Clinical Policy Title: Transvaginal and transabdominal ultrasound

Clinical Policy Number: 13.01.02

Effective Date: September 1, 2015
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Most Recent Review Date: August 17, 2016
Next Review Date: August 2017

Related policies:
CP# 12.01.02 Prenatal obstetrical ultrasound

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

A. Keystone First considers the use of either transvaginal ultrasound (TVUS) or transabdominal ultrasound (TAUS) to be clinically proven and, therefore, medically necessary for the following clinical indications:
  - Confirmation of the presence of an intrauterine pregnancy.
  - Evaluation of a suspected ectopic pregnancy.
  - Estimation of gestational (menstrual) age.
  - Confirmation of fetal cardiac activity.
  - Imaging as an adjunct to chorionic villus sampling and embryo transfer and localization, and removal of an intrauterine device (IUD).
  - Assessing for certain fetal anomalies, such as anencephaly, in high-risk patients.
  - Evaluation of pelvic masses and/or uterine abnormalities.
  - Measuring the nuchal translucency (NT) when part of a screening program for fetal aneuploidy.
  - Evaluation of suspected hydatidiform mole.
  - Follow-up evaluation of a fetal anomaly.
  - Evaluation of fetal anatomy.
  - Evaluation of fetal growth.
  - Evaluation of abnormal vaginal bleeding.
• Evaluation of abdominal or pelvic pain.
• Evaluation of cervical insufficiency.
• Evaluation of endometrial thickness.
• Adjunct to cervical cerclage placement.
• Determination of fetal presentation.
• Diagnosis or evaluation of suspected multiple gestation.
• Adjunct to amniocentesis or other procedure.
• Adjunct to follicle puncture for egg retrieval for in vitro fertilization (IVF).
• Adjunct to ovarian cyst puncture and/or aspiration.
• Adjunct to embryo transfer in “fresh” IVF cycle, cryopreservation and/or egg donation.
• Adjunct to sonohysterography.
• Evaluation of cervical length.
• Evaluation of significant discrepancy between uterine size and clinical dates.
• Evaluation of pelvic mass.
• Suspected fetal death.
• Suspected uterine abnormality.
• Suspected amniotic fluid abnormalities.
• Suspected placental abruption.
• Adjunct to external cephalic version.
• Evaluation of premature rupture of membranes and/or premature labor.
• Evaluation of abnormal biochemical markers.

B. Keystone First considers the combined use of TAUS and TVUS to be clinically proven and, therefore, medically necessary when either study is insufficient to provide adequate diagnosis.

Limitations:

All other uses of TVUS and TAUS are not medically necessary, including but not limited to:
• Screening for ovarian cancer with or without serum marker CA-125 in asymptomatic women in the absence of heritable disease.
• Screening for endometrial cancer in asymptomatic women in the absence of heritable disease.
• Determination of gender of fetus.
• Use of three-dimensional (3-D) or four-dimensional (4-D) ultrasounds.

Alternative covered services:

• Organ-specific diagnostic procedures such as cystoscopy, hysteroscopy, anoscopy or sigmoidoscopy.
• With the diagnostic exception of possible or known pregnancy:
  – Plain radiographs of the abdomen and/or pelvis.
  – Organ-specific radiographs with contrast (including air insufflation) such as cystography or hysterosalpingography.
  – Computed tomography (CT) of the abdomen with or without contrast.
  – CT of the pelvis with or without contrast.
  – Magnetic resonance imaging (MRI) of the abdomen.
  – MRI of the pelvis.
Background

TVUS is materially distinct from TAUS. TVUS provides superior imaging of pelvic structures (i.e., uterus, cervix, ovaries and adnexae). TVUS requires special instrumentation apart from the abdominal transducer employed for TAUS examination and specialized training and materials to perform. Prudent practice may require a chaperone for TVUS procedures as performed by either a male or female technician.

There are limitations to TAUS with regard to the deep pelvic organs (i.e., the reproductive organs) that can only be overcome by the transvaginal approach. For example, a calculus of the bladder or implanted mesh to the lower abdomen may create acoustic shadowing that limits adequate visualization of pelvic anatomy from the anterior approach.

Finally, TVUS-guided aspiration and biopsy of pelvic organs facilitate patient safety by placing the ultrasound transducer close to or directly at the site of a suspicious mass or cyst. For example, a patient presenting with new pelvic pain following radical cystectomy for carcinoma of the bladder in whom there is suspicion of cancer recurrence may be biopsied without risk of transperitoneal insertion of a biopsy needle. The same technical considerations hold true for any pelvic exenterative surgery for carcinoma, including cancer of the uterus, cervix or rectum.

Searches

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on July 21, 2016. Search terms were: “transvaginal,” “transabdominal,” “ultrasound” and “endovaginal sonography.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines** based on systematic reviews.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

TVUS and TAUS performed alone or in combination are established diagnostic imaging modalities for multiple clinical indications. TVUS and TAUS in combination is generally indicated when either study is insufficient to provide adequate diagnosis. In addition, limited evidence suggests TVUS and TAUS in
combination may reduce overall investigative cost and surgical delay in the diagnosis of appendicitis and can facilitate chorionic villus sampling (Bondi 2012, Bertucci 2011).

**Screening gynecological cancers:**

The United States Preventive Services Task Force (USPSTF) does not recommend screening for ovarian cancer in asymptomatic women, as there is no evidence of benefit (USPSTF 2012). This recommendation does not apply to women with known genetic mutations (e.g., BRCA mutations) that increase their risk for ovarian cancer.

The Prostate, Lung, Colon and Ovarian (PLCO) multicenter randomized control trial (RCT) considered data from the first four annual screens and found 60 of the 89 invasive ovarian or peritoneal cancers diagnosed were screen-detected (Partridge 2009). The positive-predictive value (PPV) and cancer (diagnostic) yield per 10,000 women screened on the combination of tests were similar across screening rounds (PPV range 1.0 to 1.3 percent, cancer yield 4.7 to 6.2); however, the biopsy (surgery) rate among screen positives decreased from 34 percent at T0 to 15 to 20 percent at T1-T3. The overall ratio of surgeries to screen-detected cancers was 19.5:1, and 72 percent of screen-detected cases were late stage (III/IV). The authors concluded that through four screening rounds, the ratio of surgeries to screen-detected cancers was high, and most cases were late stage. However, the effect of screening on mortality is unknown.

The Society of Gynecologic Oncologists recommends that symptomatic women (i.e., bloating, pelvic pain, abdominal pain, dysphagia or early satiety) see a gynecologist if symptoms persist for more than three weeks (Foundation for Women’s Cancer Network [FWCN] 2007). If there is suspicion of cancer the clinician may choose to perform a TVUS to check the ovaries for signs of malignancy.

Lacey (2006) found that stratifying women into risk groups based on family history slightly enhanced the PPV of a combined CA-125 and TVUS-based screening approach. Whether screening for ovarian cancer with or without serum marker CA-125 and TVUS proves to be efficacious, cost-effective, or clinically useful in screened populations awaits the results of the PLCO and other cancer screening studies. PLCO participants are being followed and additional data will be collected through 2015.

The National Cancer Institute (NCI 2004) found insufficient evidence to establish whether a decrease in mortality from endometrial cancer occurs with screening asymptomatic women by TVUS. The NCI notes that risks associated with false-positive test results include anxiety and additional diagnostic testing and surgery. In addition, ultrasound may miss many endometrial cancers.

According to Meyer (2009), approximately 2 percent to 5 percent of endometrial cancers may be due to an inherited susceptibility. Lynch syndrome (also known as hereditary non-polyposis colorectal cancer syndrome) accounts for the majority of inherited cases. Current gynecologic cancer screening guidelines for women with Lynch syndrome include annual endometrial sampling and TVUS beginning at age 30 to 35 years. Diagnosing endometrial cancer patients with Lynch syndrome has important clinical implications for the individual and family members, and screening for endometrial cancer with TVUS in this cohort can decrease the likelihood of developing additional cancers.

**Policy updates:**
We identified five new systematic reviews and meta-analyses (Nisenblat 2016, Teixeira 2015, Ruiter 2015, Polena 2015, Ezebialu 2015,) and one evidence-based practice guideline from the Society of Obstetricians and Gynaecologists of Canada (Carranza-Mamane 2015) for this policy update. The new information confirms a role for TVUS in the non-invasive assessment of: uterine disorders such as endometriosis and uterine fibroids (Nisenblat 2016, Carranza-Mamane 2015); obstetrical complications such as vasa previa and pre-induction cervical ripening (Ruiter 2015, Ezebialu 2015); and potentially life-threatening gynecological emergencies (Polena 2015). For embryonic transfer, ultrasound and clinical touch have similar effects on obstetrical outcomes, and both would be acceptable means of guiding the procedure (Teixeira 2015). Ultimately, the choice of diagnostic tool would depend on several factors, for example, clinical circumstances, available technology, clinician training and patient preferences. These findings would not change previous findings; therefore, no changes to the policy are warranted.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Nisenblat (2016)</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Cochrane review</td>
<td>Systematic review and meta-analysis of 49 cross-sectional studies and RCTs (4,807 total women) representing: pelvic endometriosis (13 studies); endometriomas (10 studies), and deeply infiltrating endometriosis (DIE) (15 studies), and 33 studies of endometriosis at specific anatomical sites.</td>
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<tr>
<td>Imaging studies as replacement for diagnostic surgery and as triage tests for diagnosis of endometriosis</td>
<td>Overall quality: low.</td>
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<td></td>
<td>No imaging modality was able to detect overall pelvic endometriosis with sufficient accuracy to replace surgery.</td>
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<td></td>
<td>For endometrioma, TVUS had sufficiently high specificity such that a positive test would rule in pathology.</td>
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<td></td>
<td>For deeply infiltrating endometriosis (DIE), TVUS could be used clinically to identify additional anatomical sites of DIE versus MRI and facilitate preoperative planning.</td>
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<td></td>
<td>TVUS, transrectal ultrasound (TRUS), and MRI accurately mapped rectosigmoid endometriosis.</td>
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<td>Insufficient evidence to assess diagnostic role of advanced imaging modalities (e.g., TVUS with bowel preparation or rectal water contrast, 3.0T MRI or multidetector CT with enema).</td>
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<td></td>
<td>Future well-designed comparative diagnostic studies are needed.</td>
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<td><strong>Carranza-Mamane (2015) for the Society of Obstetricians and Gynaecologists of Canada</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Evidence-based recommendations for uterine fibroids in unexplained infertility</td>
<td>Adequately evaluate and classify fibroids using TVUS, hysteroscopy, hysterosonography, or MRI, particularly those impinging on the endometrial cavity. (III-A)</td>
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<td>Preoperatively assess submucosal fibroids for fibroid size and location within the uterine cavity, the degree of invasion of the cavity, and thickness of residual myometrium to the serosa. Combinations of hysteroscopy and either TVUS or hysterosonography are the modalities of choice. (III-B)</td>
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<tr>
<td><strong>Ezebialu (2015)</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Cochrane review</td>
<td>Systematic review and meta-analysis of two RCTs (234 total women) comparing Bishop score (standard digital vaginal assessment) and TVUS.</td>
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<td>Assessing pre-induction cervical ripening</td>
<td>Overall quality: moderate.</td>
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<td></td>
<td>Results did not demonstrate superiority of one method over the other. Perinatal mortality not assessed.</td>
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<td></td>
<td>TVUS was associated with an increased need for misoprostol for cervical ripening, but both methods could be complementary. Choice of method may depend on</td>
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<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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<td>Polena (2015)</td>
<td><strong>Key points:</strong></td>
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| Non-invasive assessment of potentially life-threatening gynecological emergencies | - Systematic review of 45 diagnostic efficacy studies (6,885 women) for four major emergencies: complicated (ruptured) ectopic pregnancy, complicated pelvic inflammatory disease, adnexal torsion, and hemoperitoneum.  
- Overall quality: low to moderate with a high degree of spectrum bias. Mostly retrospective, single-center studies.  
- Overall TVUS was most often studied (20/45 studies) and had highest diagnostic performance (both high sensitivity [Se] and high specificity [Sp]) in the emergency setting compared with medical history, clinical exam, and biological tests.  
- Further studies needed to assess implementation and impact on health outcomes, used alone or in combination. |
| Ruiter (2015) | **Key points:** |
| Diagnosis of vasa previa | - Systematic review of two prospective (33,795 total women) and six retrospective (442,633 women) cohort studies. Four of eight studies used TVUS for primary evaluation; four studies used TAUS initially and used TVUS when vasa previa was suspected.  
- Overall quality: low in retrospective studies, moderate in prospective studies.  
- Retrospective studies: prenatal detection rates varied from 53% (10/19) to 100% (138 cases of vasa previa).  
- Prospective studies (11 cases of vasa previa): TVUS color Doppler detected all cases of vasa previa (Se 100%, Sp 99.0 to 99.8%).  
- Future studies needed to inform decision on the effectiveness of routine or targeted prenatal screening for vasa previa. |
| Teixeira (2015) | **Key points:** |
| Ultrasound-guided embryo transfer | - Systematic review of 21 RCTs: “US guidance” vs. “clinical touch” (17 RCTs), TVUS guidance versus TAUS (three RCTs), and hysterosonometry before embryo transfer vs. “US guidance” (one RCT).  
- Evidence suggests a modest benefit of using US guidance over clinical touch during embryo transfer; the increased cost and need to change the catheter type may affect choice. Results inconclusive. |
| American College of Radiologists (ACR) Appropriateness Criteria: Abnormal vaginal bleeding (2014) | **Key points:** |
| | - TVUS generally the initial imaging procedure of choice for evaluating abnormal vaginal bleeding due to ability to depict endometrial pathology and its widespread availability, excellent safety profile, and cost effectiveness.  
- TAUS often performed in conjunction with TVUS, and both are complementary.  
- TAUS offers a wider field of view, increased depth of penetration, and ability to evaluate adjacent organs.  
- TAUS approach is helpful for evaluating a markedly enlarged fibroid uterus, especially if there is extrapelvic extension of subserosal or pedunculated fibroids.  
- Optimal evaluation of the endometrium generally requires TVUS, which allows for higher-resolution imaging. If the transvaginal probe cannot be tolerated, as is often the case in a prepubertal or virginal patient, TAUS using the urinary bladder as an acoustic window becomes essential. |
<p>| Bondi (2012) | <strong>Key points:</strong> |
| | - Prospective study found combination TVUS and TAUS reduced investigational costs and unnecessary surgery. |</p>
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<tr>
<td><strong>USPSTF (2012)</strong></td>
<td><strong>Key points:</strong></td>
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<td>Ovarian cancer screening in asymptomatic women is not recommended.</td>
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<td>Women with known genetic mutations that increase their risk for ovarian cancer (for example, BRCA mutations) are not included in this recommendation.</td>
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<td><strong>ACR Appropriateness Criteria: Multiple gestations (2011)</strong></td>
<td><strong>Key points:</strong></td>
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<td>TAUS or TVUS is safe and appropriate for patients with suspected multiple gestation pregnancy or in patients who have already been diagnosed with twins.</td>
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<td>The discussion section refers to the superior accuracy of TVUS for measuring cervical length and predicting preterm birth in twin pregnancies.</td>
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<td><strong>American Institute of Ultrasound in Medicine (AIUM) Practice Guideline for the Performance of Sonohysterography (2011)</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>Preliminary endovaginal sonography (TVUS) with measurements of the endometrium and evaluation of the uterus, ovaries, and pelvic free fluid should be performed before sonohysterography.</td>
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<td><strong>Bertucci (2011)</strong></td>
<td><strong>Key points:</strong></td>
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<td>TVUS and TAUS for chorionic villous sampling (CVS)</td>
<td>Retrospective study found combination TVUS and TAUS facilitated CVS.</td>
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<td>In 89 of 90 cases in which TVUS manipulation was carried out, access to the trophoblast improved sufficiently to allow TAUS CVS to be performed with a single aspiration.</td>
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<td><strong>Champaneria (2010)</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Non-invasive diagnosis of adenomyosis</td>
<td>Systematic review including 2,312 females shows high levels of accuracy of TVUS.</td>
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<td>Until recently, the reference standard for a definitive diagnosis was histology of hysterectomy specimens.</td>
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<td>Ultrasound and MRI may allow accurate non-invasive diagnosis.</td>
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<td><strong>American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin No. 101 (2009)</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Ultrasonography in pregnancy</td>
<td>Consider TVUS or “transperitoneal” US if the cervix appears shortened.</td>
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<td></td>
<td>Does not recommend routine cervical length (CL) assessment in low-risk pregnancies because of the lack of evidence supporting this application, other than a demonstrated association between short cervix and preterm delivery.</td>
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<td>Serial assessment of CL may benefit certain women at high risk of pre-term birth.</td>
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<td><strong>Hudelist (2009)</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>TVUS for preoperative diagnosis of pelvic endometriosis</td>
<td>Systematic review (1,106 women) shows high levels of accuracy of TVUS in non-invasive diagnosis of bowel-infiltrating endometriosis.</td>
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<td>The prevalence of deeply infiltrating endometriosis (DIE) varied from 24% to 73.3%.</td>
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<td>The authors concluded that TVUS with or without prior bowel preparation is accurate for non-invasive, pre-surgical detection of DIE of the rectosigmoid.</td>
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<td><strong>Meyer (2009)</strong></td>
<td><strong>Key points:</strong></td>
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<td>Lynch syndrome</td>
<td>Narrative review of current gynecologic cancer screening guidelines for women with Lynch syndrome: Include annual endometrial sampling and TVUS beginning at age 30 to 35 years.</td>
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<td>Screening and prevention practices can decrease the likelihood of developing</td>
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<td>Citation</td>
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<tr>
<td><strong>Partridge (2009)</strong>&lt;br&gt;PLCO cancer study</td>
<td><strong>Key points:</strong>&lt;br&gt;- Multicenter RCT of ovarian cancer screening with TVUS and CA-125.&lt;br&gt;- Among 34,261 women, data from the first four annual screens found surgical intervention for screen-detected cancers was high, and most cases were late stage. The effect of screening on mortality is unknown.</td>
</tr>
<tr>
<td><strong>AIUM Practice Guideline for Ultrasonography in Reproductive Medicine (2008)</strong></td>
<td><strong>Key points:</strong>&lt;br&gt;- TVUS may distinguish a suspected mass from fluid and feces within the normal rectosigmoid.&lt;br&gt;- TVUS or TAUS follicle puncture for retrieving eggs for IVF is appropriate in the following circumstances:&lt;br&gt;  - The patient has undergone comprehensive sonographic evaluation of the pelvis within four to six months prior to the start of hormonal stimulation of the ovaries.&lt;br&gt;  - Real-time continuous guidance is available, and the image demonstrates a safe approach for the needle path.&lt;br&gt;  - The ovaries can be brought in close proximity to the ultrasound transducer, thus avoiding the puncture of vital structures (e.g., bowel and blood vessels).&lt;br&gt;- TVUS or TAUS ovarian cyst puncture and aspiration is appropriate in patients who have been diagnosed with a persistent ovarian cyst and who meet the following criteria:&lt;br&gt;  - Failed resolution of the cyst following observation and/or hormonal manipulation.&lt;br&gt;  - The cyst is unilocular and thin-walled without internal excrescences or septations.&lt;br&gt;  - Real-time continuous guidance is available, and the image demonstrates a safe approach for the needle path.&lt;br&gt;  - The cyst can be brought in close proximity to the ultrasound transducer, thus avoiding the puncture of vital structures (e.g., bowel and blood vessels).&lt;br&gt;- Embryo transfer: Ultrasound-assisted embryo transfer is appropriate in patients undergoing a “fresh” IVF cycle or following embryo cryopreservation or embryo/egg donation. If an abdominal ultrasound examination is performed, the bladder should be full to facilitate visualization of the endometrium and the transfer catheter.&lt;br&gt;- TAUS or TVUS in the first 10 weeks of pregnancy may be performed; TVUS preferred.</td>
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<td><strong>Bazot (2007)</strong>&lt;br&gt;TVUS versus transrectal ultrasound (TRUS) for DIE</td>
<td><strong>Key points:</strong>&lt;br&gt;- Prospective study (81 consecutive patients).&lt;br&gt;- TVUS: Se 87.3 %, PPV 98.6%, accuracy 86.4%.&lt;br&gt;- TRUS: Se 74.7%, PPV 98.3%, accuracy 74%.&lt;br&gt;- TVUS is more accurate than TRUS for predicting DIE in specific locations.</td>
</tr>
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<td><strong>FWCN (2007) for the Society for Gynecologic Oncologists Early detection of ovarian cancer</strong></td>
<td><strong>Key points:</strong>&lt;br&gt;- Consensus statement recommendations:&lt;br&gt;  - Women who have symptoms — specifically bloating, pelvic, or abdominal pain; difficulty eating or feeling full quickly; and urinary frequency and urgency — should see a gynecologist if symptoms are new and persist for more than three weeks.&lt;br&gt;  - If suspicion of cancer, the clinician may perform a TVUS to check the ovaries.&lt;br&gt;  - Testing for CA-125 levels should be considered.</td>
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<tr>
<td><strong>Lacey (2006)</strong>&lt;br&gt;Ovarian cancer</td>
<td><strong>Key points:</strong>&lt;br&gt;- RCT of 28,460 women with a history of breast or ovarian cancer classified as...</td>
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<td>screening with TVUS and CA-125 serum marker.</td>
<td>average-risk (n = 22,687), moderate-risk (n = 2,572), or high-risk (n = 2,163) based on family history, or high-risk due to a personal history of breast cancer (n = 1,038).&lt;br&gt;• The PPV for abnormal screening results: 0.7% in average-risk, 1.3% in moderate-risk, and 1.6% in high-risk groups; one ovarian cancer occurred among breast cancer survivors.&lt;br&gt;• The probabilities of abnormal annual CA-125 and TVUS screens were similar across groups based on family history of breast or ovarian cancer.&lt;br&gt;• Stratifying women into risk groups based on family history slightly enhanced the PPV of a combined CA-125 and TVUS-based screening approach.&lt;br&gt;• Clinical utility and cost-effectiveness of this screening approach awaits confirmation from the PLCO and other cancer screening studies.</td>
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<tr>
<td>ACOG Committee Opinion No. 48 (2004) Cervical insufficiency</td>
<td>Key points:&lt;br&gt;• Serial ultrasound examinations should be considered in a patient with historical risk factors for cervical insufficiency and initiated between 16 and 20 weeks of gestation or later.&lt;br&gt;• The evaluation of a patient with cervical shortening or funneling should include a comprehensive sonographic assessment of the fetus.</td>
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<tr>
<td>NCI (2004) Statement on screening for endometrial cancer</td>
<td>Key points:&lt;br&gt;• Insufficient evidence to establish whether screening by TVUS decreases mortality from endometrial cancer.&lt;br&gt;• Risks associated with false-positive test results include anxiety and additional diagnostic testing and surgery.&lt;br&gt;• Ultrasound may miss endometrial cancers.</td>
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<tr>
<td>Persadie (2002) Measurement of endometrial thickness with TVUS</td>
<td>Key points:&lt;br&gt;• Narrative review.&lt;br&gt;• TVUS offer superior detail in imaging pelvic structures.&lt;br&gt;• Measurement of endometrial thickness with ultrasonography:&lt;br&gt;  - Is a modality in common clinical use today.&lt;br&gt;  - Is used to monitor infertility treatment in pre-menopausal women.&lt;br&gt;  - Is useful as an initial investigation for endometrial hyperplasia or cancer in post-menopausal women with abnormal uterine bleeding.</td>
</tr>
<tr>
<td>ACOG Practice Bulletin No. 27 (2001) Prenatal diagnosis of fetal chromosomal abnormalities.</td>
<td>Key points:&lt;br&gt;• Guideline describes the key elements of standard sonographic examinations in the first trimester and the second and third trimesters, a more detailed anatomic examination of the fetus may be necessary in some cases, such as when an abnormality is found or suspected on the standard examination or in pregnancies at high risk for fetal anomalies.</td>
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**Glossary**

**Clinical utility** — The rate at which biopsies (or other test results) guide treatment decisions.

**Diagnostic yield** — The likelihood that a test or procedure will provide the information needed to establish a diagnosis. For example, a technically diagnostic biopsy may or may not be helpful in making a diagnosis.

**Pelvic exenteration** — The removal of the pelvic organs and adjacent structures to surgically remove cancerous organs and prevent recurrence.
**Positive predictive value (PPV)** — A test performance characteristic defined as the proportion of persons with a positive test result who actually have the disease, e.g., a test with a low PPV indicates that many of the positive results from this test are false positives.

**Sonohysterography** — An ultrasound technique in which fluid is injected through the cervix into the uterus. The fluid shows more detail of the inside of the uterus than when ultrasound is used alone.

**Transabdominal ultrasound (TAUS)** — Ultrasound using the probe (transducer) outside the body to study structures above the iliac crests (e.g., hepatic ultrasound).

**Transpelvic ultrasound** — Ultrasound using the transducer outside the body to study structures below the iliac crests (e.g., uterus and ovaries).

**Transvaginal ultrasound (TVUS)** — Ultrasound using a transducer in the vagina often with the tip against the cervix, etc.

**Ultrasound (ultrasonography)** — The application of sound waves to image internal structures.

**Vasa previa** — An obstetric complication in which fetal blood vessels cross or run near the internal orifice of the uterus.

**References**

**Professional society guidelines/others:**


Peer-reviewed references:


**Personal correspondence:**

Raymond Tu MD MS FACR Chairman, Department of Radiology, Vice Chief of Staff, NFPHC/United Medical Center, Clinical Associate Professor, Radiology, The George Washington University, Washington, DC.

**Clinical trials:**

Searched clinicaltrials.gov on July 24, 2016, using terms "transvaginal ultrasound" OR "transabdominal ultrasound" | Open Studies | United States. Thirty studies found, six relevant.


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**

No LCDs as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly. Further guidance is available in the ACR Frequently Asked Questions (Appendix A) and Practice Parameters (Appendix B) of this document.

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<th>CPT Code</th>
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<td>Ultrasound, transvaginal</td>
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<tr>
<td>76856</td>
<td>Ultrasound, pelvic (nonobstetric), real time with image documentation; complete</td>
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<td>78657</td>
<td>Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or followup</td>
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**Appendix A**


Because of the recent Office of Inspector General (OIG) report recommending that the Centers for Medicare & Medicaid Services monitor ultrasound claims for questionable coding practices, the following Q&As, previously published in ACR publications, are provided as a review of appropriate ultrasound coding guidelines. The guidance provided in these answers will be helpful to defend your billing practices should you be audited.
1. Is it appropriate to report the nonobstetrical transvaginal sonogram of the pelvis code (76830) in combination with other abdominal and/or OB/GYN sonogram codes?

The ACR’s Ultrasound Coding User’s Guide states that the pelvic ultrasound using a full bladder as a window to the pelvis and a transvaginal ultrasound using a vaginal probe as a window to the pelvis are separately coded procedures. A common practice is for ultrasound departments to begin with a pelvic ultrasound performed through a full bladder and to supplement the examination with a transvaginal examination when necessary. Use 76856 or 76857, as appropriate, for the pelvic ultrasound procedure. Add 76830 for the transvaginal ultrasound. When the transvaginal examination is used as the only technique, use 76830 to code for the procedure.

This has been a long-standing ACR coding guideline that was first published in an October 1993 Radiology Business Management Association Bulletin coding article. The article titled Transvaginal Sonogram of the Pelvis (76830) stated:

“In order to properly evaluate a patient it is often necessary to perform additional studies during one session. These studies are done in order to acquire additional clinical information not evident from the initial study, or to further investigate an area that appears suspicious or problematic. Performing a transabdominal and a transvaginal pelvic sonogram at one sitting is an example of this type of evaluation.

Transvaginal sonogram is used for both obstetrical and non-obstetrical evaluations. This procedure represents the performance and interpretation of the pelvis structures including the uterus, endometrium, ovaries, and adnexa. A special probe is used transvaginally to aid in such studies as fetal viability, ectopic pregnancies, harvest of ova, and fertility studies.”

If a woman has vaginal bleeding, a transvaginal scan is needed to assess the endometrium at higher resolution than that available with the transabdominal probe. If an adnexal mass is visualized, a transvaginal examination allows for improved characterization of the internal characteristics of the mass.

When coding for both transabdominal and transvaginal studies in a single setting, it is important for the report to clearly state the indication for performing the second examination, for example, for better assessment of the endometrium and/or adnexa.
Appendix B


Female pelvic ultrasound may be performed transabdominally or transvaginally
Same billed procedure, just a different approach


1. Indications for pelvic sonography include, but are not limited to, the following:
2. Evaluation of pelvic pain
3. Evaluation of pelvic masses
4. Evaluation of endocrine abnormalities, including polycystic ovaries
5. Evaluation of dysmenorrhea (painful menses)
6. Evaluation of amenorrhea
7. Evaluation of abnormal vaginal bleeding
8. Evaluation of delayed menses
9. Follow-up of a previously detected abnormality
10. Evaluation, monitoring, and/or treatment of infertility patients
11. Evaluation when there is limited clinical examination of the pelvis
12. Evaluation for signs or symptoms of pelvic infection
13. Further characterization of a pelvic abnormality noted on another imaging study
14. Evaluation of congenital uterine and lower genital tract anomalies
15. Evaluation of excessive bleeding, pain, or signs of infection after pelvic surgery, delivery, or abortion
16. Localization of an intrauterine contraceptive device
17. Screening for malignancy in high-risk patients
18. Evaluation of incontinence or pelvic organ prolapse
19. Guidance for interventional or surgical procedures
20. Preoperative and postoperative evaluation of pelvic structures

All relevant structures should be identified by the transabdominal and/or transvaginal approach. A transrectal or transperineal approach may be useful in patients who are not candidates for introduction of a vaginal probe and in assessing the patient with pelvic organ prolapse. More than one approach may be necessary.

For a complete transabdominal pelvic sonogram, the patient’s bladder can be distended if necessary to displace the small bowel from the field of view. If an abnormality of the urinary bladder is detected, it should be documented and reported.

For a transvaginal sonogram, the urinary bladder is preferably empty. The patient, the sonographer, or the physician may introduce the vaginal transducer, preferably under real-time monitoring. Consideration of having a chaperone present should be in accordance with local policy.
In examining the uterus, the following should be evaluated:

a) The uterine size, shape, and orientation;
b) The endometrium;
c) The myometrium; and
d) The cervix. The vagina may be imaged as a landmark for the cervix.

Sonohysterography may be a useful adjunct to evaluate the patient with abnormal uterine bleeding or to further clarify an abnormally thickened endometrium. (See the ACR–ACOG–AIUM–SRU Practice Parameter for the Performance of Sonohysterography)

The addition of 3-D to 2-D ultrasound (transabdominal, transvaginal, transperineal, and/or transrectal) can be helpful in many circumstances, including, but not limited to, evaluating the relationship of masses to the endometrial cavity, identifying uterine congenital anomalies and thickened and/or heterogenous endometrium, and evaluating the location of an IUD and the integrity of the pelvic floor.

Adnexa Including Ovaries and Fallopian Tubes

The cul-de-sac and bowel posterior to the uterus may not be clearly defined. This area should be evaluated for the presence of free fluid or mass. If a mass is detected, its size, position, shape, sonographic characteristics, and relationship to the ovaries and uterus should be documented. Differentiation of normal loops of bowel from a mass may be difficult if only a transabdominal examination is performed. A transvaginal examination may be helpful to distinguish a suspected mass from fluid and feces within the normal rectosigmoid colon.

Ultrasound studies of the abdomen and/or retroperitoneum

Depending on the clinical indications, an examination may include the entirety of the abdomen and/or retroperitoneum, a single organ, or several organs. A combination of structures may be imaged because of location (e.g., upper abdominal scan, right upper quadrant organs) or function (e.g., biliary system [liver, gallbladder, and bile ducts], both kidneys).

C. Indications for ultrasound examination of the abdomen and/or retroperitoneum include:

1. Abdominal, flank, and/or back pain.
2. Signs or symptoms that may be referred from the abdominal and/or retroperitoneal regions, such as jaundice or hematuria.
3. Palpable abnormalities such as an abdominal mass or organomegaly.
4. Abnormal laboratory values or abnormal findings on other imaging examinations suggestive of abdominal and/or retroperitoneal pathology.
5. Follow-up of known or suspected abnormalities in the abdomen and/or retroperitoneum.
6. Search for metastatic disease or occult primary neoplasm.
7. Evaluation of suspected congenital abnormalities.
8. Abdominal trauma.
11. Search for the presence of free or loculated peritoneal and/or retroperitoneal fluid.
12. Suspicion of hypertrophic pyloric stenosis or intussusception.
B. Abdominal and/or retroperitoneal ultrasound should be performed when there is a valid medical reason. There are no absolute contraindications. Spectral, color, and power Doppler may be useful to differentiate vascular from nonvascular structures in any location. Measurements should be considered for any abnormal area.

1. Liver - The examination of the liver should include long axis and transverse views. The liver parenchyma should be evaluated for focal and/or diffuse abnormalities. If possible, the echogenicity of the liver should be compared with that of the right kidney. In addition, the following should be imaged:
   a) The major hepatic and perihepatic vessels, including the inferior vena cava (IVC), the hepatic veins, the main portal vein, and, if possible, the right and left branches of the portal vein.
   b) The hepatic lobes (right, left, and caudate) and, if possible, the right hemidiaphragm and the adjacent pleural space.
   c) For vascular examinations of the native or transplanted liver, Doppler evaluation should be used to document blood flow characteristics and blood flow direction. The structures that may be examined include the main and intrahepatic arteries, hepatic veins, main and intrahepatic portal veins, intrahepatic portion of the IVC, collateral venous pathways, and transjugular intrahepatic portosystemic shunt (TIPS) stents.

2. Gallbladder and biliary tract - Routine gallbladder examination should be conducted on an adequately distended gallbladder whenever possible. In most cases, fasting prior to elective examination will permit adequate distension of a normally functioning gallbladder. In infants and children, fasting may not be necessary in all cases. The gallbladder evaluation should include long-axis and transverse views obtained in the supine position. Other positions such as left lateral decubitus, erect, or prone may be helpful to evaluate the gallbladder and its surrounding areas completely. Measurements may aid in determining gallbladder wall thickening. If the patient presents with pain, tenderness to transducer compression should be assessed. The intrahepatic ducts can be evaluated by obtaining views of the liver demonstrating the right and left branches of the portal vein. Doppler may be used to differentiate hepatic arteries and portal veins from bile ducts. The intrahepatic and extrahepatic bile ducts should be evaluated for dilatation, wall thickening, intraluminal findings, and other abnormalities. The bile duct in the porta hepatis should be measured and documented. When visualized, the distal common bile duct in the pancreatic head should be evaluated.

3. Pancreas - Whenever possible, all portions of the pancreas – head, uncinate process, body, and tail – should be identified. Orally administered water or contrast agent may afford better visualization of the pancreas. The following should be assessed in the examination of the pancreas:
   a) Parenchymal abnormalities.
   b) The distal common bile duct in the region of the pancreatic head.
   c) The pancreatic duct for dilatation and any other abnormalities, with dilatation confirmed by measurement.
   d) The peripancreatic region for adenopathy and/or fluid.

4. Spleen - Representative views of the spleen in long-axis and transverse projections should be obtained. Splenic length measurement may be helpful in assessing enlargement. Echogenicity of the left kidney should be compared to splenic echogenicity when possible. An attempt should be made to demonstrate the left hemidiaphragm and the adjacent pleural space.
5. **Bowel** - The bowel may be evaluated for wall thickening, dilatation, muscular hypertrophy, masses, vascularity, and other abnormalities. Sonography of the pylorus and surrounding structures may be indicated in the evaluation of the vomiting infant. Graded compression sonography aids in the visualization of the appendix and other bowel loops. Measurements may aid in determining bowel wall thickening [20-26].

6. **Peritoneal fluid** - Evaluation for free or loculated peritoneal fluid should include documentation of the extent and location of any fluid identified. For evaluating peritoneal spaces for bleeding after traumatic injury, particularly blunt trauma, the examination known as focused abdominal sonographic examination for trauma (FAST) assessment (or focused assessment with sonography for trauma) may be performed [27]. The objective of the abdominal portion of the FAST examination is to screen the abdomen for free fluid. Longitudinal and transverse plane images should be obtained in the right upper quadrant through the area of the liver with attention to fluid collections peripheral to the liver and in the subhepatic space. Longitudinal and transverse plane images should be obtained in the left upper quadrant through the area of the spleen, with attention to fluid collections peripheral to the spleen. Longitudinal and transverse images should be obtained at the periphery of the left and right abdomen in the areas of the left and right paracolic gutters for evidence of free fluid. Longitudinal and transverse midline images of the pelvis are obtained to evaluate for free pelvic fluid. Analysis through a fluid filled bladder (which if necessary can be filled through a Foley catheter, when possible) may help in the evaluation of the pelvis.

7. **Abdominal wall** - The examination should include images of the abdominal wall in the location of symptoms or signs. The relationship of any identified mass to the peritoneum should be demonstrated. Any defect in the peritoneum and abdominal wall musculature should be documented. The presence or absence of bowel, fluid, or other tissue contained within any abdominal wall defect should be noted. Images obtained in upright position and/or with use of the Valsalva maneuver may be helpful. Doppler examination may be useful to define the relationship of blood vessels to a detected mass.

8. **Kidneys** - The examination of native or transplanted kidneys should include long-axis and transverse views of the kidneys. The cortices and renal pelves should be assessed. A maximum measurement of renal length should be recorded for both kidneys. Decubitus, prone, or upright positioning may provide better images of the native kidneys. When possible, renal echogenicity should be compared to the adjacent liver or spleen. The kidneys and perirenal regions should be assessed for abnormalities [6,28-35]. For vascular examination of the native or transplanted kidneys, Doppler can be used:
   a) To assess renal arterial and venous patency.
   b) To evaluate suspected renal artery stenosis. For this application, angle-adjusted measurements of the peak systolic velocity should be made proximally, centrally, and distally in the extrarenal portion of the main renal arteries when possible. Peak systolic velocity of the adjacent aorta should also be documented for calculating the ratio of renal to aortic peak systolic velocity. Spectral Doppler evaluation of the intrarenal arteries may be of value as indirect evidence of proximal stenosis in the main renal artery.
   c) For vascular examinations of the transplanted kidney(s), Doppler evaluation should be used to document vascular patency and blood flow characteristics. The structures that may be examined include the main renal artery and vein, arterial and venous anastomoses, the iliac artery and vein, and the intrarenal arteries.

9. **Urinary bladder and adjacent structures** - When performing a complete ultrasound evaluation of the urinary tract, transverse and longitudinal images of the distended urinary bladder and its
wall should be included, if possible. Bladder lumen or wall abnormalities should be noted. Dilatation or other distal ureteral abnormalities should be documented. Transverse and longitudinal scans may be used to demonstrate any postvoid residual, which may be quantitated and reported.

10. Adrenal glands - When possible, usually in the newborn or young infant, long-axis and transverse images of the adrenal glands may be obtained. Normal adrenal glands are less commonly seen by ultrasound in adults.


12. Inferior vena cava - Representative images of the IVC should be obtained. Patency and abnormalities may be evaluated with Doppler.

Obstetrical US (Fetal US)

A. First Trimester Ultrasound Examination
   A standard obstetrical sonogram in the first trimester includes evaluation of the presence, size, location, and number of gestational sac(s). The gestational sac is examined for the presence of yolk sac and embryo/fetus. When an embryo/fetus is detected, it should be measured and cardiac activity recorded by 2D video clip or Mmode. Use of spectral Doppler is discouraged. The uterus, cervix, adnexa, and cul de sac region should be examined.

B. Standard Second or Third Trimester Examination
   A standard obstetrical sonogram in the second or third trimester includes an evaluation of fetal presentation, amniotic fluid volume, cardiac activity, placental position, fetal biometry, and fetal number, plus an anatomic survey. The maternal cervix and adnexa should be examined as clinically appropriate when technically feasible.

C. Limited Examination
   A limited examination is performed when a specific question requires investigation. For example, in most routine nonemergency cases a limited examination could be performed to confirm fetal heart activity in a bleeding patient, or to verify fetal presentation in a laboring patient. In most cases limited sonographic examinations are appropriate only when a prior complete examination is on record.

D. Specialized Examinations
   A detailed anatomic examination is performed when an anomaly is suspected on the basis of history, biochemical abnormalities, or the results of either the limited or standard scan. Other specialized examinations might include fetal Doppler ultrasound, biophysical profile, fetal echocardiogram, or additional biometric measurements.