APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well but selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Sonohysterography (also referred to as “hysterosonography”, “saline infusion sonohysterography” (SIH), and “saline-injected uterine ultrasound”), involves the injection of a fluid into the cervix and uterus just prior to ultrasound of these structures. In general, saline is the fluid used for this procedure, although the use of gel preparations is now under study. The injected fluid aids in the visual imaging of the reproductive anatomy. Sonohysterography is normally an outpatient procedure and takes approximately 15 minutes. (ACOG, 2012, 2011). Saline infusion sonohysterography (SIS) is a useful imaging modality prior to planned hysteroscopic or laparoscopic procedures for...
fibroids, polyps, and uterine anomalies to ensure safe and appropriate interventions (Singh, & et al., 2013). Substantial evidence exists to indicate that sonohysterography is superior to transvaginal ultrasonography in the detection of intracavitary lesions, such as polyps and submucosal leiomyomas (ACOG, 2012).

Contraindications

Sonohysterography should not be performed in a woman who is pregnant or who could be pregnant. This is usually avoided by scheduling the examination in the follicular phase of the menstrual cycle, after menstrual flow has essentially ceased but before the patient has ovulated. In a patient with regular cycles, sonohysterography should not in most cases be performed later than the 10th day of the menstrual cycle. Sonohysterography should not be performed in patients with a pelvic infection or unexplained pelvic tenderness, which could be due to pelvic inflammatory disease. Active vaginal bleeding is not a contraindication to the procedure but may make the interpretation more challenging. (AIUM, 2011)

Limitations of Sonohysterography

Sonohysterography should typically not be performed in women with active pelvic inflammatory disease. In women with stenosis of the cervix, it may be somewhat difficult to insert the catheter into the cervical canal so that saline may be injected. Inadequate distension (expansion) of the uterine cavity from the saline injection may also prevent good-quality ultrasound images from being obtained. This can occur especially with uterine adhesions (scarring) or large benign tumors called fibroids, which may partially obliterate the uterine cavity. Also, sonohysterography is limited in the assessment of the patency, or openness, of the fallopian tubes because of their size and structure. In such cases where an abnormality of the fallopian tubes is suspected, a procedure such as hysterosalpingography might be recommended for further evaluation. (ACR & RSNA, 2013)

Food and Drug Administration (FDA)

Sonohysterography for the assessment of abnormal uterine bleeding is a procedure and, therefore, not subject to FDA regulation. However any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. Several sonohysterography accessories (catheters and biopsy devices) were located in a search of the 510(k) and premarket approval (PMA) databases. Please see the FDA Approvals and Clearances section below for more information.

A search of the 510(k) and premarket approval (PMA) databases, using the terms sonohysterography, sonohysterogram, and ultrasound AND uterus, in the “Quick Search” form, retrieved nothing in the PMA database and 2 saline injection catheters for sonohysterography and 2 saline infusion/endometrial biopsy devices for sonohysterography in the 510(k) database. Ultrasound devices are categorized under the FDA Product Classification Codes IYN (ultrasonic pulsed Doppler imaging system) and IYO (ultrasonic pulsed echo imaging system, while ultrasound transducers are categorized under the FDA Product Classification Codes ITX (diagnostic ultrasonic transducer).

There is no National Coverage Determination (NCD) for sonohysterography on the CMS website. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers. However, the CMS does have an NCD for diagnostic uses of ultrasound (please see the CMS NCD section below), but it does not specifically mention sonohysterography or the use of ultrasound for the assessment of abnormal uterine bleeding.

POSITION STATEMENT

Applicable To:

☑ Medicaid
☑ Medicare

Exclusions and Contraindications

Saline sonohysterography for abnormal uterine bleeding is considered experimental and investigational for indications not listed above and therefore is not considered medically necessary. Further conclusions about the safety and effectiveness of this technology cannot be made until a full assessment has been completed. Abnormal
uterine bleeding can be managed by other alternative options such as a dilatation and curettage (D&C), hysteroscopy with or without biopsy, or transvaginal ultrasound with or without endometrial biopsy or D&C.

Sonohysterography is contraindicated for women:

- Who are pregnant or who could be pregnant; OR,
- With a pelvic infection or unexplained pelvic tenderness (could be due to pelvic inflammatory disease)

Active vaginal bleeding is not a contraindication to the procedure however interpretation may be more challenging.

**Coverage**

Saline sonohysterography for abnormal uterine bleeding is considered medically necessary for the following:

- Abnormal uterine bleeding; OR,
- Uterine cavity, especially with regard to uterine myomas, polyps, and synechiae; OR,
- Abnormalities detected on endovaginal sonography, including focal or diffuse endometrial or intracavitary abnormalities; OR,
- Congenital abnormalities of the uterus; OR,
- Recurrent pregnancy loss.

**Clinical Evidence**

The results presented in the majority of study abstracts report overall positive findings for health outcomes for the use of sonohysterography when assessing abnormal uterine bleeding, however, it should be noted that there was great variation in the conditions of the patients enrolled in the study abstracts retrieved, as well as differences in the type of sonohysterography conducted and whether it was carried out in combination with other tests. (Hayes, 2014). An SHG is a very safe procedure. It may cause cramping, spotting and vaginal discharge. Some women experience cramping for several hours. The most common serious complication with SHG is pelvic infection; however, this occurs less than 1% of the time and usually occurs when a woman also has a disease of the fallopian tubes. You should call your doctor if you experience pain or fever one or two days after the SHG. Some doctors prescribe pain medication and/or antibiotics before the procedure. (ASRM, 2012). Further full text review is required to confirm abstract content and therefore, conclusions about the safety and effectiveness of this procedure cannot be made until a full assessment has been completed.

**Coding**

**Covered CPT® Codes**

- 58340 Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography
- 76831 Saline infusion sonohysterography (SIS), including color flow Doppler, when performed

**HCPCS® Codes** – No applicable codes.

**Covered ICD-10-CM Diagnosis Codes** – This list may not be all inclusive

- D25.0 Submucous leiomyoma of uterus
- D25.1 Intramural leiomyoma of uterus
- D25.2 Subserosal leiomyoma of uterus
- D25.9 Leiomyoma of uterus, unspecified
- N80.0 Endometriosis of uterus
- N84.0 Polyp of corpus uteri
- N85.6 Intrauterine synechiae
- N89.7 Hematocolpos
- N92.0 Excessive and frequent menstruation with regular cycle
- N92.1 Excessive and frequent menstruation with irregular cycle
- N92.2 Excessive menstruation at puberty
N92.4 Excessive bleeding in the premenopausal period
N92.5 Other specified irregular menstruation
N92.6 Irregular menstruation, unspecified
N93.8 Other specified abnormal uterine and vaginal bleeding
N93.9 Abnormal uterine and vaginal bleeding, unspecified
N96 Recurrent pregnancy loss
Q51.0 Angenesis and aplasia of uterus
Q51.10 Doubling of uterus with doubling of cervix and vagina without obstruction
Q51.11 Doubling of uterus with doubling of cervix and vagina with obstruction
Q51.3 Bicornate uterus
Q51.4 Unicornate uterus
Q51.810 Arcuate uterus
Q51.811 Hypoplasia of uterus
Q85.818 Other congenital malformations of uterus

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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<tr>
<td>4/2/2015</td>
<td>Approved by MPC. Updated coverage per ACR/ACOG/AIUM/ARU practice parameters released in late 2014..</td>
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<tr>
<td>10/2/2014</td>
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Clinical Coverage Guideline