated, of which 39 (11.5%) were diagnosed with endometrial cancer (4 participants had an ET of 5-7 mm and 35 participants had an ET > 8 mm) based on histopathology from curettage. No endometrial cancer was diagnosed in individuals with a recurrent postmenopausal bleeding who had an ET of less than 4 mm at the initial scan. The authors reported 100% sensitivity and 60% specificity of TVU for diagnosing endometrial cancer when using a cutoff point of 4 mm.

An ACOG practice bulletin on endometrial cancer (2015; reaffirmed in 2017) includes the following recommendation (“limited or inconsistent scientific evidence: Level B”) for use of TVU, stating “when transvaginal ultrasonography is performed for the initial evaluation of patients with postmenopausal bleeding and an endometrial thickness of less than or equal to 4 mm is found, endometrial sampling is not required.” This recommendation is reiterated in the ACOG committee opinion bulletin on endometrial intraepithelial neoplasia (2015; reaffirmed in 2019), a clinically significant condition that is often a precursor lesion to adenocarcinoma of the endometrium, stating that TVU has excellent negative predictive value (NPV) for endometrial cancer in women with postmenopausal bleeding. Likewise, the ACOG practice bulletin on the role of TVU in the evaluation of postmenopausal bleeding (2018) concludes:

- The clinical approach to postmenopausal bleeding requires prompt and efficient evaluation to exclude or diagnose endometrial carcinoma and endometrial intraepithelial neoplasia.
- Transvaginal ultrasonography is appropriate for an initial evaluation of postmenopausal bleeding if the ultrasound images reveal a thin endometrial echo (less than or equal to 4 mm), given that an endometrial thickness of 4 mm or less has a greater than 99% negative predictive value for endometrial cancer.
- Transvaginal ultrasonography is a reasonable alternative to endometrial sampling as a first approach in evaluating a postmenopausal woman with an initial episode of bleeding.
- Transvaginal ultrasonography can be useful in the triage of women in whom office endometrial sampling was performed but tissue was insufficient for diagnosis.

An ACOG practice bulletin on the diagnosis of abnormal uterine bleeding (AUB) in reproductive-aged women (2012; reaffirmed in 2016) states the primary imaging test of the uterus for the evaluation of AUB is TVU. TVU “is useful as a screening test to assess the endometrial cavity for leiomyomas and polyps.” While TVU is helpful for evaluating the myometrium itself, its sensitivity and specific are lower for evaluating intracavitary pathology (56% and 73%, respectively). Regarding use of TVU in evaluation of AUB in premenopausal women, an ACOG practice bulletin (2015; reaffirmed in 2017) on endometrial cancer states that data is insufficient to support the use of endometrial thickness in the evaluation of AUB in women of reproductive age who are at low risk. “Ultrasound measurement of endometrial thickness in premenopausal women has no diagnostic value and should not be performed.”

For use of TVU in individuals without vaginal bleeding, the National Cancer Institute (NCI) PDQ® for endometrial cancer screening (2022) states that “although TVU can be used to evaluate asymptomatic and occult endometrial pathology, the technique has not been evaluated as a screening method for reducing mortality in asymptomatic women.” The NCI PDQ concludes:

> Routine screening of asymptomatic individuals for endometrial cancer has not been evaluated for its impact on endometrial cancer mortality. No studies have evaluated the efficacy of screening with TVU in reducing mortality from endometrial cancer. Although high-risk groups can be identified, the benefit of screening in reducing endometrial cancer mortality in these high-risk groups has not been evaluated. Using the same cutoffs to define an abnormal ET in asymptomatic individuals (Smith-Bindman, 2004) as used in symptomatic individuals (Smith-Bindman, 1998) would result in large numbers of false-positive test results and larger numbers of unnecessary referrals for cytological evaluations. Published recommendations for screening certain groups of individuals at high risk for endometrial cancer are based on opinion regarding presumptive benefit (Burke, 1997).

TVU has been evaluated for use in individuals taking tamoxifen as part of adjuvant therapy for breast cancer and as chemoprevention for women at risk of breast cancer. The effects of tamoxifen may increase the individuals’ risk of developing endometrial pathology, including endometrial polyps, endometrial hyperplasia, and endometrial cancer (NCI, 2019). Fung and colleagues (2003) performed a prospective, longitudinal observational study of 304 individuals using tamoxifen over 6 years. Participants underwent annual TVU screening and those with abnormal TVU findings or symptomatic with bleeding underwent endometrial biopsy. A total of 43% of the TVU examinations had associated significant uterine abnormalities identified that required further medical or surgical investigation and treatment. However, most abnormalities (80%) represented benign polyps for which no treatment was needed. A total of 6 cases of primary endometrial cancer were detected, and all cases presented with irregular bleeding. The sensitivity of ultrasound was only 63.3%, with a specificity of 60.4%, and had a low positive predictive value (PPV) for cancer of only 1%. The investigators concluded that routine sequential TVU in asymptomatic women on tamoxifen “…is not useful because of its low specificity and positive predictive value.”

The ACOG committee opinion bulletin on tamoxifen and uterine cancer (2014; reaffirmed in 2021), citing the study by Fung (2003) and two earlier studies, states “in symptomatic women using tamoxifen, screening for endometrial cancer with routine transvaginal ultrasonography, endometrial biopsy, or both has not been shown to be effective.”

Screening for Other Endometrial Conditions with TVU

Adenomyosis occurs when endometrial tissue, which normally lines the uterus, exists within and grows into the muscular wall of the uterus. The displaced endometrial tissue thickens, breaks down, and bleeds during each menstrual cycle. An enlarged uterus and painful, heavy menstrual periods can result. Symptoms most often start late in the childbearing years after having children. The cause of adenomyosis remains unknown, but the disease typically disappears after menopause.

Meredith and colleagues (2009) evaluated the accuracy of TVU for diagnosing adenomyosis in individuals undergoing hysterectomy. The presence or absence of adenomyosis was confirmed by histopathologic analysis of hysterectomy specimens. A total of 14 trials with 1895 participants were included in the meta-analysis. The authors reported that TVU predicted adenomyosis with a likelihood ratio of 4.67 (95% CI, 3.13-6.17). The overall prevalence of adenomyosis was 27.9% (95% CI, 25.5-30.3). The probability of adenomyosis with an abnormal TVU was 66.2% (95% CI, 61.6-70.6). The probability of adenomyosis with a normal TVU was 9.1% (95% CI, 7.3-11.1).

Champaneria and colleagues (2010) conducted a systematic review and meta-analysis of individuals with adenomyosis who had a TVU and/or magnetic resonance imaging (MRI) and whose results were compared with a reference standard. A meta-regression was performed to examine how the index tests compared on diagnostic accuracy. A total of 23 articles involving 2312 individuals met the inclusion criteria. TVU had a pooled sensitivity of 72% (95% CI, 65%-79%), specificity of 81% (95% CI, 77%-85%), positive likelihood ratio of 3.7 (95% CI, 2.1-6.4) and negative likelihood ratio of 0.3 (95% CI, 0.1-0.5). MRI had a pooled sensitivity of 77% (95% CI, 67%-85%), specificity of 89% (95% CI, 84%-92%), positive likelihood ratio of 6.5 (95% CI, 4.5-9.3), and negative likelihood ratio of 0.2 (95% CI, 0.1-0.4). The results demonstrated that a correct diagnosis was obtained more often with MRI; however, both TVU and MRI showed high levels of accuracy for the non-invasive diagnosis of adenomyosis.

The ACOG practice bulletin on the diagnosis of abnormal uterine bleeding in reproductive-aged women (2012, reaffirmed in 2016) states adenomyosis can be diagnosed with TVU, in particular, in an individual with an abnormal physical examination, such as an enlarged or globular uterus on bimanual examination. “Ultrasonographic findings that support a diagnosis of adenomyosis include heterogeneous myometrium, myometrial cysts, asymmetric myometrial thickness, and subendometrial echogenic linear striations.”

A retrospective cohort study of 754 individuals (n=256, reproductive age and n=498, postmenopausal) evaluated the diagnostic performance of TVU compared to hysteroscopy (gold standard) for evaluation of suspected endometrial pathologies. In the reproductive-age group, for the diagnosis of endometrial disease, TVU had a sensitivity of 96.0%, specificity of 58.0%, PPV of 94.4%, NPV of 66.6%, and accuracy of 91.5%; hysteroscopy had a sensitivity of 91.8%, specificity of 76.6%, PPV of 96.0%, NPV of 60.5%, and accuracy of 89.7%. In the postmenopausal group, TVU had a sensitivity of 99.0%, specificity of 19.0%, PPV of 96.1%, NPV of 50.0%, and accuracy of 95.3%; hysteroscopy had a sensitivity of 96.7%, specificity of 86.9%, PPV of 99.2%, NPV of 58.8%, and accuracy of 96.2%. Authors conclude that TVU demonstrated a comparable diagnostic performance to hysteroscopy for diagnosing endometrial pathologies (Yela, 2018).

A small retrospective study sought to compare the efficacy of magnetic resonance imaging (MRI) and TVU in detecting deep infiltrating endometriosis. A total of 48 women with suspicion of deep infiltrating endometriosis and no previous hysterectomy, bowel resection, or urinary tract surgery were enrolled. The diagnosis made using MRI or TVU was considered positive when it correlated with histology. Sensitivity, specificity and accuracy were calculated. For recto-vaginal and vaginal endometriosis examination, TVU demonstrated greater accuracy than MRI (77% vs 69% and 94% vs 89%, respectively), whereas for bladder endometriosis MRI was superior to TVU (96% vs 92%). The sensitivity and specificity varied widely by the nodule’s suspected anatomical location (recto-vaginal, vaginal, utero-sacral ligaments, recto-sigmoid, bladder, or ureter) This study adds to the body of literature demonstrating the clinical utility of TVU as a diagnostic tool in diagnosing deep infiltrating endometriosis but suggests it’s accuracy may depend on the suspected location of affected tissue (Hernández, 2019).

A systematic review sought to characterize the value of TVU compared to MRI in the evaluation of adenomyosis. A total of 32 studies were ultimately chosen for inclusion in the analysis (case reports were excluded). While both TVU and MRI demonstrated high sensitivity and specificity, TVU surpassed MRI in terms of sensitivity (0.81 vs 0.71, respectively), while MRI had a higher specificity than TVU (0.91 vs 0.87, respectively). The authors concluded that “this systematic review and meta-analysis demonstrates comparably high accuracy for both TVUS and MRI in the diagnosis of adenomyosis” (Liu, 2021).

Screening for Ovarian Cancer with TVU

There is substantive evidence in the peer-reviewed literature in population-based studies to indicate that routine screening of women at average risk of developing ovarian cancer with annual TVU screening does not result in a decrease in ovarian cancer mortality (NCI, 2022). In a randomized controlled clinical trial of individuals recruited from 13 centers across the United Kingdom from 2001 to 2005 (Ovarian Cancer Screening and Mortality in the UK Collaborative Trial of Ovarian Cancer Screening [UKCTOCS] [NCT00058032]), outcomes among 50,623 postmenopausal individuals aged 50 to 74 years who were randomly assigned to 7 to 11 rounds of annual screening with TVU alone and 50,264 who underwent multimodal screening with cancer antigen (CA)-125 testing and TVU were compared with results of 101,299 individuals who were not screened (the comparison group). After trial initiation, but before the final analysis, the protocol was amended twice: 1) the study was extended to achieve greater power, and 2) criteria for referral in the multimodal arm were liberalized to increase the percentage of positive screens (Jacobs, 2016). TVUs were scored as normal, resulting in continued annual screening; intermediate, leading to repeat CA-125 and TVU at 3 months; or abnormal, requiring repeat testing within 6 weeks. In the TVU arm, 314 cancers were diagnosed and 154 ovarian cancer-related deaths occurred compared with the non-screened arm, in which 630 cancers were diagnosed and 347 ovarian cancer-related deaths occurred. Mortality was non-significantly lower with TVU screening (11%; 95% CI, -7% to 27%; p=0.21). TVU screening resulted in 50 surgeries per 10,000 women for a false-positive screen. Complications resulted from less than 1% of screens and 3.4% of operations. Over a median of 11.1 years, ovarian cancer deaths occurred among 0.30% of screened women and 0.34% of unscreened women (Jacobs, 2016; Sharma, 2012). The ovarian cancer mortality rate was 3.8 deaths per 10,000 women in the screened group and 3.6 deaths per 10,000 person-years in the usual-care group, yielding a mortality rate ratio of 1.06 (95% CI, 0.87-1.30) (NCI, 2022).

Buys and colleagues (2011) evaluated the effect of screening for ovarian cancer on mortality in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. This clinical trial conducted at 10 screening centers across the United States randomly assigned 78,216 women aged 55 to 74 years to undergo either annual screening (n=39,105) or usual care (n=39,111). The intervention group was offered annual screening with CA-125 for 6 years and TVU for 4 years. Participants and their health care practitioners received the screening test results and managed evaluation of abnormal results. The usual care group was not offered annual screening with CA-125 for 6 years or TVU but received their usual medical care. Participants were followed up for a maximum of 13 years (median [range], 12.4 years [10.9-13.0 years]) for cancer diagnoses and death until February 28, 2010. The primary outcome was mortality from ovarian cancer, including primary peritoneal and fallopian tube cancers. Secondary outcomes included ovarian cancer incidence and complications associated with screening examinations and diagnostic procedures. A total of 212 women were diagnosed with ovarian cancer (5.7 per 10,000 person-years) in the intervention group and 176 (4.7 per 10,000 person-years) in the usual care group (rate ratio [RR], 1.21; 95% CI, 0.99-1.48). There were 118 deaths as a result of ovarian cancer (3.1 per 10,000 person-years) in the intervention group and 100 deaths (2.6 per 10,000 person-years) in the usual care group (mortality RR, 1.18;

95% CI, 0.82-1.71). Of 3285 women with false-positive results (approximately 10%), 1080 underwent surgical follow-up; 163 women experienced at least one serious complication (15%). A total of 2924 deaths were attributed to other causes (excluding ovarian, colorectal, and lung cancer) (76.6 per 10,000 person-years) in the intervention group and 2914 deaths (76.2 per 10,000 person-years) in the usual care group (RR, 1.01; 95% CI, 0.96-1.06). The results of this large population-based clinical trial among women in the general U.S. population concluded that simultaneous screening with CA-125 and TVU compared with usual care did not reduce ovarian cancer mortality. The PPV of CA-125 and TVU screening was just greater than 1% across all screening rounds. In addition, diagnostic evaluation following a false-positive screening test result was associated with complications (Buys, 2011; Partridge, 2009).

The current U.S. Preventive Services Task Force (USPSTF, 2018) guidelines for ovarian cancer screening among asymptomatic, average-risk women recommend against screening for ovarian cancer in women, as “there is moderate or high certainty that the service has no net benefit or that harms outweigh the benefits (Grade D: The USPSTF recommends against the service).” This reaffirmation statement indicates the USPSTF found adequate evidence that annual screening with TVU and testing for a serum tumor marker CA-125 in women does not reduce the number of ovarian cancer deaths (Henderson, 2018). This recommendation applies to asymptomatic women; however, women with known genetic mutations that increase their risk for ovarian cancer (for example, BRCA mutations) are not included in this recommendation.

The ACOG Committee on Gynecologic Practice and Society of Gynecologic Oncologists offers the following recommendations and conclusions on the role of the obstetrician-gynecologist in the early detection of epithelial ovarian cancer in women at average risk (2017), stating:

- Currently, there is no strategy for early detection of ovarian cancer that reduces ovarian cancer mortality.
- 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 proven to reduce mortality, and harms exist from invasive diagnostic testing (eg, surgery) resulting from false-positive test results.

TVU in Individuals with Hereditary Breast and Ovarian Cancer Syndrome (including Cowden Syndrome), Lynch Syndrome and Peutz-Jeghers Syndrome

Hereditary Breast and Ovarian Cancer Syndrome

The National Comprehensive Cancer Network (NCCN) clinical practice guideline (CPG) for genetic/familial high-risk assessment in breast and ovarian cancer (V3.2023) states:

> Transvaginal ultrasound combined with serum CA-125 for ovarian cancer screening, although of uncertain benefit, may be considered at the clinician’s discretion.

However, they also state:

Transvaginal ultrasound to screen for endometrial cancer in postmenopausal individuals has not been shown to be sufficiently sensitive or specific as to support a positive recommendation, but may be considered at the clinician’s discretion. Transvaginal ultrasound is not recommended as a screening tool in premenopausal individuals due to the wide range of endometrial stripe thickness throughout the normal menstrual cycle.

For management of *BRCA* mutation-positive individuals who have not elected risk-reducing salpingo-oophorectomy (RRSO), the NCCN states “…transvaginal ultrasound combined with serum CA-125 for ovarian cancer screening, although of uncertain benefit, may be considered at the clinician’s discretion.” This category 2A recommendation (based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate) considers screening guidelines reported in a systematic review (Lindor, 2006) and outcomes of the UKCTOCS clinical trial (Jacobs, 2016; Menon, 2009).

Cowden syndrome is a disorder characterized by multiple noncancerous, tumor-like growths called hamartomas and an increased risk of developing certain cancers, in particular, cancers of the breast, thyroid gland, and the endometrium. For management of women with Cowden syndrome/*PTEN* hamartoma tumor syndrome (PHTS), the NCCN states that “transvaginal ultrasound to screen for endometrial cancer in postmenopausal women has not been shown to be sufficiently sensitive or specific as to support a positive recommendation, but may be considered at the clinician’s discretion.” However, the NCCN further states, “Transvaginal ultrasound is not recommended as a screening tool in premenopausal individuals due to the wide range of endometrial stripe thickness throughout the normal menstrual cycle.”.

The National Society of Genetic Counselors (NSGC) has published a practice guideline on risk assessment and genetic counseling for hereditary breast and ovarian cancer (Berliner, 2013). Medical management (surveillance) options for high-risk women are as follows:

> Although unproven, annual or semiannual transvaginal ultrasound, pelvic exam and testing for serum CA-125 to screen for ovarian cancer beginning at 30 years of age should be considered.

The ACOG practice bulletin on hereditary breast and ovarian cancer syndrome (2017) recommends that RRSO, including removal of the ovaries and fallopian tubes in their entirety, be offered by age 40 years for women with *BRCA*1 or *BRCA*2 mutations. In addition, the practice bulletin 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, which is the only intervention to reduce ovarian cancer-specific mortality.

In support of this recommendation, ACOG cites the current NCCN for genetic/familial high-risk assessment in breast and/or ovarian cancer (V3.2023) and outcomes of the phase II United Kingdom Familial Ovarian Cancer Screening Study (UK-FOCSS) (Rosenthal, 2017), the largest trial to date in high-risk women monitored with CA-125 level screening (using the risk of ovarian cancer algorithm [ROCA]) every 4 months and annual TVU, or screening within 2 months of an abnormal ROCA result. RRSO was encouraged throughout the study. Participants were observed via cancer registries, questionnaires, and notification by centers. Between June 14, 2007, and May 15, 2012, 4348 women underwent 13,728 women-years of screening. The median follow-up time was 4.8 years. Cases of cancer that were detected during the screening trial were more often early stage compared with cases of cancer diagnosed more than 1 year after screening ended. A significant number of cases of cancer were identified at risk-reducing surgery. Survival analysis could not be performed. The authors concluded that screening may be an option for women at high risk of ovarian cancer who defer or decline RRSO. Further investigation is necessary to identify better serum markers and improved screening algorithms to improve the positive and negative predictive value of testing. However, it remains unknown whether this strategy would improve survival in screened high-risk women.

Lynch Syndrome

Lynch syndrome, also known as hereditary non-polyposis colorectal cancer (HNPCC), is a rare genetic (autosomal dominant) inherited cancer susceptibility syndrome that increases the risk of many types of cancer, particularly, cancers of the colon (large intestine) and rectum, collectively referred to as colorectal cancer, and cancers of the endometrium, ovaries, stomach, small intestine, liver, gallbladder duct, upper urinary tract, and brain. Women with Lynch syndrome are at increased risk for endometrial and ovarian cancers, up to 60% for the former. For the latter, risk varies significantly based on affected gene and age (NCCN, V2.2022).

The NCCN CPGs address the use of TVU in the assessment and management of individuals with a genetic/familial high-risk for colorectal cancer (V2.2022) and a genetic/familial high-risk for breast and/or ovarian cancer (V1.2022). Both NCCN CPGs state for women with Lynch syndrome who have completed childbearing and carry a *MLH*1, *MSH*2, *MSH*6, *EPCAM*, or *PMS*2 gene mutation, total abdominal hysterectomy and/or bilateral salpingo-oophorectomy are options that may be considered for risk reduction; however,

- Data do not support routine ovarian cancer screening for LS. Transvaginal ultrasound for ovarian cancer screening has not been shown to be sufficiently sensitive or specific to support a routine recommendation, but may be considered at the clinician's discretion. Serum CA-125 is an additional ovarian screening test with caveats similar to transvaginal

There is no recommendation for use of TVU for screening or surveillance for hereditary colorectal cancer syndrome (NCCN, V2.2023).

Two early studies evaluating TVU and measurement of the endometrial lining for endometrial cancer surveillance in a population of women at high-risk of HNPCC and familial colorectal cancer reported that TVU screening had a high false-positive rate and lacked efficacy (Dove-Edwin, 2002; Rijcken, 2003).

Lindor and colleagues (2006) performed a systematic review of the literature on cancer risks and data on screening efficacy for Lynch syndrome with the intent to provide recommendations for clinical management for affected families. While the authors acknowledged the absence of demonstrated efficacy, the current gynecologic cancer screening guidelines for women with Lynch syndrome should include annual endometrial sampling and TVU beginning at age 30 to 35 years.

Lecuru (2010) and colleagues assessed the performance of TVU to screen for atypical hyperplasia and endometrial cancer in women at risk for Lynch syndrome. Endometrial biopsy was the reference standard. Of 85 women with mismatch repair gene mutations or Amsterdam II criteria, 58 had 96 paired ultrasound-biopsy evaluations and were included in the study. TVU or transabdominal ultrasonographic finding was considered normal if no polyps or intrauterine abnormalities were seen and if the maximum endometrial thickness was less than 4 mm in postmenopausal women not receiving hormonal replacement therapy or less than 6 mm in other women. Endometrial biopsy results were categorized as not interpretable, normal, or showing atypical hyperplasia or cancer. Sensitivity, specificity, PPV, NPV, and likelihood ratio of ultrasonography were computed. The median follow-up duration was 51.4 months, with cancer diagnosed in 2 individuals. TVU had 100% sensitivity and 100% NPV, 2.2 positive likelihood ratio, and 0 negative likelihood ratio. No interval cancers occurred.

The ACOG practice bulletin on the clinical management of Lynch syndrome (2014; reaffirmed 2016) states there is no consensus on ovarian cancer surveillance in women with Lynch syndrome. Citing results from the largest gynecologic cancer surveillance study to date (Renkonen-Sinisalo, 2007), neither TVU nor CA-125 testing led to the diagnosis of ovarian cancer in any of the 175 Lynch syndrome mutation carriers screened; therefore, it is unclear whether screening with TVU is effective in women with Lynch syndrome.

The American College of Gastroenterology (ACG) (Syngal, 2015) has published guidelines for the surveillance and management of individuals with hereditary gastrointestinal cancer syndromes, including those addressing the surveillance and management of extracolonic malignancies. For individuals with Lynch syndrome, the recommendations state:

> Screening for endometrial cancer (EC) and ovarian cancer should be offered to women at risk for or affected with Lynch syndrome (LS) by endometrial biopsy and transvaginal ultrasound annually, starting at age 30 to 35 years before undergoing surgery or if surgery is deferred (conditional recommendations, very low quality of evidence).

Peutz-Jeghers Syndrome

Peutz-Jeghers syndrome is a rare autosomal dominant condition characterized by the development of noncancerous growths called hamartomatous polyps in the gastrointestinal tract (particularly the stomach and intestines). Most people with Peutz-Jeghers syndrome develop multiple polyps in the stomach and intestines during childhood or adolescence. Polyps can cause health problems such as recurrent bowel obstructions, chronic bleeding, and abdominal pain. Individuals with Peutz-Jeghers syndrome have an increased risk of developing certain types of cancers (such as, colorectal, pancreas, cervix, ovary, gallbladder, or breast cancer) during their lifetime.

The ACG clinical guideline on genetic testing and management of hereditary gastrointestinal cancer syndromes (Syngal, 2015) states in affected or at-risk individuals with Peutz-Jeghers syndrome, surveillance should include monitoring for colon, stomach, small bowel, pancreas, breast, ovary, uterus, cervix, and testes cancers. Pelvic exam and pelvic ultrasound or TVU are recommended surveillance procedures for endometrial cancer beginning around 25 years of age (conditional recommendation). For ovarian cancer surveillance, "pelvic exam and pelvic or transvaginal ultrasound, CA-125 are probably not helpful." No peer-reviewed publications are cited with this recommendation.

The NCCN CPG for genetic/familial high-risk assessment for colorectal cancer (V1.2022) includes cancer risk and surveillance guidelines for the management of Peutz-Jeghers syndrome, including screening of the ovaries, cervix, and uterus beginning at "approximately 18-20 years" of age. The category 2A recommendation is based on the following:

> As there are limited data regarding the efficacy of various screening modalities in Peutz-Jeghers syndrome (PJS), panel recommendations were made while taking into consideration cancer risk in PJS and the known utility of specific screening modalities. To monitor for gynecologic cancer…transvaginal ultrasound may also be considered.

TVU for Evaluation of Adnexal Masses, Abnormal Uterine Bleeding, and Other Pelvic and Gynecologic-Related Conditions

Adnexal Masses

Adnexal masses (that is, masses of the ovary, fallopian tube, or surrounding tissues) may be detected incidentally on physical examination or at the time of pelvic imaging. Less commonly, a mass may present with symptoms of acute or intermittent pain. TVU has been used with or without other imaging modalities including transrectal ultrasonography (TRUS) and TRUS-guided transrectal biopsy to: 1) evaluate the extension of adnexal and pelvic masses, including masses of the cervix, fallopian tube, ovary, retroperitoneum, uterus, or surrounding tissues; and, 2) guide or manage further treatment (such as drainage of deep pelvic and perirectal abscesses) (Giede, 2004; Lorentzen, 2011; Nielsen, 2004; Valentin, 2013a; Valentin, 2013b; Zaritzky, 1979).

The ACOG practice bulletin on the evaluation and management of adnexal masses (2016) states "although most adnexal masses are benign, the main goal of the diagnostic evaluation is to exclude malignancy." Based on "good and consistent scientific evidence (Level

A)," ACOG provides the following recommendations and conclusions:

- Transvaginal ultrasonography is the recommended imaging modality for a suspected or an incidentally identified pelvic mass. No alternative imaging modality has demonstrated sufficient superiority to transvaginal ultrasonography to justify its routine use.
- Ultrasound findings that should raise the clinician's level of concern regarding malignancy include cyst size greater than 10 cm, papillary or solid components, irregularity, presence of ascites, and high color Doppler flow.

Based on "limited or inconsistent scientific evidence (Level B)," the ACOG practice bulletin (2016) recommends:

- Simple cysts up to 10 cm in diameter on transvaginal ultrasonography performed by experienced ultrasonographers are likely benign and may be safely monitored using repeat imaging without surgical intervention, even in postmenopausal patients.

Abnormal Uterine Bleeding (AUB)

The ACOG practice bulletin on endometrial ablation (2007; reaffirmed 2018) refers to the procedure as "…a number of minimally invasive surgical procedures designed to treated AUB in selected women who have no desire for future fertility." Preoperative assessment should include evaluation of structure and histology of the endometrial cavity "…to assess for malignancy or endometrial hyperplasia and to ensure that the length and configuration is suitable for endometrial ablation"; however, "women with endometrial hyperplasia or uterine cancer should not undergo endometrial ablation."

The ACOG practice bulletin on management of AUB associated with ovulatory dysfunction (AUB-O) (2013; reaffirmed 2021) describes the condition as a "spectrum of disorders most commonly associated with heavy, irregular uterine bleeding." TVU is one test that may be used to rule out an anatomic abnormality in order to diagnose a structural cause of AUB-O. The practice bulletin states that traditional methods of endometrial surveillance, including TVU, "…may be compromised after endometrial ablation" in individuals with AUB-O who have completed childbearing. For women with AUB-O who have failed medical management, TVU "…is generally not recommended in the virginal patient." In the premenopausal woman, TVU "…ideally should be scheduled between days 4-6 of the menstrual cycle, when the endometrium is the thinnest."

The American College of Radiology (ACR) Expert Panel on GYN and OB Imaging released their Appropriateness Criteria® for the evaluation of fibroids in 2022. That document provided the following information:

- Clinically suspected fibroids. Initial imaging: US pelvis transvaginal May Be Appropriate
- Known fibroids. Treatment planning. Initial imaging: US pelvis transvaginal May Be Appropriate
- Known fibroids. Surveillance or posttreatment imaging. US pelvis transvaginal May Be Appropriate

TVU for the Evaluation and Management of Endometriosis

According to the ACOG practice bulletin for management of endometriosis (2010; reaffirmed in 2018), the condition is a gynecologic disorder whose principal symptoms are chronic pain and infertility. The condition occurs in 6% to 10% of women of reproductive age with a greater prevalence in infertile women and women with chronic pelvic pain (38% and 71%-87%, respectively). Clinical manifestations of endometriosis are unpredictable and variable in both presentation and course, and include dysmenorrhea, chronic pelvic pain, dyspareunia, utero-sacral ligament nodularity, and either a symptomatic or asymptomatic adnexal mass.

Guerriero and colleagues (2015) performed a systematic review and meta-analysis to determine the diagnostic accuracy of TVU in the preoperative detection of endometriosis in the uterosacral ligaments (USL), rectovaginal septum (RVS), and the vagina and bladder in individuals with clinical suspicion of deep infiltrating endometriosis (DIE). A total of 11 studies (n=1583) were included in the meta-analysis including those by Bazot (2014), Bazot (2009), and Hudelist (2011a). For detection of endometriosis in the USL, the overall pooled sensitivity and specificity of TVU were 53% (95% CI, 35%-70%) and 93% (95% CI, 83%-97%), respectively. The pretest probability of USL endometriosis was 54%, which increased to 90% when suspicion of endometriosis was present after TVU examination. The overall pooled sensitivity and specificity were 49% (95% CI, 36%-62%) and 98% (95% CI, 95%-99%), respectively for detection of endometriosis in the RVS. The pretest probability of RVS endometriosis was 24%, which increased to 89% when suspicion of endometriosis was present after TVU examination. For detection of vaginal endometriosis, the overall pooled sensitivity and specificity were 58% (95% CI, 40%-74%) and 96% (95% CI, 87%-99%), respectively. The pretest probability of vaginal endometriosis was 17%, which increased to 76% when suspicion of endometriosis was present after TVU assessment. The overall pooled sensitivity and specificity were 62% (95% CI, 40%-80%) and 100% (95% CI, 97%-100%), respectively for the detection of bladder endometriosis. The pretest probability of bladder endometriosis was 5%, which increased to 92% when suspicion of endometriosis was present after TVU assessment. The authors concluded that the overall diagnostic performance of TVU for detecting DIE in USL, RVS, and the vagina and bladder "is fair with high specificity."

Xiang 2022 and colleagues conducted a systematic review and meta-analysis on the value of TVU in the diagnosis of deep invasive endometriosis. The review included 12 studies comprised of 1707 study participants. Overall, diagnosis with TVU showed high sensitivity (98%) and specificity (near 100%) in the diagnosis of deep invasive endometriosis.

The ACOG practice bulletin recommendation for the management of endometriosis (2010; reaffirmed in 2018) is based on "good and consistent scientific evidence (Level A)," stating that "imaging studies alone appear to have high predictive accuracy in differentiating an ovarian endometrioma from other adnexal masses, and transvaginal ultrasonography is the imaging modality of choice when assessing the presence of endometriosis." In addition, TUV "is also the imaging technique of choice to detect the presence of deeply infiltrating endometriosis of the rectum or rectovaginal septum."

TVU for Confirmation of an Intrauterine Device (IUD)

De Kroon and colleagues (2003) conducted a prospective study comparing clinical evaluation with TVU measurement of intrauterine device position both immediately following placement and 6 weeks after placement. The primary outcome measures were the PPV and NPV of the clinical evaluation of the IUD position. A total of 195 consecutive women were implanted with an IUD, of which 181 (92.8%) were available for follow-up. Immediately following placement the PPV and NPV of clinical evaluation of IUD position were 0.60 (95% CI, 0.39-0.81) and 0.98 (95% CI, 0.96-1.0), respectively. The prevalence of an abnormally position IUD was 7.7% (95% CI, 3.9-11.4). The PPV and NPV of clinical evaluation at follow-up were 0.54 (95% CI, 0.26-0.81) and 1.0 (95% CI, 0.98 to 1.0), respectively. The prevalence of abnormal position was 4.0% (95% CI, 1.7 to 7.1). The investigators concluded that the routine use of TVU to monitor the position of an IUD is not indicated as the results of this study show that "without clinical suspicion of an erroneous position, the chances of an inadequately positioned IUD are negligible."

The ACOG committee opinion bulletin on clinical challenges of long-acting reversible contraceptive methods (2019) states that when IUD strings are not visualized, correct location should be confirmed before the IUD can be relied on for contraception. In these situations where the string is no longer visible, TVU is a viable modality to confirm or reject that the IUD is correctly located in the endometrial cavity.

Pelvic Floor Dysfunction

The American College of Radiology (ACR) Expert Panel on GYN and OB Imaging released their Appropriateness Criteria® for the evaluation of pelvic floor dysfunction in females in 2022. That document provided the following information:

- Vaginal protrusion or bulge, or clinically suspected pelvic organ prolapse. Initial imaging: US pelvis transvaginal Usually Not Appropriate
- Female. Urinary dysfunction (involuntary leakage of urine, or frequent urination, or urgency, or straining to void, or incomplete voiding, or splinting, or digital maneuvers to void). Initial imaging: US pelvis transvaginal May Be Appropriate
- Female. Defecatory dysfunction (incontinence of stool or liquid or gas, or straining during defecation, or difficulty initiating defecation, or incomplete evacuation, or splinting or digital maneuvers to defecate). Initial imaging: US pelvis transvaginal Usually Not Appropriate
- Female. Follow-up imaging after pelvic floor surgery. Subacute or chronic complications other than recurrent pelvic floor dysfunction. Initial imaging: US pelvis transvaginal May Be Appropriate

Use of TVU for screening in other populations

The use of TVU in populations at low risk for the conditions addressed above and in individuals with no symptoms is not recommended by any authoritative organization. The likelihood of finding actionable findings in such populations is low compared to the potential harms

Definitions

Endocavitary Ultrasound Probe: A long, thin ultrasound acoustic transducer that captures internal diagnostic images when introduced externally into an anatomic space.

Transvaginal: Through the vagina.

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Index

Transvaginal ultrasound
TVU
TV-US
TVUS

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Background/Overview, Definitions, References, and Websites for Additional Information sections.
Reviewed	08/11/2022	MPTAC review. Updated Background/Overview, References, and Websites for Additional Information.
Reviewed	08/12/2021	MPTAC review. Updated Background/Overview, References, and Websites for Additional Information.
Reviewed	08/13/2020	MPTAC review. Updated Discussion/General Information, References, and Websites for Additional Information sections. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated Discussion/General Information, References, and Websites for Additional Information sections.
Reviewed	11/08/2018	MPTAC review. Updated Discussion/General Information, References, and Websites for Additional Information sections.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Discussion/General Information, References, and Websites for Additional Information sections.
New	02/02/2017	MPTAC review. Initial document development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.