



**SANDHILLS
CENTER**



Transvaginal and transabdominal ultrasound

Clinical Policy ID: CCP.1116

Recent review date: 9/2021

Next review date: 1/2023

Policy contains: Nonobstetric; obstetric; transabdominal ultrasound; transvaginal ultrasound; ultrasound.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center'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 Sandhills Center 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. Sandhills Center 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. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

Transvaginal ultrasound and transabdominal ultrasound are clinically proven and, therefore, medically necessary for the following clinical indications (American College of Obstetricians and Gynecologists, 2017a, 2017b, 2018, 2019, 2020a, 2020b; American College of Radiology, 2019):

Obstetrical indications:

- Confirmation of the presence of an intrauterine pregnancy.
- Evaluation of a suspected ectopic pregnancy.
- Evaluation of suspected multiple gestation.
- Estimation of gestational (menstrual) age.
- As an adjunct to chorionic villus sampling.
- Confirmation of fetal cardiac activity.
- Assessing for certain fetal anomalies, such as anencephaly, in high-risk patients.
- Measuring the nuchal translucency 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 cervical insufficiency.
- Adjunct to cervical cerclage placement.

- Adjunct to amniocentesis or other procedure.
- Evaluation of cervical length.
- Evaluation of significant discrepancy between uterine size and clinical dates.
- Suspected amniotic fluid abnormalities.

Nonobstetrical indications:

- Localization of an intrauterine device.
- Evaluation of pelvic masses and/or uterine abnormalities.
- Evaluation of endometrial thickness.
- Evaluation of abnormal vaginal bleeding.
- Evaluation of abdominal or pelvic pain.
- Adjunct to ovarian cyst puncture and/or aspiration.
- Adjunct to sonohysterography.
- Evaluation of abnormal biochemical markers.
- Screening for malignancy in high-risk members (American College of Radiology, 2019).

The combined use of transabdominal ultrasound and transvaginal ultrasound is clinically proven and, therefore, medically necessary when either study is insufficient to provide adequate diagnosis.

Limitations

All other uses of transvaginal ultrasound and transabdominal ultrasound 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 considered average-risk (Henderson, 2018).
- Screening for endometrial cancer in asymptomatic women in the absence of heritable disease (Meyer, 2009; National Cancer Institute, 2021).
- Determination of gender of fetus.
- Use of three-dimensional or four-dimensional 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 of the abdomen with or without contrast.
 - Computed tomography of the pelvis with or without contrast.
 - Magnetic resonance imaging of the abdomen.
 - Magnetic resonance imaging of the pelvis.

Background

Transabdominal ultrasound images deep pelvic organs using an ultrasound transducer overlying the abdominal wall (Kurzweil, 2020). The scanning technique applied depends on the organ or pathology of interest. The procedure requires a distended urinary bladder using lower sonographic frequencies to overcome the longer distance between the transducer and deep pelvic organs (i.e., the reproductive organs), which can degrade image quality. An anterior approach may create acoustic shadowing that can limit adequate visualization of some

structures.

Transvaginal ultrasound was developed to overcome the limitations of an anterior approach (Herbst, 2021). An endocavitary, high-frequency transducer is inserted in the vagina to achieve closer proximity to deep pelvic structures and provide superior imaging quality. Transvaginal ultrasound facilitates aspiration and biopsy procedures and exenterative procedures. It also avoids the discomfort of a full urinary bladder. Prudent practice may require a chaperone for transvaginal ultrasound procedures, as well as specialized training and materials to perform. Before performing a transvaginal ultrasound, a transabdominal ultrasound should be performed to look for uterine landmarks and intrauterine pregnancy.

Findings

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

Screening gynecological cancers

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

The Prostate, Lung, Colon, and Ovarian multicenter randomized controlled trial 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 and cancer (diagnostic) yield per 10,000 women screened on the combination of tests were similar across screening rounds (positive predictive value range 1.0 to 1.3%, cancer yield 4.7 to 6.2); however, the biopsy (surgery) rate among screen positives decreased from 34% at T0 to 15% to 20% at T1-T3. The overall ratio of surgeries to screen-detected cancers was 19.5:1, and 72% 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, 2007). If there is suspicion of cancer, the clinician may choose to perform a transvaginal ultrasound for signs of ovarian malignancy.

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

The National Cancer Institute (2018) found insufficient evidence to establish whether a decrease in mortality from endometrial cancer occurs with screening asymptomatic women by transvaginal ultrasound. The 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% to 5% 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 transvaginal ultrasound 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 transvaginal ultrasound in this cohort can decrease the likelihood of developing additional cancers.

In 2016, we identified five new systematic reviews and meta-analyses (Ezebialu, 2015; Nisenblat, 2016; Polena, 2015; Ruiter, 2015; Teixeira, 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 transvaginal ultrasound in the non-invasive assessment of: uterine disorders such as endometriosis and uterine fibroids (Carranza-Mamane, 2015; Nisenblat, 2016); obstetrical complications such as vasa previa and pre-induction cervical ripening (Ezebialu, 2015; Ruiter, 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.

In 2017, we found no new information that would materially change previous findings. No policy changes are warranted.

In 2018, we updated several professional guidelines from the American College of Obstetricians and Gynecologists, the American College of Radiology, and the American Institute of Ultrasound in Medicine. No policy changes are warranted at this time. The policy ID was changed from CP# 13.01.02 to CCP.1116.

In 2019, we removed one guideline from the American College of Obstetricians and Gynecologists (2018b), two guidelines from the American College of Radiology (2013, 2014), and three guidelines from the American Institute of Ultrasound in Medicine (2015, 2017a, 2017b) from the policy. We added one guideline from the American College of Radiology (2018) to the policy. In addition, we added results of three systematic reviews that failed to support a clear role for transabdominal ultrasound for: diagnosing suspected pelvic congestion syndrome relative to the gold standard venography (Steenbeek, 2018); detecting intestinal inflammation in pediatric inflammatory bowel disease (van Wassenae, 2019); or diagnosing gallbladder polyps (Wennmacker, 2018). The new information warrants no policy changes.

In 2020, we updated the reference list. We added a Cochrane review (seven randomized controlled trials; n = 923 participants) (Berghella, 2019) that found inconclusive evidence from very low-quality studies supporting a correlation between transvaginal ultrasound-measured cervical length and prevention of preterm births in women with asymptomatic twin or singleton pregnancies, singleton pregnancies with preterm premature rupture of membranes, or other populations and clinical scenarios. The results were also inconclusive for incidence of other perinatal and maternal health outcomes such as maternal and neonatal infections.

We updated guidance from the American College of Radiology (2019) on screening for malignancy in high-risk patients and added this indication to the coverage section. As fertility treatments are not covered by the health plan, indications related to in vitro fertilization were removed from the coverage section. The list of indications was separated into obstetrical and nonobstetrical indications for clarity.

A systematic review of four trials (n = 293,587 total participants), including results from the Prostate, Lung, Colon, and Ovarian study (clinicaltrials.gov identifier NCT01696994 for the ovarian study portion) found no significant difference in ovarian cancer mortality between average-risk, asymptomatic screened women and those with no screening or in usual care (Henderson, 2018). Screening interventions included transvaginal ultrasound with or

without CA-125 testing, and CA-125 testing alone. Screening with transvaginal ultrasound with or without CA-125 led to surgery for suspected ovarian cancer in 3% of women who did not have cancer, with major surgical complications in 3% to 15%.

In 2021, we update the reference list and added three new systematic reviews and meta-analyses of the diagnostic performance of transvaginal ultrasound for evaluating deep endometriosis (Gerges, 2021), abnormal uterine bleeding (Kaveh, 2020), and adenomyosis (Liu, 2020). No policy changes are warranted.

References

On June 16, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Ultrasonography, Doppler” (MeSH), “Ultrasonography, Interventional” (MeSH), “Ultrasonography, Prenatal” (MeSH), “transvaginal,” “transabdominal,” “ultrasound,” and “endovaginal sonography.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

American College of Obstetricians and Gynecologists. Committee Opinion No. 557: Management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. *Obstet Gynecol.* 2013;121(4):891-896. (Reaffirmed 2020). Doi: 10.1097/01.AOG.0000428646.67925.9a.(a)

American College of Obstetricians and Gynecologists. Committee Opinion No 700: Methods for estimating the due date. *Obstet Gynecol.* 2017;129(5):e150-e154. Doi: 10.1097/aog.0000000000002046.(a)

American College of Obstetricians and Gynecologists. Committee Opinion No. 716: The role of the obstetrician-gynecologist in the early detection of epithelial ovarian cancer in women at average risk. *Obstet Gynecol.* 2017;130(3):e146-e149. (Reaffirmed 2019). Doi: 10.1097/aog.0000000000002299.

American College of Obstetricians and Gynecologists. Committee Opinion No. 723: Guidelines for diagnostic imaging during pregnancy and lactation. *Obstet Gynecol.* 2017;130(4):e210-e216. Doi: 10.1097/aog.0000000000002355.(b)

American College of Obstetricians and Gynecologists. Committee Opinion No. 734: The role of transvaginal ultrasonography in evaluating the endometrium of women with postmenopausal bleeding. *Obstet Gynecol.* 2018;131(5):e124-e129. (Reaffirmed 2020). Doi: 10.1097/aog.0000000000002631.(b)

American College of Obstetricians and Gynecologists. Practice bulletin No. 193: Tubal ectopic pregnancy. *Obstet Gynecol.* 2018;131(3):e91-e103. Doi: 10.1097/aog.0000000000002560.

American College of Radiology. ACR–ACOG–AIUM–SMFM–SRU Practice parameter for the performance of ultrasound of the female pelvis. Res. 27. <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Pelvis.pdf>. Published 2018. Revised 2019.

Berghella V, Saccone G. Cervical assessment by ultrasound for preventing preterm delivery. *Cochrane Database Syst Rev.* 2019;9(9):Cd007235. Doi: 10.1002/14651858.CD007235.pub4.

Bertucci E, Pati M, Cani C, et al. The transvaginal probe as a uterine manipulator: A new technique to simplify transabdominal chorionic villus sampling in cases with difficult access to the trophoblast. *Prenat Diagn.* 2011 Sep;31(9):897-900. Epub 2011 Jun 27. Doi: 10.1002/pd.2801.

Carranza-Mamane B, Havelock J, Hemmings R, et al. The management of uterine fibroids in women with otherwise unexplained infertility. *J Obstet Gynaecol Can.* 2015;37(3):277-288. Doi: 10.1016/S1701-

2163(15)30318-2.

Centers for Medicare & Medicaid Services. Local Coverage Article. A56671 Billing and Coding: Nonobstetric Pelvic Ultrasound. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=56671&ver=11&bc=CAAAAAAAAAAAAA>. Effective April 24, 2020.

Centers for Medicare & Medicaid Services. Local Coverage Article. A55336 Billing and Coding: Retroperitoneal Ultrasound. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55336&ver=34&bc=CAAAAAAAAAAAAA>. Effective October 1, 2020.

Centers for Medicare & Medicaid Services. Local Coverage Determination. L37636 Nonobstetric Pelvic Ultrasound. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33619&ver=24&keyword=ultrasound&keywordType=starts&areald=s11,s10,s12,s23,s25,s27,s37,s34,s45,s48&docType=NCD,6,F&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAA&KeywordLookup=Doc&KeywordSearchType=Exact>. Effective October 1, 2019.

Centers for Medicare & Medicaid Services. National Coverage Determination. 220.5 Ultrasound Diagnostic Procedures. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=263&ncdver=3&keyword=ultrasound&keywordType=any&areald=s11,s10,s12,s23,s25,s27,s37,s34,s45,s48&docType=NCD,F&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAA&KeywordLookup=Doc&KeywordSearchType=Or>. Effective May 22, 2007.

Ezebialu IU, Eke AC, Eleje GU, Nwachukwu CE. Methods for assessing pre-induction cervical ripening. *Cochrane Database Syst Rev.* 2015;(6):Cd010762. Doi: 10.1002/14651858.CD010762.pub2.

Gerges B, Li W, Leonardi M, Mol BW, Condous G. Meta-analysis and systematic review to determine the optimal imaging modality for the detection of bladder deep endometriosis. *Eur J Obstet Gynecol Reprod Biol.* 2021;261:124-133. Doi: 10.1016/j.ejogrb.2021.04.030.

Henderson JT, Webber EM, Sawaya GF. U.S. Preventive Services Task Force evidence syntheses, formerly systematic evidence reviews. *Screening for ovarian cancer: An updated evidence review for the U.S. Preventive Services Task Force.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2018.

Herbst MK, Shanahan MM. Obstetric Ultrasound. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-. National Center for Biotechnology Information. <https://www.ncbi.nlm.nih.gov/books/NBK470450/>. Updated January 7, 2021.

Kaveh M, Sadegi K, Salarzai M, Parooei F. Comparison of diagnostic accuracy of saline infusion sonohysterography, transvaginal sonography, and hysteroscopy in evaluating the endometrial polyps in women with abnormal uterine bleeding: A systematic review and meta-analysis. *Wideochir Inne Tech Maloinwazyjne.* 2020;15(3):403-415. Doi: 10.5114/wiitm.2020.93791.

Kurzweil A, Martin J. Transabdominal Ultrasound. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-. National Center for Biotechnology Information. <https://www.ncbi.nlm.nih.gov/books/NBK534813/>. Updated August 13, 2020.

Lacey JV, Jr., Greene MH, Buys SS, et al. Ovarian cancer screening in women with a family history of breast or ovarian cancer. *Obstet Gynecol.* 2006;108(5):1176-1184. Doi: 10.1097/01.AOG.0000239105.39149.d8.

Liu L, Li W, Leonardi M, et al. Diagnostic accuracy of transvaginal ultrasound and magnetic resonance imaging for adenomyosis: Systematic review and meta-analysis and review of sonographic diagnostic criteria. *J Ultrasound Med.* 2021. Doi: 10.1002/jum.15635.

Meyer L, Broaddus R, Lu K. Endometrial cancer and Lynch syndrome: Clinical and pathologic considerations. *Cancer Control.* 2009;16(1):14-22. Doi: 10.1177/107327480901600103.

Moyer VA. Screening for ovarian cancer: U.S. Preventive Services Task Force reaffirmation recommendation statement. *Ann Intern Med.* 2012;157(12):900-904. Doi: 10.7326/0003-4819-157-11-201212040-00539.

National Cancer Institute. Endometrial cancer screening (PDQ®)-Health professional version. <http://www.cancer.gov/types/uterine/hp/endometrial-screening-pdq>. Updated March 24, 2021.

Nisenblatt V, Bossuyt PM, Farquhar C, Johnson N, Hull ML. Imaging modalities for the non-invasive diagnosis of endometriosis. *Cochrane Database Syst Rev.* 2016;2:Cd009591. Doi: 10.1002/14651858.CD009591.pub2.

Partridge E, Kreimer A, Greenlee R, et al; Prostate, Lung, Colon, and Ovarian Project Team. Results from four rounds of ovarian cancer screening in a randomized trial. *Obstet Gynecol.* 2009;113(4):775-782. Doi: 10.1097/AOG.0b013e31819cda77.

Polena V, Huchon C, Varas Ramos C, et al. Non-invasive tools for the diagnosis of potentially life-threatening gynaecological emergencies: A systematic review. *PLoS One.* 2015;10(2):e0114189. Doi: 10.1371/journal.pone.0114189.

Ruiter L, Kok N, Limpens J, et al. Systematic review of accuracy of ultrasound in the diagnosis of vasa previa. *Ultrasound Obstet Gynecol.* 2015;45(5):516-522. Doi: 10.1002/uog.14752.

Steenbeek MP, van der Vleuten CJM, Schultze Kool LJ, Nieboer TE. Noninvasive diagnostic tools for pelvic congestion syndrome: A systematic review. *Acta Obstet Gynecol Scand.* 2018;97(7):776-786. Doi: 10.1111/aogs.13311.

Teixeira DM, Dassuncao LA, Vieira CV, et al. Ultrasound guidance during embryo transfer: A systematic review and meta-analysis of randomized controlled trials. *Ultrasound Obstet Gynecol.* 2015;45(2):139-148. Doi: 10.1002/uog.14639.

van Wassenaer EA, de Voogd FAE, van Rijn RR, et al. Diagnostic accuracy of transabdominal ultrasound in detecting intestinal inflammation in paediatric IBD patients — a systematic review. *J Crohns Colitis.* 2019. Doi: 10.1093/ecco-jcc/jjz085.

Wennmacker SZ, Lamberts MP, Di Martino M, et al. Transabdominal ultrasound and endoscopic ultrasound for diagnosis of gallbladder polyps. *Cochrane Database Syst Rev.* 2018;8:Cd012233. Doi: 10.1002/14651858.CD012233.pub2.

Policy updates

6/2015: initial review date and clinical policy effective date: 9/2015

9/2016: Policy references updated.

9/2017: Policy references updated.

9/2018: Policy references updated. Policy ID changed.

9/2019: Policy references updated.

9/2020: Policy references updated. Coverage updated.

9/2021: Policy references updated.