

ABNORMAL UTERINE BLEEDING AND UTERINE FIBROIDS

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

Some plan documents exclude benefit coverage for contraception. In those plan documents, coverage for intrauterine devices (IUD), including the levonorgestrel-releasing intrauterine device (LNG-IUD), is excluded when used for contraceptive purposes. However, in those plan documents, coverage exists for the levonorgestrel-releasing intrauterine device (LNG-IUD) when used for a non-contraceptive purpose, including treatment of abnormal uterine bleeding, when supported by clinical evidence.

Most plan documents provide coverage for unproven services for a life-threatening sickness or condition, at our discretion. If an enrollee has a life-threatening sickness or condition (one that is likely to cause death within one year of the request for treatment) we may, in our discretion, consider an otherwise unproven service to be a covered health service for that sickness or condition. Prior to such a consideration, we must first establish that there is sufficient evidence to conclude that, albeit unproven, the service has significant potential as an effective treatment for that sickness or condition.

Additionally, some plan documents may provide coverage for unproven services under certain non-life-threatening conditions at our discretion. For members with these affected plan documents, all of the following conditions must be met in order for coverage to apply to magnetic resonance-guided focused ultrasound (MRgFUS):

- The service must be performed by a network physician and/or a network facility. UnitedHealthcare enrollees have no out-of-network benefits for MRgFUS.
- The service must be performed by a physician and in a facility with demonstrated experience and expertise in MRgFUS, as determined by UnitedHealthcare.
- The physician or facility must follow FDA labeled indications for use.
- The enrollee must consent to the procedure acknowledging that UnitedHealthcare does not believe that sufficient clinical evidence has been published in peer-reviewed medical literature to conclude that the service is safe and/or effective.

The enrollee-specific Certificate of Coverage or Summary Plan Description must always be consulted to determine coverage in this situation. In addition, other conditions for payment to the participating provider may apply, including compliance with prior notification requirements and verification of enrollee eligibility for coverage. Providers should refer to the current UnitedHealthcare Administrative Guide for additional details.

COVERAGE RATIONALE

Levonorgestrel-Releasing Intrauterine Device

The Mirena[®] levonorgestrel-releasing intrauterine device (LNG-IUD) is proven and medically necessary for treating menorrhagia in premenopausal women.

No other LNG-IUDs have been U.S. Food and Drug Administration (FDA)-approved for this indication.

Uterine Fibroids

Uterine artery embolization (UAE) is proven and medically necessary for treating symptomatic uterine fibroids for women who do NOT wish to preserve their childbearing potential. For information regarding medical necessity review, when applicable, see MCG[™] Care Guidelines, 18th edition, 2014, Uterine Artery Embolization, ACG: A-0287 (AC).

Uterine artery embolization (UAE) is unproven and not medically necessary for treating symptomatic uterine fibroids for women who wish to preserve their childbearing potential. The effects of UAE on ovarian and uterine function and on fertility are relatively unknown. Further studies of safety and/or efficacy in published, peer-reviewed medical literature are necessary.

Magnetic resonance imaging (MRI)-guided cryoablation is unproven and not medically necessary for treating uterine fibroids.

The published evidence on MRI-guided cryoablation for uterine fibroids is very limited, as the procedure has been evaluated in very few patients. The long-term outcomes and overall health benefits remain unknown. Further long-term studies on larger samples published in peer-reviewed medical literature are necessary to demonstrate the safety and efficacy of this technology.

Magnetic resonance imaging (MRI)-guided focused ultrasound ablation (FUA) is unproven and not medically necessary for treating uterine fibroids.

Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatments for uterine fibroids. See the [Benefit Considerations](#) section for potential coverage of unproven services.

Laparoscopic ultrasound-guided radiofrequency ablation is unproven and not medically necessary for treating uterine fibroids.

Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatments for uterine fibroids.

APPLICABLE CODES

The Current Procedural Terminology (CPT[®]) codes and/or Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

Uterine Fibroids

CPT [®] Code	Description
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue
0336T	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
58578	Unlisted laparoscopy procedure, uterus
58999	Unlisted procedure, female genital system (nonobstetrical)

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Levonorgestrel-Releasing Intrauterine Device

HCPCS Code	Description
J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg
J7306	Levonorgestrel (contraceptive) implant system, including implants and supplies
S4981	Insertion of levonorgestrel-releasing intrauterine system

DESCRIPTION OF SERVICES

Abnormal uterine bleeding in women of childbearing age is defined as any change in menstrual period frequency or duration, a change in amount of flow, or any bleeding between cycles. In postmenopausal women, abnormal uterine bleeding includes vaginal bleeding 12 months or more after the cessation of menstruation, or unpredictable bleeding in patients who have been receiving hormone therapy for 12 months or more. Abnormal uterine bleeding terms include oligomenorrhea (bleeding occurs at intervals of more than 35 days), polymenorrhea (bleeding occurs at intervals of less than 21 days), menorrhagia (bleeding occurs at normal intervals but with heavy flow or duration of more than 7 days), menometrorrhagia (bleeding occurs at irregular, noncyclic intervals and with heavy flow or duration more than 7 days) and metrorrhagia (irregular bleeding occurs between ovulatory cycles). Menorrhagia can be idiopathic or can be associated with underlying uterine lesions such as fibroids or polyps, pelvic pathology, anatomical abnormalities, systemic illness, hormonal imbalance or certain medications. Idiopathic menorrhagia that is not related to a specific underlying condition is called abnormal uterine bleeding (AUB). All these conditions associated with menorrhagia can be referred to as abnormal uterine bleeding, although it is also possible to have some conditions such as fibroids or an anatomical abnormality with normal menses. The focus in this policy is on treatment options when the bleeding pattern is abnormal.

Conservative management of AUB includes watchful waiting and pharmacological therapy. Another treatment option is dilation and curettage. Hysterectomy is available when symptoms cannot be controlled by conservative treatment. Conservative management of symptomatic fibroids includes watchful waiting and hormonal therapy. Hormone therapy may cause the fibroids to shrink; however they will quickly return to their original mass once therapy has been discontinued. Hysterectomy has been the primary treatment for symptomatic or rapidly enlarging fibroids. Hysteroscopic removal of fibroids has been the procedure of choice for those women who want to maintain their fertility, but this is a demanding and lengthy procedure and sometimes more difficult to perform than a hysterectomy and does not prevent the recurrence of fibroids. The resulting endometrial cavity may be problematic for fertility.

Alternate minimally invasive techniques have emerged. An advantage of these procedures over hysterectomy is that they do not involve surgical removal of the uterus; therefore, the operative and recovery times are shorter and the complication rates seem to be lower. Some may be performed as outpatient procedures, avoiding the hospital stay required after hysterectomy.

Uterine fibroids (also known as leiomyomata) are benign tumors of the uterus. They have a rich blood supply and may cause excessive uterine bleeding, uterine enlargement and mass or bulk related symptoms such as pelvic pain and pressure, urinary frequency and abdominal distension.

Levonorgestrel-Releasing Intrauterine Device (LNG-IUD): The local administration of the progestin levonorgestrel is delivered via an intrauterine device (IUD). The Mirena® device consists of a T-shaped polyethylene frame with a steroid reservoir around the vertical stem. The reservoir contains 52 mg of levonorgestrel, which is released at a dose of 20 ug per day. The local delivery of this hormone causes the endometrium to become insensitive to ovarian estradiol leading to atrophy of the endometrial glands, inactivation of the endometrial epithelium and suppression of endometrial growth and activity. The effects of this IUD last for approximately 5 years and are reversible upon removal of the IUD.

Uterine Artery Embolization (UAE): This procedure injects particles via the uterine arteries to block blood supply to uterine fibroids, causing them to shrink.

Magnetic Resonance Imaging (MRI)-Guided Cryoablation: This procedure is also known as interventional MRI (I-MRI) cryoablation. It uses a specially designed, i-MRI scanner to locate the fibroids and guide their cryosurgical destruction through a transabdominal percutaneous approach.

Magnetic Resonance Imaging (MRI)-Guided Focused Ultrasound (FUA): This procedure combines real-time MRI-guidance with high-intensity focused ultrasound for the noninvasive thermal ablation of uterine fibroids. Tumor ablation is performed by focusing a collection of ultrasonic beams to increase sonic beam intensity at a point deep within the tissue to cause thermal coagulation while sparing normal tissues. The procedure is also referred to as MRgFUS.

Laparoscopic Ultrasound-Guided Radiofrequency Ablation: This minimally invasive procedure uses a laparoscopic ultrasound probe to determine the location and size of fibroids. Then a small electrode array delivers radiofrequency energy to destroy the fibroids.

CLINICAL EVIDENCE

Levonorgestrel-Releasing Intrauterine Device (LNG-IUD)

In a systematic review of twenty-six studies, Matteson et al. (2013) compared the effectiveness of nonsurgical abnormal uterine bleeding treatments for bleeding control, quality of life (QOL), pain, sexual health, patient satisfaction, additional treatments needed and adverse events. Interventions included the levonorgestrel intrauterine system, combined oral contraceptive pills (OCPs), progestins, nonsteroidal anti-inflammatory drugs (NSAIDs) and antifibrinolytics. For reduction of menstrual bleeding in women with abnormal uterine bleeding presumed secondary to endometrial dysfunction, the levonorgestrel intrauterine system (71-95% reduction), combined OCPs (35-69% reduction), extended cycle oral progestins (87% reduction), tranexamic acid (26-54% reduction) and NSAIDs (10-52% reduction) were all effective treatments. The levonorgestrel intrauterine system, combined OCPs and antifibrinolytics were all superior to luteal-phase progestins (20% increase in bleeding to 67% reduction). The levonorgestrel intrauterine system was superior to combined OCPs and NSAIDs. Antifibrinolytics were superior to NSAIDs for menstrual bleeding reduction. Data were limited on other important outcomes such as QOL for women with abnormal uterine bleeding presumed secondary to endometrial dysfunction and for all outcomes for women with abnormal uterine bleeding presumed secondary to ovulatory dysfunction.

In another systematic review, Matteson et al. (2012) compared hysterectomy with less-invasive alternatives for abnormal uterine bleeding (AUB). Nine randomized controlled trials comparing bleeding, quality of life, pain, sexual health, satisfaction, need for subsequent surgery and adverse events were included. Endometrial ablation, levonorgestrel intrauterine system and medications were associated with lower risk of adverse events but higher risk of additional treatments than hysterectomy. Compared to ablation, hysterectomy had superior long-term pain and bleeding control. Compared with the levonorgestrel intrauterine system, hysterectomy had superior control of bleeding. No other differences between treatments were found. The review group concluded that less-invasive treatment options for AUB result in improvement in quality of life but carry significant risk of retreatment caused by unsatisfactory results. Although hysterectomy is the most effective treatment for AUB, it carries the highest risk for adverse events.

Kaunitz et al. (2010) compared the efficacy and safety of the levonorgestrel-releasing intrauterine system and oral medroxyprogesterone acetate in the treatment of idiopathic heavy menstrual bleeding. In this multicenter, randomized, controlled study, women aged 18 years or older with heavy menstrual bleeding (menstrual blood loss 80 mL or more per cycle) were randomly assigned to six cycles of treatment with either levonorgestrel-releasing intrauterine system or oral medroxyprogesterone acetate. Of 807 women screened, 165 were randomly assigned to treatment (levonorgestrel-releasing intrauterine system n=82, oral medroxyprogesterone acetate n=83). At the end of the study, the absolute reduction in median menstrual blood loss was significantly greater in the levonorgestrel-releasing intrauterine system group than in the medroxyprogesterone acetate arm, and the proportion of women with successful treatment was significantly higher for the levonorgestrel-releasing intrauterine system (84.8%) than for medroxyprogesterone acetate (22.2%).

There is evidence from several randomized controlled trials and a few nonrandomized controlled trials and prospective case series that the LNG-IUD is a relatively safe and efficacious minimally invasive therapy for AUB in premenopausal women with confirmed menorrhagia that is refractory to oral medications or for whom surgery has been recommended, who have no benign or malignant pelvic pathology that requires another type of therapy, who do not want or are ineligible for surgery, who cannot tolerate the drug side effects and/or who wish to retain their childbearing capacity. Overall, treatment with the LNG-IUD for 3 to 12 months resulted in significant reductions in menstrual blood loss (MBL) (ranging from 67% to 96%), improvement in menstrual bleeding patterns in the majority of patients, increases in blood hemoglobin and iron levels, high levels of satisfaction and improved quality of life (QOL). Surgery was cancelled or postponed in approximately 70% of patients on surgical waiting lists whose menstrual bleeding improved during LNG-IUD therapy. The rates of treatment discontinuation or failure varied from 3% to 52% (Hurskainen, 2001; Lahteenmaki, 1998; Istre, 2001; Crosignani, 1997; Barrington, 1997; Fedele, 1997; and Romer, 2000).

The evidence from the randomized controlled trials comparing the LNG-IUD with drug therapy (the progestin norethisterone, an NSAID and an antifibrinolytic) showed that the IUD reduced MBL by over 90% and induced amenorrhea in 32% to 44% of patients. While patients were more satisfied with the LNG-IUD than with oral norethisterone, and no serious side effects were reported, IUD use was associated with a higher incidence of spotting and intermenstrual bleeding at 3 months. While spotting and intermenstrual bleeding are initially common following insertion of the LNG-IUD, these symptoms tend to lessen or disappear. LNG-IUD was significantly more efficacious than the NSAID flurbiprofen and the antifibrinolytic tranexamic acid for reducing MBL and improving blood Hb and ferritin levels; however, the IUD was removed in 15% of patients due to side effects or persistent menorrhagia, and 5% of patients had a hysterectomy after device expulsion. No major side effects were associated with the LNG-IUD (Hurskainen, 2001; Lahteenmaki, 1998; Istre, 2001; Crosignani, 1997; Barrington, 1997; Fedele, 1997; and Romer, 2000).

Kaunitz et al. (2009) compared the effects of the levonorgestrel intrauterine system and endometrial ablation in reducing heavy menstrual bleeding. The systematic review and meta-analysis was restricted to randomized controlled trials in which menstrual blood loss was reported using pictorial blood loss assessment chart scores. Six randomized controlled trials that included 390 women (levonorgestrel intrauterine system, n=196; endometrial ablation, n=194) were reviewed. Three studies pertained to first-generation endometrial ablation (manual hysteroscopy) and three to second-generation endometrial ablation (thermal balloon). Both treatment modalities were associated with similar reductions in menstrual blood loss after 6 months, 12 months and 24 months. In addition, both treatments were generally associated with similar improvements in quality of life in five studies that reported this as an outcome. No major complications occurred with either treatment modality in these small trials. The authors concluded that the efficacy of the levonorgestrel intrauterine system in the management of heavy menstrual bleeding appears to have similar therapeutic effects to that of endometrial ablation up to 2 years after treatment.

Lethaby et al. (2005) conducted a metaanalysis of randomized controlled trials of women of reproductive age treated for heavy menstrual bleeding with progesterone or progestogen-releasing intrauterine devices. One trial compared LNG-IUD with medical therapy, two trials compared it with transcervical resection of the endometrium (TCRE), and three trials compared it with balloon ablation. There was a significantly greater mean reduction in menstrual bleeding in one trial in women who had balloon ablation, a lower score on the pictorial blood loss chart and higher rates of successful treatment in 3 trials including both balloon and TCRE. The LNG-IUD was compared to hysterectomy in one trial and the LNG-IUD treatment had lower costs than the hysterectomy at one- and at five-year follow-up.

Busfield et al. (2006) compared LNG-IUD (n=40) to thermal balloon ablation (n=39) in a prospective, randomized trial. Both treatments resulted in significant reductions in pictorial

bleeding assessment chart (PBAC) scores. However at 12 and 24 months, median PBAC scores in women treated by LNG-IUD were significantly lower than those of women treated by thermal balloon (11.5 versus 60.0 and 12.0 versus 56.5, respectively) supporting LNG-IUD as more efficacious. Treatment failed in 11 (28%) women using the LNG-IUD and in 10 (26%) women treated with thermal balloon ablation.

Uterine Artery Embolization (UAE)

Panagiotopoulou et al. (2014) evaluated the effectiveness of uterine-sparing interventions for women with symptomatic uterine fibroids who wish to preserve their uterus. Five trials, involving 436 women were included. Two compared uterine artery embolization with myomectomy and three compared uterine artery embolization with laparoscopic uterine artery occlusion. Indirect treatment comparison showed that myomectomy and uterine artery embolization resulted in higher rates of patient satisfaction and lower rates of clinical failure than laparoscopic uterine artery occlusion. Myomectomy resulted in a lower reintervention rate than uterine artery embolization and laparoscopic uterine artery occlusion even though the latter techniques had an advantage over myomectomy because of shorter hospitalization and quicker recovery. There was no evidence of difference between the three techniques in ovarian failure and complications rates. The evidence for reproductive outcomes is poor. The authors concluded that these results suggest that laparoscopic uterine artery occlusion is less effective than uterine artery embolization and myomectomy in treatment of symptomatic fibroids. The choice between uterine artery embolization and myomectomy should be based on individuals' expectations and fully informed discussion.

Martin et al. (2013) performed a systematic review of complications and reinterventions in uterine artery embolization (UAE) for symptomatic uterine fibroids. In randomized clinical trials, common complications were discharge and fever (4%), bilateral uterine artery embolization (UAE) failure (4%) and postembolization syndrome (2.86%). Two trials showed a significantly decreased risk in major complications with UAE. None of the trials showed a significant difference in minor complications of UAE. None of the trials showed a significant difference in risk for overall complications of UAE. Three trials showed a significantly increased risk for reintervention with UAE. In 76 nonrandomized studies, common complications were amenorrhea (4.26%), pain (3.59%) and discharge and fever (3.37%). In 41 case studies, common complications were discharge and fever (n=22 cases), repeat UAE (n=6 cases) and fibroid expulsion (n=5 cases). The authors concluded that, overall, UAE has a significantly lower rate of major complications relative to surgery, but it comes at the cost of increased risk of reintervention.

Toor et al. (2012) performed a systematic review and meta-analysis to determine complication rates and effectiveness of uterine artery embolization (UAE) in the treatment of symptomatic uterine fibroids. Fifty-four studies met the inclusion criteria (n=8159). There were no reported deaths. Major complications occurred at a rate of 2.9%. The rate of hysterectomy for resolution of a complication from UAE was 0.7% (0.5-0.9%) and the rate of readmission was 2.7% (1.9-3.7%). Other complications recorded were leiomyoma tissue passage (4.7% [3.9-5.7%]), deep venous thrombosis or pulmonary embolism (0.2% [0.2-0.4%]) and permanent amenorrhea (3.9% [2.7-5.3%]). Reintervention rates including repeat UAE, myomectomy, or hysterectomy calculated per patient-year occurred at 5.3% (4.2-6.4%) with follow-up ranging from 0.25 to 5 years. Clinical symptomatic improvement ranged from 78% to 90%, with follow-up ranging from 0.25 to 2 years. The authors concluded that symptomatic uterine leiomyoma treatment by UAE is an effective procedure with a low rate of major complications supporting its use as an alternative to hysterectomy.

In an updated Cochrane review, Gupta et al. (2012) evaluated the benefits and risks of uterine artery embolization (UAE) versus other medical or surgical interventions for symptomatic uterine fibroids. Five randomized controlled trials (RCTs) of UAE versus any medical or surgical therapy for symptomatic uterine fibroids were included in the review. Three trials compared UAE with abdominal hysterectomy in 291 women. A fourth trial included 157 women and compared UAE with surgery (43 hysterectomies and 8 myomectomies). The fifth trial included 121 women and

compared UAE with myomectomy in women wishing to preserve fertility. Based on moderately good evidence, the authors concluded that UAE had an overall patient satisfaction rate similar to hysterectomy and myomectomy and offered an advantage of shorter hospital stay and a quicker return to routine activities. However, UAE was associated with a higher rate of minor complications and an increased likelihood of requiring surgical intervention within two to five years of the initial procedure. Very low level evidence suggested that myomectomy may be associated with better fertility outcomes than UAE, but more research is needed.

Jun et al. (2012) compared the efficacy and safety of uterine artery embolization (UAE) for symptomatic uterine fibroids with surgery. Patients were randomly assigned to undergo either UAE (n=63) or surgery (n=64). A meta-analysis of existing studies was also performed. There were significant improvements in UAE groups in most components of quality of life assessment at 6 months. The UAE group had a shorter hospital stay and a shorter recovery time compared with the surgical group. During the follow-up, there were no differences in complications incidence, but the UAE group had less major complications. A meta-analysis of this and existing studies further suggested that the UAE group had a shorter hospital stay, a shorter recovery time and less major complications than the surgical group. The authors concluded that more studies are needed to evaluate the long-term effects and impact of UAE on fertility.

In a systematic review and meta-analysis, van der Kooij et al. (2011) analyzed the evidence on short-, mid- and long-term results of uterine artery embolization (UAE) compared to surgery (hysterectomy/myomectomy) in premenopausal women with heavy menstrual bleeding caused by symptomatic uterine fibroids. Four randomized controlled trials with a total of 515 patients were included. Short-term advantages of uterine artery embolization over surgery included less blood loss, shorter hospital stays and quicker return to usual activities. Mid- and long-term results showed comparable health-related quality of life results and a higher reintervention rate in the uterine artery embolization group.

In a multicenter, randomized trial, Moss et al. (2011) compared the long-term results of uterine artery embolization (UAE) with surgery for women with symptomatic uterine fibroids. A total of 157 women were randomized (in a 2:1 ratio) to UAE (n=106) and surgery (hysterectomy n=42; myomectomy n=9). There were no significant differences between groups regarding quality of life at 5 years. Rates of adverse events were similar in both groups. The 5-year intervention rate for treatment failure or complications was 32% in the UAE arm and 4% in the surgery arm. The authors concluded that UAE is a satisfactory alternative to surgery for fibroids. The less invasive nature of UAE needs to be balanced against the need for re-intervention in almost a third of patients.

According to an evidence report prepared for the Agency for Healthcare Research and Quality (AHRQ), studies comparing uterine artery embolization (UAE) with other procedures reported procedure time and length of stay favoring UAE. However, the absence of key information on longer-term outcomes suggests that the evidence base is inadequate to comment on the relative risks and benefits of UAE versus hysterectomy or myomectomy (AHRQ, 2007).

A National Institute for Health and Care Excellence (NICE) guidance document states that current evidence on uterine artery embolization (UAE) for fibroids shows that the procedure is efficacious for symptom relief in the short and medium term for a substantial proportion of patients. There are no major safety concerns. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance and audit (NICE, 2010).

van der Kooij et al. (2010) compared clinical outcomes and health related quality of life (HRQOL) 5 years after uterine artery embolization (UAE) or hysterectomy in the treatment of menorrhagia caused by uterine fibroids. Patients with symptomatic uterine fibroids who were eligible for hysterectomy were assigned randomly 1:1 to hysterectomy (n=89) or UAE (n=88). Endpoints after 5 years were reintervention rates, menorrhagia and HRQOL measures that were assessed by validated questionnaires. Five years after treatment 23 of 81 UAE patients (28.4%) had

undergone a hysterectomy because of insufficient improvement of complaints (24.7% after successful UAE). HRQOL measures improved significantly and remained stable until the 5-year follow-up evaluation, with no differences between the groups. UAE had a positive effect both on urinary and defecation function.

Goodwin et al. (2008) assessed the long-term clinical outcomes of uterine artery embolization across a wide variety of practice settings in 2112 patients with symptomatic leiomyomata. At 36 months after treatment, 1,916 patients remained in the study, and of these, 1,278 patients completed the survey. The primary measures of outcome were the symptom and health-related quality-of-life scores from the Uterine Fibroid Symptom and Quality of Life questionnaire. Mean symptom scores improved 41.41 points ($P < .001$), and the quality of life scores improved 41.47 points ($P < .001$), both moving into the normal range for this questionnaire. The improvements were independent of practice setting. During the 3 years of the study, Kaplan-Meier estimates of hysterectomy, myomectomy, or repeat uterine artery embolization were 9.79%, 2.82%, and 1.83% of the patients, respectively. The investigators concluded that uterine artery embolization results in a durable improvement in quality of life.

Goodwin et al. (2006) compared results of UAE ($n=149$) with myomectomy ($n=60$) 6 months after procedure. Both groups experienced statistically significant improvements in menstrual bleeding and uterine volume as compared to menstrual bleeding and uterine volume pretreatment. When the two groups were compared to each other, there were no significant differences in bleeding improvement and uterine volume reduction. Patients who received UAE required fewer days off work, fewer hospital days and experienced fewer adverse events.

Siskin et al. (2006) compared UAE to hysterectomy in 146 women for treatment of fibroids. UAE was associated with greater sustained improvements in symptom severity and quality of life scores and with fewer complications than myomectomy. MRI at 6-month follow-up demonstrated significant reductions in uterine and tumor volumes.

Spies et al. (2004) completed a randomized comparative study to evaluate the differences in response to PVA particles and tris-acryl gelatin microspheres used to complete the embolization. Recovery for all women was brief and "relatively mild". There were no differences between the two methodologies. Complications occurred in 19 of the 100 study participants and included allergic reactions, pain with fibroid passage, urinary retention, hematoma, and one person had a pulmonary embolus.

Pinto et al. (2003) completed a randomized trial comparing UAE with hysterectomy. They concluded that UAE reduced abnormal bleeding in 86% of the patients and was associated with significantly shorter hospitalization and recovery time compared with hysterectomy. The total complication rate was higher for UAE than hysterectomy, although there were few major complications with UAE. Patient satisfaction was high for both procedures.

Razavi et al. (2003) studied 111 patients who had an UAE or a myomectomy. The authors concluded that UAE was less invasive and safer than myomectomy with a shorter hospitalization, recovery time and duration of pain medication. UAE was also superior for control of menorrhagia, whereas myomectomy was superior for correction of mass/bulk effect. Both procedures were equal with respect to pain control. Of the patients who had complications, 11% were in the UAE group but 25% of the myomectomy patients had complications that were more serious and included blood transfusions, wound infections, ileus and adhesions.

Magnetic Resonance Imaging (MRI)-Guided Cryoablation

Two feasibility studies representing an ongoing, manufacturer-sponsored clinical trial on this specific technique that were conducted at the same study center were identified in the peer-reviewed literature. The first study consisted of 2 patients who were included in the second study. The second published study is a prospective case series that evaluated the efficacy and safety of MRI-guided cryoablation of uterine fibroids in 9 symptomatic women whose disease was

confirmed by clinical examination and MRI. The outcomes assessed included surgical time, postoperative fibroid volume, postoperative hemoglobin level, overall reduction in fibroid size, and complications. Postoperative MRI findings were available for the patients for a period of 48 to 334 days after surgery (Sewell, 2001; Cowan, 2002).

While the preliminary data from a manufacturer-sponsored pilot study show that MRI-guided cryoablation of uterine fibroids can reduce the volume of uterine fibroids by an average of 65% as determined by serial MRI and improve patient-reported symptoms over the short term, the procedure has been evaluated in very few patients, and the long-term outcomes and overall health benefits remain unknown. During this short-term study, none of the fibroids disappeared completely, and it remains unclear whether this would eventually occur. In the clinical trial, 3 of 9 (33%) patients experienced what the researchers described as important procedure-related complications. One patient developed persistent bleeding following laceration of a tumor blood vessel. The patient required emergent laparotomy and myomectomy. She recovered without complications but was ineligible for follow-up of the cryoablation procedure since her fibroids were removed. Another patient sustained a mild peroneal nerve injury that resulted in a mild footdrop, which resolved at 4 months postoperatively. A third patient was observed for 24 hours due to nausea. No other serious complications were reported during follow-up.

Dohi et al. (2004) published a study evaluating MRI-guided transvaginal cryotherapy to treat 8 uterine fibroids. They assessed the ratio of pre-treatment to post-treatment volume of the uterine fibroids as well as symptoms of anemia, abdominal pain and dysfunctional uterine bleeding. The mean ratio of reduction in uterine fibroid volume was 31.0% at 9-12 months (0-75.0%). Symptoms caused by uterine fibroids improved in seven cases. There were no complications requiring surgical intervention.

Magnetic Resonance Imaging (MRI)-Guided Focused Ultrasound Ablation (FUA)

A Hayes report concluded that, although evidence from prospective studies suggests that magnetic resonance-guided focused ultrasound (MRgFUS) reduces fibroid volume and symptoms in many patients, the overall quality of the evidence is low due to the lack of well-designed controlled studies. Most studies involve the same patient population studied in the pivotal trial sponsored by the manufacturer. In addition, there is no published data comparing this procedure to other uterus-sparing treatments such as myomectomy or uterine artery embolization. Additional long-term studies, particularly randomized controlled trials that compare outcomes following MRgFUS with other therapies, are needed before firm conclusions can be drawn. MRgFUS may be an appropriate treatment for certain patients who wish to avoid more definitive treatment and when performed by a surgical team that is experienced in this procedure; however, patient selection criteria have not been fully defined (Hayes, 2014).

A manufacturer-sponsored, multicenter, prospective uncontrolled clinical trial evaluated the efficacy and safety of MRgFUS including symptom relief and quality of life (QOL) in 109 patients who were otherwise candidates for hysterectomy due to the severity of their symptoms. The results were published in several studies. At 6 months, Hindley et al. (2004) reported that 79.3% of women who had been treated reported a significant improvement in their uterine fibroid symptoms on follow-up health-related quality-of-life questionnaires. The mean reduction in fibroid volume was 13.5%, but nonenhancing volume remained within the treated fibroid. The authors concluded that despite the small change in the volume of treated tumors, the improvement in symptoms was meaningful. At 12 months, Stewart et al. (2006) reported outcomes in 82 of the original patient population. Fifty-one percent of women who had been treated reached the targeted symptom reduction. The magnitude of improvement was greater than predicted, with subjects having a mean volume decrease of 36%. A modest volume reduction similar in magnitude to the treated volume was seen. The authors concluded that the rate of symptom relief was fairly high considering that only 10% of the fibroid volume was treated on average due to the strict treatment guidelines. They added that this undertreatment may have accounted for the need for alternative therapy in 28% of patients. At 3 years, Kim et al. (2011) evaluated outcomes in 29 of the original patient population. The results showed sustained symptomatic relief among

enrolled patients. The mean volume decrease was 32.0%. Thirty-one percent sought alternative treatments due to inadequate control of symptoms. There were no long-term complications. The authors concluded that, although the results are preliminary, MRgFUS for the treatment of uterine fibroids may result in acceptable long-term outcomes at 3 years. Limitations of these studies include lack of randomization and control, no comparison of MRgFUS to other minimally invasive technologies intended to treat uterine fibroids and small sample size.

In a nonrandomized clinical trial, Froeling et al. (2013) compared the long-term outcome after uterine artery embolization (UAE) (n=41) versus magnetic resonance-guided high-intensity focused ultrasound (MR-g HIFU) (n=36) in women with symptomatic uterine fibroids. Symptom severity and total health-related quality of life scores were assessed by questionnaire before treatment and at long-term follow-up after UAE (median 61.9 months) and after MR-g HIFU (median: 60.7 months). Reintervention was significantly lower after UAE (12.2%) than after MR-g HIFU (66.7%) at long-term follow-up. The authors reported that improvement of symptom severity and health-related quality of life scores was significantly better after UAE resulting in a significant lower reintervention rate compared to MR-g HIFU.

In a prospective cohort study, Dobrotwir and Pun (2012) evaluated the efficacy and safety of MRgFUS in 100 patients (mean age 42 years) with symptomatic fibroids (n=104 treatments). Mean pretreatment fibroid volume was 185 cm³ (range 2 to 1109). The authors reported that fibroid volume significantly decreased by the 12-month follow-up, and that the symptom severity score decreased by 55%. However, 14% of these patients required reintervention for persistent or recurrent fibroid disease. This study is limited by lack of randomization and control and short-term follow-up.

A retrospective study of 130 patients with symptomatic uterine leiomyomas treated with MRgFUS reported that the cumulative incidence of subsequent treatments for leiomyomas, such as hysterectomy or myomectomy, was 7.4% at 12-months. Patients were followed through retrospective review of medical records and phone interviews. At 3-, 6- and 12-month follow-up, 86% (90 of 105), 93% (92 of 99), and 88% (78 of 89) of patients reported relief of symptoms, respectively. Treatment-related complications were observed in 17 patients (13.1%): 16 patients had minor complications and one had a major complication (deep vein thrombosis). All complications were resolved within the 12-month follow-up period. This study is limited by its retrospective design (Gorny et al., 2011).

Taran et al. (2009) compared women undergoing MRgFUS to a group of contemporaneously recruited women undergoing total abdominal hysterectomy. Patient demographics, safety parameters, quality of life outcomes and disability measures are reported. One hundred and nine women were recruited in seven centers for MRgFUS treatment and 83 women who underwent abdominal hysterectomy were recruited in seven separate centers to provide contemporaneous assessment of safety. Overall, the number of significant clinical complications and adverse events was lower in women in the MRgFUS group compared to women undergoing hysterectomy. MRgFUS was associated with significantly faster recovery, including resumption of usual activities. At 6 months of follow-up, there were four (4%) treatment failures in the MRgFUS arm. There was improvement in all quality of life scales for both treatment groups at 6 months. However, scores were significantly better in the hysterectomy group than in the MRgFUS group. Women undergoing MRgFUS had steady improvement in all parameters throughout the 6-month follow-up period, despite the fact that they continued to have symptomatic myomatous uteri and menstruation. The authors concluded that MRgFUS treatment of uterine leiomyomas leads to clinical improvement with fewer significant clinical complications and adverse events compared to hysterectomy at 6 months' follow-up. Longer follow-up from randomized trials is needed to confirm these results.

In a prospective cohort study, Funaki et al. (2009) assessed the efficacy of MRgFUS in women with symptomatic myomas who otherwise would have been treated with conventional surgery. The study included 91 premenopausal Japanese patients (mean age 40.4 years) with 141 fibroids

measuring 4 to 10 cm in diameter. Fibroids were characterized by their appearance on MR images as type 1 (low intensity similar to that of skeletal muscle) (n=25 patients; mean fibroid volume 129.0 cm³, range 14.4 to 724.1), type 2 (intermediate intensity between that of myometrium and skeletal muscle) (n=55 patients; mean fibroid volume 211.7 cm³, range 14.9 to 757.7) and type 3 (high intensity, \geq that of myometrium) (n=11 patients; mean fibroid volume 180.8 cm³; range 34.6 to 501.9). The follow-up time was 24 months. The authors found that patients with type 1 or 2 fibroids had a significant reduction in the symptom severity score at 3 months, which was sustained at 2 years. However, nearly 16% of the 80 patients with type 1 or 2 fibroids required reintervention. MRgFUS was ineffective in 11 patients with type 3 fibroids. This study is limited by lack of randomization and control.

According to an evidence report prepared for the Agency for Healthcare Research and Quality (AHRQ), the strength of evidence for MRI-guided ultrasound ablation of fibroids is weak (AHRQ, 2007).

A National Institute for Health and Care Excellence (NICE) guidance document states that current evidence on the efficacy of magnetic resonance image (MRI)-guided transcuteaneous focused ultrasound for uterine fibroids in the short term is adequate, although further treatment may be required and the effect on subsequent pregnancy is uncertain. There are well-recognized complications, but the evidence on safety is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit. NICE encourages further research into the efficacy of MRI-guided transcuteaneous focused ultrasound for uterine fibroids. Research studies should report long-term outcomes, including the need for further treatment (NICE, 2011).

Laparoscopic Ultrasound-Guided Radiofrequency Ablation

A Hayes report concluded that there is insufficient published evidence to assess the safety and/or impact on health outcomes of the Acessa System for the treatment of uterine fibroids (Hayes, 2013).

An ECRI report states that evidence suggests that the Acessa System works for radiofrequency thermal ablation in women with symptomatic uterine fibroids. However, evidence is insufficient to determine whether it works as well as or better than invasive (e.g., myomectomy) or minimally invasive surgical alternatives (e.g., MRgFUS) because comparison studies are lacking. Results from ongoing clinical trials may provide further information on comparative effectiveness (ECRI, 2013).

Berman et al. (2013) followed 104 patients for 36 months after treatment of uterine myomas with laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation (RFVTA). Questionnaire responses indicated sustained relief from symptoms and continued improvement in health-related quality of life through 36 months after ablation. The cumulative repeat intervention rate was 11% (14 of 135 participants) at 36 months. This study is limited by lack of randomization and control.

Chudnoff et al. (2013) reported preliminary results of a prospective clinical trial designed to evaluate laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation for treating symptomatic uterine fibroids. The study included a cohort of 135 premenopausal symptomatic women with uterine fibroids and objectively confirmed heavy menstrual bleeding. Primary outcome measures were menstrual bleeding at 12 months compared to baseline (pre-procedure), adverse events and surgical reintervention rates. At 3-, 6- and 12-month follow-ups, menstrual blood loss decreased from baseline levels by 31.8%, 40.7% and 38.3%, respectively. Symptom severity decreased from baseline and health-related quality of life improved. The authors reported one serious adverse event requiring readmission 5 weeks postprocedure and one surgical reintervention for persistent bleeding. Ninety-four percent of the women reported satisfaction with the treatment. This study is limited by lack of randomization and control and short-term follow-up.

In a 24-month follow-up of the same trial, Guido et al. (2013) reported significant improvements in symptom severity scores and health-related quality of life in 112 premenopausal women with symptomatic uterine fibroids and confirmed heavy menstrual bleeding. Improvements occurred more readily between baseline and 3 months compared with any other follow-up period (e.g., 6, 12, and 24 months). A reintervention rate of 4.8% was reported due to fibroid-related bleeding between 12 and 24 months. This study is also limited by lack of randomization and control.

In a prospective study, Robles et al. (2013) assessed the safety and efficacy of laparoscopic radiofrequency volumetric thermal ablation (RFVTA) in women with symptomatic uterine fibroids. Thirty-five premenopausal women (ages 33-51 years) with symptomatic fibroids were enrolled and followed for 12 months. Uterine fibroid symptom and health-related quality-of-life (UFS-QOL) questionnaires were completed at 0, 3, 6 and 12 months. Symptom severity scores reduced significantly: baseline (63.3), 3 months (23.1), 6 months (15.4), 12 months (9.6). Health-related quality-of-life scores improved significantly: baseline (37.3), 3 months (79.9), 6 months (85.1), 12 months (87.7). Nine adverse events among 8 individuals were minor and unrelated to the procedure. This study is limited by lack of randomization and control, short-term follow-up and small sample size.

Thirty-one women (ages 28 to 51 years) with symptomatic uterine fibroids who desired uterine preservation underwent outpatient laparoscopic, ultrasound-guided, radiofrequency volumetric thermal ablation using the Halt 2000 System. Postoperative follow-up occurred at 3, 6 and 12 months. The primary outcome measures were patient safety, frequency of adverse events, repeat intervention rate, symptom severity and health-related quality-of-life scores from the validated Uterine Fibroid Symptom and Quality-of-Life Questionnaire. Secondary outcome measures were uterine volume changes over time. At 3, 6 and 12 months, respectively, mean symptom severity scores improved significantly compared with baseline, by 59.7%, 71.7% and 82.0%. The increase in mean health-related quality-of-life scores over time reached statistical significance: 60.15 at baseline, 87.9 at 3 months, 90.8 at 6 months and 97.8 at 12 months. Mean (SD) uterine volume decreased from 194.4 at baseline to 159.5 at 3 months, 147.2 at 6 months and 113.2 at 12 months. There were no procedure-related repeat hospitalizations, repeat treatments or any procedures related to fibroid symptoms following treatment. This study is limited by lack of randomization and control, short-term follow-up and small sample size. The authors concluded that additional larger multicenter studies are needed to confirm these results (Garza et al., 2011).

Professional Societies

American College of Obstetricians and Gynecologists (ACOG)

An ACOG committee opinion on acute abnormal uterine bleeding concludes that surgical management should be considered for patients who are not clinically stable, are not suitable for medical management or have failed to respond appropriately to medical management. The choice of surgical management should be based on the patient's underlying medical conditions, underlying pathology and desire for future fertility. The report also mentions the use of levonorgestrel-releasing IUDs as an option for the long-term treatment of chronic AUB (ACOG, 2013).

Levonorgestrel-Releasing Intrauterine Device

An ACOG practice guideline on the use of noncontraceptive uses of hormonal contraceptives states the following:

- Combined oral contraceptives (OC) have been shown to regulate and reduce menstrual bleeding, treat dysmenorrhea, reduce premenstrual dysphoric disorder symptoms and ameliorate acne. (Evidence Level A – based on good and consistent scientific evidence.)
- Hormonal contraception should be considered for the treatment of menorrhagia in women who may desire further pregnancies. (Evidence Level B – based on limited or inconsistent scientific evidence.) (ACOG, 2010; reaffirmed 2012)

In an updated practice bulletin, ACOG states that the levonorgestrel intrauterine system leads to minimal systemic effects, and the localized endometrial effect is beneficial for treatment of menorrhagia. Small studies suggest that the levonorgestrel intrauterine system may be effective for treatment of heavy uterine bleeding in women with leiomyomas. However, these women may have a higher rate of expulsion and vaginal spotting. (ACOG, 2008; reaffirmed 2012)

Uterine Artery Embolization

In a practice bulletin on alternatives to hysterectomy in managing uterine fibroids, ACOG states that based on long- and short-term outcomes, uterine artery embolization is a safe and effective option for appropriately selected women who wish to retain their uteri (ACOG, 2008; reaffirmed 2012).

Magnetic Resonance Imaging-Guided Focused Ultrasound Ablation

While short-term studies show safety and efficacy, long-term studies are needed to discern whether the minimally invasive advantage of MRI-guided focused ultrasound surgery will lead to durable results beyond 24 months (ACOG, 2008; reaffirmed 2012).

American College of Radiology (ACR)

ACR appropriateness criteria conclude the following:

- Uterine artery embolization (UAE) is effective in managing symptomatic uterine fibroids.
- Myomectomy may be superior to UAE in women planning future pregnancy.
- There is little long-term information on the efficacy of MR-guided high-intensity focused ultrasound (ACR, 2009; last review date 2012).

Society of Interventional Radiology (SIR)

SIR quality improvement guidelines state that uterine artery embolization (UAE) is indicated for the treatment of uterine leiomyomas that are causing significant symptoms, specifically menstrual bleeding that is prolonged or is causing anemia, severe menstrual cramping and/or bulk symptoms including pelvic pressure, urinary frequency and constipation. A desire to maintain childbearing potential is a relative contraindication to UAE. Myomectomy remains the standard of care for preserving fertility (Stokes et al., 2010).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Levonorgestrel-Releasing Intrauterine Device

Mirena® received FDA approval on December 8, 2000 for use as an intrauterine contraceptive. Treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception was approved as an additional indication on October 1, 2009. See the following website for more information:
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails>. Accessed July 28, 2014.

Skyla™ received FDA approval on January 9, 2013 for use as an intrauterine contraceptive only. The device is contraindicated in patients with uterine bleeding of unknown etiology.

Uterine Artery Embolization

Uterine artery embolization (UAE) is a procedure and, therefore, not subject to FDA regulation. However, the embolic agents used are subject to FDA oversight. A number of agents are approved by the FDA for embolization procedures of the neurological system, but several have been specifically approved for UAE. See the following website for additional information.
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails>. Accessed July 28, 2014.

Magnetic Resonance Imaging-Guided Focused Ultrasound

The ExAblate 2000 System (Insightec) received premarket approval (PMA) on October 22, 2004 (P040003). The device is indicated for ablation of uterine fibroid tissue in pre- or perimenopausal

women with symptomatic uterine fibroids who desire a uterine sparing procedure. Patients must have a uterine size of less than 24 weeks in gestational size and have completed child bearing. See the following website for more information:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P040003>.

Accessed July 24, 2014.

Laparoscopic Ultrasound-Guided Radiofrequency Ablation

The Acessa System received FDA clearance for marketing on November 5, 2012 (K121858). The device is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. See the following website for additional information.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K121858>. Accessed July 24, 2014.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Levonorgestrel-Releasing Intrauterine Device

Medicare does not have a National Coverage Determination (NCD) for the levonorgestrel-releasing intrauterine device (LNG-IUD) for the treatment of menorrhagia in premenopausal women. Local Coverage Determinations (LCDs) do not exist at this time.

(Accessed June 26, 2014)

Uterine Fibroids

There is an NCD for therapeutic embolization which states therapeutic embolization is covered when done for hemorrhage and for other conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient. See the NCD for [NCD for Therapeutic Embolization \(20.28\)](#). LCDs do not exist at this time. However, there are Local Articles for uterine artery embolization. Refer to the Local Articles for [uterine artery embolization](#).

Medicare does not have an NCD for magnetic resonance imaging (MRI)-guided cryoablation for the treatment of uterine fibroids. LCDs do not exist at this time.

Medicare does not have an NCD for magnetic resonance imaging (MRI)-guided focused ultrasound ablation (FUA) for the treatment of uterine fibroids (CPT codes 0071T and 0072T). These codes are referenced in the LCDs for [Category III CPT Codes](#), [Non-Covered Services](#), [Services that are Not Reasonable and Necessary](#), [Ablative Therapy](#) and [Non-Covered Category III CPT Codes](#).

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2014	<ul style="list-style-type: none"> • Reorganized policy content • Updated benefit considerations: <ul style="list-style-type: none"> ○ Added language for <i>Essential Health Benefits for Individual and Small Group</i> plans to indicate: <ul style="list-style-type: none"> ▪ For plan years beginning on or after January 1, 2014, the

	<p>Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)</p> <ul style="list-style-type: none"> ▪ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans ▪ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage ▪ Replaced references to “Certificates of Coverage (COC) and Summary Plan Descriptions (SPD)” with “plan documents” <ul style="list-style-type: none"> ○ Added language to indicate most plan documents provide coverage for unproven services for a life-threatening sickness or condition, at our discretion <ul style="list-style-type: none"> ▪ If an enrollee has a life-threatening sickness or condition (one that is likely to cause death within one year of the request for treatment) we may, in our discretion, consider an otherwise unproven service to be a covered health service for that sickness or condition ▪ Prior to such a consideration, we must first establish that there is sufficient evidence to conclude that, albeit unproven, the service has significant potential as an effective treatment for that sickness or condition <ul style="list-style-type: none"> • Updated coverage rationale: <ul style="list-style-type: none"> ○ Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is “medically necessary” or “not medically necessary” to applicable proven/unproven statement ○ Removed reference to specific product name (“Acessa™”) for laparoscopic ultrasound-guided radiofrequency ablation • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references • Archived previous policy version 2014T0442M
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