Anthem

Medical Policy

Subject: Uterine Fibroid Ablation: Laparoscopic, Percutaneous or Transcervical Image Guided Techniques
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Description/Scope

This document addresses laparoscopic and percutaneous ablative techniques for the treatment of symptomatic uterine fibroids, including radiofrequency ablation using a transcervical approach. Uterine fibroids, also referred to as leiomyomas, is a common condition that affects women in their reproductive years; symptoms include excessive menstrual bleeding and pelvic pain.

Note: Please see the following related documents for additional information:

- MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications
- CG-SURG-28 Transcatheter Uterine Artery Embolization

Position Statement

Medically Necessary

The use of laparoscopic or transcervical radiofrequency ablation as a treatment for symptomatic uterine fibroids (e.g. excessive uterine bleeding or pelvic discomfort caused by uterine fibroids) is considered **medically necessary** when *all* of the following criteria are met:

1. Uterine preservation is desired; **and**
2. Fibroids are less than 10 cm in any diameter;**and**
3. Uterine size does not exceed 16 weeks' gestation.

Not Medically Necessary:

The use of laparoscopic or transcervical radiofrequency ablation as a treatment for uterine fibroids is considered**not medically necessary** for individuals who do not meet the above criteria.

Investigational and Not Medically Necessary:

The use of all other laparoscopic or percutaneous ablation techniques in combination with imaging guidance as a treatment of uterine fibroids is considered **investigational and not medically necessary,** including but not limited to lasers, bipolar electrodes, interstitial thermotherapy and cryotherapy.

Rationale

Laparoscopic radiofrequency volumetric thermal ablation

In 2012, the U.S. Food and Drug Administration (FDA) cleared the Acessa System (Originally Halt Medical, Inc., now Hologic, Inc.) through the 510(k) process for use in percutaneous coagulation and ablation of soft tissue under laparoscopic ultrasound guidance, including treatment of symptomatic uterine fibroids. No controlled data were presented in the 510(k) summary.

One published randomized controlled trial (RCT) has evaluated radiofrequency volumetric thermal ablation (RFVTA) for the treatment of uterine fibroids. The blinded study by Brucker and colleagues (2014) compared RFVTA and laparoscopic myomectomy in 51 women with symptomatic fibroids and reported on length of hospitalization and perioperative outcomes. Study participants were at least 18 years old with symptomatic uterine fibroids, had a uterine size ≤ 16 gestational weeks as determined by pelvic exam and had fibroids that were less than 10 cm in any diameter. Individuals in the treatment group experienced significantly faster discharge from the hospital and less mean operative blood loss. In 2016, Kramer and colleagues published 2-year results of this study. At 2 years, there were no significant differences between the RFVTA and myomectomy groups in the frequency of symptoms including heavy menstrual bleeding, pelvic pain and frequency of urination. Three individuals in the RFVTA group sought additional surgical interventions; the authors noted this was not due to fibroid symptoms. No one in the myomectomy group had surgical re-intervention. Three individuals in the RFVTA group and 6 in the myomectomy group conceived and there were no miscarriages. Limitations include manufacturer sponsorship of the trial, homogenous sample population (lack of ethnic diversity), and interim reporting of study results (2-year findings out of 5 years total that participants will be followed).

In addition to the RCT, there are several case series. Some had sample sizes of fewer than 50 participants (Garza 2011; Robles 2013). One of the larger case series evaluating RFVTA, reported by Galen and colleagues (2014), was retrospective and included 206 individuals. From baseline to 12 months, participants experienced significant reductions in symptom severity ($p<0.001$); health-related quality of life (HR-QOL) scores ($p<0.001$); and mean uterine volume ($p=0.008$). The rate of adverse events associated with the RFVTA procedure was relatively low at 1.4% (1 of 69).

Chudnoff and colleagues (2013) reported on a case series involving 135 subjects with symptomatic uterine myomas who underwent laparoscopic ultrasound-guided RFVTA. Subjects were premenopausal women with uterine size of 14 weeks gestation or less and six or fewer treatable myomas. No myoma was larger than 7 cm in diameter and total myoma volume was 300 cm^3 or less. At 12 months, 127 subjects were included in the analysis. The authors reported that, compared with baseline, monthly menstrual blood loss, myoma volume and total uterine volume were significantly lower at 12 months. Results on the Uterine Fibroid Symptom and Quality of Life Questionnaire indicated significant improvements in both symptom severity and HR-QOL ($p<0.001$ for both measures). Similar results were also reported for the responses on the EQ-5D™ Health Status score ($p<0.001$).

Guido and colleagues (2013) conducted a case series to evaluate RFVTA of symptomatic uterine fibroids in 121 premenopausal women (HALT Trial). At the 24-month follow-up, subjects showed significant improvement in symptom severity compared with baseline values ($p<0.001$), as well as significant improvements in HR-QOL scores in all categories ($p<0.001$). A total of 6 individuals (4.8%) required repeat surgical intervention for bleeding related to fibroids between 12 and 24 months. At 36 months of follow-up,

Berman (2014) reported similar results in 104 subjects from the same trial. RFVTA resulted in continued and significant relief from symptoms of uterine fibroids, including significant improvements in HR-QOL scores. At 36 months, the total rate of re-intervention was 11% (14 of 135 subjects).

Data from the published studies have been summarized in systematic reviews (Bradley, 2019; Lin, 2019). Both the Bradley and Lin systematic reviews presented data on RFVTA only. Bradley (2019), which focused on laparoscopic radiofrequency ablation, included eight studies in their review, among them the Kramer RCT, discussed above, as well as seven uncontrolled studies. In an analysis pooling study findings on RFVTA, the mean change from baseline to 12 months in HR-QOL was 42 points (95% confidence interval [CI], 39 to 44 points; p<0.001), and in the symptom score was -39 points (95% CI, 35 to 44; p<0.001). The overall rate of reintervention in seven studies was 4.39%. (95% CI, 1.60 to 8.45%).

A post-market study of safety data was published by Yu and colleagues in 2020. The authors reported on 48-hour and 30-day outcomes in individuals undergoing RFVTA conducted by 29 surgeons who were trained in performing the procedure during the study run-in period. A total of 110 individuals were enrolled, of which 101 and 104, respectively, completed the 48-hour and 30-day post-procedure visits. The individuals in the study were enrolled in an ongoing RCT and met the criteria of being at least 18 years old, menstruating, with symptomatic uterine fibroids no larger than 10 cm in the greatest diameter and who desired uterine-sparing treatment. There were no serious adverse events reported within 48 hours, and one serious adverse event (1/105, 0.95%) was reported within 30 days. This was a hospitalization for post-operative fever and tachycardia, and the adverse event was determined by an independent review committee to be 'probably device-related." Longer term adverse events were not reported in this analysis.

The American College of Obstetricians and Gynecologists (ACOG) guideline on management of symptomatic uterine leiomyomas (June 2021) included the following "Level B" recommendation (recommendation based on limited or inconsistent scientific evidence), "Laparoscopic radiofrequency ablation can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes". The bulletin noted that "laparoscopic RFA with a leiomyoma specific FDA-approved device has been studied primarily in nonrandomized trials" and the recommendation was based in part on recent meta-analyses, Bradley (2019) and Lin (2019), discussed above. The guideline provides three "Level A" recommendations (recommendations based on good and consistent scientific evidence):

- Gonadotropin-releasing hormone (GnRH) agonists, either with or without add-back hormonal therapy, are recommended for the short-term treatment of AUB-L [Abnormal Uterine Bleeding associated with Leiomyomas] and uterine enlargement associated with uterine leiomyomas and as a bridge to other treatment strategies.
- Uterine artery embolization (UAE) is recommended as an interventional procedure for the treatment of uterine leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes.
- When hysterectomy is selected for the surgical management of symptomatic uterine leiomyomas, the most minimally invasive route is recommended whenever possible, and the vaginal approach is preferred among the minimally invasive approaches when it is feasible.

Transcervical radiofrequency ablation

In 2018, the FDA cleared the Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics, Inc.) through the 510(k) process for treatment of symptomatic uterine fibroids. Data from single-arm trials, but no controlled data, were presented in the 510(k) summary.

Transcervical ablation was evaluated in an uncontrolled prospective multicenter study known as the SONATA trial (Chudnoff, 2019). The study included 147 premenopausal individuals between the ages of 25 and 50 years who had 1 to 10 uterine fibroids, at least 1 of which indented or impeded on the endometrial cavity. Moreover, participants were required to have a minimum pictorial blood loss assessment chart score between 150 and 500. The chart is a validated instrument that asks individuals to estimate blood loss by choosing among icons representing various types of sanitary products. Exclusion criteria included a desire for future pregnancy, uterine volume 1000 cm^3 or greater, a type 0 myomata that was 1.0 cm or greater, endometrial polyps 1.5 cm or greater or multiple polyps. Co-primary endpoints, assessed at 12 months after ablation, were reduction in menstrual blood loss (assessed by a pictorial blood loss assessment chart) and the rate of surgical reintervention for heavy menstrual bleeding. At 12 months, the mean pictorial blood loss assessment chart score was 51% lower than baseline and 99.3% of individuals did not undergo surgical reintervention.

Findings up to 3 years have been reported. Two-year findings of the SONATA trial were published by Miller and Osman in 2019. Data were available on 125 of 147 (85%) study participants. During the 2-year follow-up period, 5.5% of individuals had undergone reintervention for heavy menstrual bleeding. The article did not report 2-year results on the other co-primary outcome, change in blood loss. Among secondary outcomes, the symptom severity score (SSS) decreased from a mean of 55 (Standard Deviation [SD]: 19) to 24 (SD: 18) at 2 years, p<0.001. Moreover, health-related quality of life scores increased from a mean of 40 (SD: 21) to 83 (SD: 19), p<0.001. Lukes and Green (2020) reported 3-year results of the SONATA trial, at which time the investigators accounted for 132 (90%) of participants. The rate of surgical reintervention was 9.2% at 3 years using the binomial method and 8.2% using the Kaplan-Meiier method. At 3 years, the mean SSS was 22 (SD: 21) and the mean health-related quality of life score was 83 (SD: 23).

An uncontrolled prospective multicenter study, the FAST-EU trial, evaluated treatment with the VizAblate System, an earlier version of Sonata (Bongers, 2015; Brolmann, 2016). The study included 50 non-pregnant individuals age 28 and older with regular menstrual cycles and abnormal uterine bleeding for at least 3 months. Eligible individuals had 1 to 5 uterine fibroids between 1 and 5 cm in maximum diameter. A desire for future fertility was an exclusion criterion. The primary endpoint was the percentage change in fibroid perfused volume from baseline to 3 months, as assessed by contrast-enhanced MRI. Mean total fibroid volume decreased from 18.8 cm^3 (SD: 21.4) at baseline to 8.0 cm^3 (SD: 1.9) at 3 months, a mean percent reduction of 54.7%, p<0.001. At 12 months, the mean percent reduction of total fibroid volume was 66.1%. In addition, mean perfused fibroid volume decreased from 18.3 cm^3 (SD: 20.6) at baseline to 5.8 cm^3 (SD: 9.6) at 3 months and 6.6 cm^3 (SD: 11.3) at 12 months. Mean percent reduction of perfused fibroid volume was 68.1% at 3 months and 67.4% at 12 months.

Shifrin (2022) conducted a pooled analysis of data on submucous fibroids and fibroids > 5.0 cm in diameter from the SONATA and FAST-EU trials. In these two studies, there were a total of 72 women with at least one submucous fibroid and 19 women with at least one fibroid > 5.0 cm; the largest fibroid was 6.5 cm in diameter. For women with submucous fibroids, the mean SSS at 12 months improved by 39 points in the FAST-EU trial and by 31 points in the SONATA trial. For women with fibroids > 5.0 cm, the mean SSS at 12 months improved by 35 points in the FAST-EU trial and by 41 points in the SONATA trial. The rates of surgical reintervention through 1 year in women with submucous fibroids was 3.7% in the FAST-EU trial and 0% in the SONATA trial.

In 2021, Arnreiter and colleagues published a systematic review of studies evaluating the Sonata device. The authors identified 10 eligible studies, of which 7 were single-arm studies and 3 were case reports. No controlled studies were identified. In the 4 studies that reported these outcomes, the mean decrease in fibroid volume 3 months after treatment was 68.1% in perfused volume and 54.7% in absolute myoma volume. At 12 months, there was a mean reduction of 63.2% in myoma volume and 64.5% in perfused volume.

Moreover, the mean SSS was 56.7 at baseline and 23.7 at the 12 months. The average health-related quality of life score was 38.8 at baseline and 83.3 at 12 months.

A retrospective review of data on 53 individuals who underwent Sonata treatment at a single center was published by van der Meulen and colleagues in 2022. The median number of ablated fibroids was 1, with a range of 1 to 5. The median fibroid maximum diameter at baseline was 41 mm. Median length of follow-up post-surgery was 36 months, with a range of 13 to 101 months. During follow-up, 24 of 53 women (45%) underwent surgical reintervention. The median time to first surgical reintervention was 11 months and the most common reintervention was a hysteroscopic myomectomy. A total of 49 of the 53 women gave consent to participate in a survey and all of these responded to the survey. A total of 35 of the 49 respondents (71%) indicated that their fibroid-related symptoms had improved post-surgery. Among the remaining women, 13 stated their symptoms were unchanged and 1 indicated that symptoms had deteriorated. Fibroid size was evaluated in 39 women by transvaginal ultrasound at a mean time of 4.3 months post-procedure.

Christoffel (2022) evaluated data from manufacturer-sponsored trials of Sonata treatment and post-marketing data. They identified 36 pregnancies reported to physicians that occurred in 28 women after Sonata treatment. There were 20 deliveries, 3 therapeutic abortions and 8 first-trimester spontaneous abortions. There were also 5 ongoing pregnancies at the time of data analysis. Of the 8 spontaneous abortions in 5 women, 4 of these occurred in an individual with a history of pregnancy loss and an immune disorder. Among the 20 deliveries, all were at term and birthweights were within normal limits (i.e., >2500g).

Microwave ablation

In 2018, Ierardi and colleagues published a systematic review of the published literature on percutaneous high-frequency microwave ablation for the treatment of uterine fibroids. The authors identified six studies with a total of 541 participants. All of the studies were case series; there were no RCTs or non-randomized controlled studies. The rate of clinical success, defined as reduction in uterine fibroid volume, in the individual studies ranged from 15.9% to 93.1%. The authors stated that this wide range in findings was due, at least in part, to different lengths of follow-up in the studies. No major complications were reported in any of the studies and the minor complications were primarily those that would be expected after this type of intervention. The authors did not pool study findings.

The largest series was published by Liu and colleagues in 2017. The study prospectively enrolled 311 Chinese women who underwent ultrasound-guided percutaneous microwave ablation therapy for symptomatic uterine fibroids. Women were evaluated at baseline, 3, 6 and 12 months for fibroid size, hemoglobin level, uterine fibroid symptoms and HR-QOL scores. The mean reduction rate in fibroid volume was 63.5%, 78.5% and 86.7% at 3, 6 and 12 months, respectively ($p<0.001$). The mean hemoglobin level increased significantly from 88.84 ± 9.31 g/L at baseline to 107.14 ± 13.32, 116.05 ± 7.66 and 117.79 ± 6.51 g/L at 3, 6 and 12 months posttreatment, respectively ($p<0.000$). The symptom severity score (SSS) and HR-QOL scores were also significantly improved at each follow-up compared with baseline ($p<0.000$). While these results are promising, a randomized trial comparing microwave ablation of uterine fibroids to standard of care in a diverse population with long-term outcomes is warranted.

A case series published by Yang and colleagues in 2019 enrolled 69 participants. Data were available for 48 participants (70%) at 3 months. Compared with baseline, the symptom severity score decreased from 34.5 to 12.7 ($p<0.001$) and the mean myoma volume decreased from 221.7 cm^3 to 87.2 cm^3. Loss to follow-up was close to 50% at 6 and 12 months. As with previous case series, this study lacks a comparison group and it was also limited by the high drop-out rate.

Nd:YAG laser myolysis

Hindley (2002) and colleagues reported on a case series of 66 women with symptomatic fibroids who were treated with MRI-guided percutaneous Nd:YAG laser myolysis. Outcome measures included assessment of fibroid size and a menorrhagia questionnaire. The mean reduction in size of fibroids was 31%. Compared to a control group of those undergoing hysterectomy, the total outcome score was less in those undergoing percutaneous myolysis but the quality of life score was similar. Although not entirely clear, it appears that treatment was targeted to only the largest fibroid in each woman. The study does not provide details on the number and location of fibroids. It should also be noted that MRI guidance was provided with a high field (0.5T) open machine.

Cryomyolysis

Zreik and colleagues (2008) reported findings in 14 women who underwent cryomyolysis, while Zupi and colleagues (2004; 2005) presented initial experience with 20 women. In both of these small case series, the authors reported post-intervention symptom resolution. In the Zreik study, the participants were given GnRH agonist before the procedure; cryomyolysis maintained or slightly reduced the post-GnRH uterine size. In contrast, GnRH was not used in the Zupi study, and cryomyolysis was associated with a 25% reduction in fibroid size, and a resolution of bleeding at 12 months.

Other Considerations
In 2008, the American Society of Reproductive Medicine (ASRM) in collaboration with the Society of Reproductive Surgeons (SRS) published a joint statement regarding myomas and reproductive function. In this document they stated:

> Another laparoscopic technique, myolysis, involves thermal destruction of myomas via insertion of cryoprobes, electrocautery needles, or fiberoptic lasers. A nonsurgical method for myolysis involving MRI-guided focused ultrasound has also been described. Data relating to the short- and long-term outcomes achieved with such treatments are still lacking and, until they become available, myolysis cannot be recommended for women hoping to maintain or improve their fertility.

Background/Overview

Uterine fibroids is one of the most common conditions affecting women during their reproductive years. Symptoms include menorrhagia, pelvic pressure, or pain. Hysterectomy and various myomectomy procedures are considered the gold standard of treatment. However, there has been continual research interest in developing minimally invasive alternatives that may preserve fertility, including endometrial ablation (for submucosal fibroids), uterine artery embolization, and various techniques to induce myolysis.

Several types of energy sources have been used for myolysis, including Nd:YAG lasers, bipolar electrodes, cryotherapy, or radiofrequency ablation. Radiofrequency ablation can be applied using the laparoscopic or transcervical approach. In general, the procedures involve the insertion of probes multiple times into the fibroid. When activated, the various energy sources induce devascularization and ultimately ablation of the target tissue.

Myolysis, a surgical procedure that involves the destruction of uterine fibroids (also referred to as leiomyomas), has typically been performed during a laparoscopic procedure focusing on subserosal and intramural fibroids; more recently, percutaneous approaches with MRI guidance have been reported. Typically, women are pretreated with depot gonadotropin-releasing hormone (GnRH) agonists, over a period of 2 to 6 months, to shrink fibroids prior to the procedure.

Cryomyolysis is a technique in which a cryoprobe is inserted into the center of a fibroid. Freezing temperatures of minus 180 degrees centigrade create an “iceball” within the fibroid. Several freeze/thaw cycles are typically used.

Incidence rates of fibroids are typically found to be two to three times higher in black women than in white women, with symptoms developing on average 4 to 6 years sooner in black women compared with white women (Marsh, 2013; Templeman, 2009; Yu, 2018). Moreover, rates of hysterectomy and myomectomy for fibroids are higher in black women than white women, and among women undergoing hysterectomy or myomectomy, black women tend to have surgery at a younger age and have larger uteri, more severe anemia, and experience increased rates of hospitalization (Alexander, 2019; Wechter, 2011). While healthcare disparities continue to present a complex challenge, minimally invasive ablative techniques for the treatment of uterine fibroids lack robust supporting data, including evaluation of long-term health outcomes, and have not been shown improve net healthcare outcomes relative to the gold standard of treatment (hysterectomy and various myomectomy procedures), irrespective of race, geographic residence, and access to health care.

Uterine size, measured via pelvic exam, is a common method of reporting uterine size. As in the Brucker (2014) study, uterine size (as part of candidacy assessment for radiofrequency ablation of uterine fibroids) can be estimated using weeks’ gestation. The uterine size is described in terms of the fundal height in the superior-inferior axis in comparison to a gravid uterus:12 weeks is palpable just above the pubic symphysis, 16 weeks is midway between the symphysis and umbilicus, and 20 weeks is at the umbilicus. Uterine size as determined by gestational age can be converted to an approximate length in cm in the absence of an ultrasound measurement. A uterus that is 16-weeks’ gestational size correlates to 16 cm.

Definitions

Cryomyolysis: Use of a freezing agent for the dissolution of tissue.

Fibroids: Fibrous tissue collected in the uterine wall; also referred to as leiomyomas.

Laparoscopic: A surgical procedure performed using a laparoscope, a thin fiberoptic scope introduced into a body cavity for diagnostic and surgical purposes.

Magnetic resonance imaging (MRI): The use of a nuclear magnetic resonance spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially human cells, tissues and organs.

Myolysis: The dissolution of muscular tissue.

Percutaneous: A medical procedure in which access to inner organs or other tissue is achieved via puncture of the skin.

Transcervical: A medical procedure performed through the cervical opening of the uterus.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
58580	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
ICD-10 Procedure	
	For the following procedures **when specified as radiofrequency ablation:**
0U593ZZ	Destruction of uterus, percutaneous approach
0U594ZZ	Destruction of uterus, percutaneous endoscopic approach
0U597ZZ	Destruction of uterus, via natural or artificial opening
0U598ZZ	Destruction of uterus, via natural or artificial opening endoscopic
ICD-10 Diagnosis	
D25.0-D25.9	Leiomyoma of uterus
N93.8-N93.9	Other specified/unspecified abnormal uterine and vaginal bleeding
R10.2	Pelvic and perineal pain

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met and for all other diagnoses not listed.

When services are Investigational and Not Medically Necessary:

CPT	
58578	Unlisted laparoscopy procedure, uterus [when specified as laparoscopic ablation by laser, bipolar electrodes, interstitial thermotherapy, cryotherapy]
58999	Unlisted procedure, female genital system (nonobstetrical) [when specified as image-guided percutaneous ablation by laser, bipolar electrodes, interstitial thermotherapy, cryotherapy]
ICD-10 Procedure	
	For the following procedures when specified as ablation other than radiofrequency:
0U593ZZ	Destruction of uterus, percutaneous approach
0U594ZZ	Destruction of uterus, percutaneous endoscopic approach
0U597ZZ	Destruction of uterus, via natural or artificial opening
0U598ZZ	Destruction of uterus, via natural or artificial opening endoscopic
ICD-10 Diagnosis	
D25.0-D25.9	Leiomyoma of uterus

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Government Agency, Medical Society, and Other Authoritative Publications:

1. American College of Obstetricians and Gynecologists (ACOG). Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstet Gynecol. 2021 Jun 1; 137(6):e100-e115.
2. American Society of Reproductive Medicine. Myomas and reproductive function. The Practice Committee of the American Society of Reproductive Medicine in collaboration with the Society of Reproductive Surgeons. Fertili Steril. 2008; 910(5 Suppl):S125-S130.

3. Food and Drug Administration. 510(k) Summary (K121858). Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121858.pdf. Accessed on June 26, 2023.
4. Food and Drug Administration. 510(k) Summary (K173703). Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173703.pdf. Accessed on June 26, 2023.

Websites for Additional Information

1. National Institute of Child Health and Human Development. Surgical treatments for fibroids. Available at: https://www.nichd.nih.gov/health/topics/uterine. Accessed on June 26, 2023.
2. National Library of Medicine. Medline Plus Health Topics: Uterine fibroids. Available at: http://www.nlm.nih.gov/medlineplus/uterinefibroids.html. Accessed on June 26, 2023.

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Document History

Status	Date	Action
	12/28/2023	Updated Coding section with 01/01/2024 CPT changes, added 58580 replacing 0404T deleted as of 01/01/2024.
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background/Overview and References sections.
Reviewed	08/11/2022	MPTAC review. Rationale and References sections updated.
Revised	08/12/2021	MPTAC review. Added 'medically necessary' statement on use of laparoscopic or transcervical radiofrequency ablation. Added 'not medically necessary' statement on use of laparoscopic or transcervical radiofrequency ablation when criteria in medically necessary statement are not met. Removed laparoscopic radiofrequency ablation from 'investigational and not medically necessary' statement. Deleted 'investigational and not medically necessary' statement on radiofrequency ablation using a transcervical approach. Rationale, Coding and References sections updated.
Revised	08/13/2020	MPTAC review. "Transcervical" added to title. Addition of statement that radiofrequency ablation using a transcervical approach in combination with imaging guidance as a treatment of uterine fibroids is considered investigational and not medically necessary. Rationale, Background/Overview, Definitions, References and Index sections updated. Updated Coding section, added 0404T, 0U597ZZ, 0U598ZZ.
Reviewed	05/14/2020	MPTAC review. Rationale and References sections updated.
Reviewed	06/06/2019	MPTAC review. Rationale and References sections updated.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date". Rationale, Background/Overview, Definitions and References sections updated.
Reviewed	08/03/2017	MPTAC review. Rationale, Background/Overview and References sections updated.
	01/01/2017	Updated Coding section with 01/01/2017 CPT changes; removed code 0336T deleted 12/31/2016.
Reviewed	08/04/2016	MPTAC review. References section updated. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. Rationale and References sections updated.
Reviewed	08/14/2014	MPTAC review. Rationale and Reference sections updated.
	01/01/2014	Updated Coding section with 01/01/2014 CPT and HCPCS changes; removed C9736 deleted 12/31/2013.
Reviewed	08/08/2013	MPTAC review. Clarified title and position statement. Rationale, References and Index sections updated.
	07/01/2013	Updated Coding section with 07/01/2013 HCPCS changes.
Reviewed	08/09/2012	MPTAC review. Rationale and References updated.
Reviewed	08/18/2011	MPTAC review. Rationale and References updated.
Reviewed	08/19/2010	MPTAC review. References updated.
Reviewed	08/27/2009	MPTAC review. Rationale and references updated.
Reviewed	08/28/2008	MPTAC review. References updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	08/23/2007	MPTAC review. References updated.
Reviewed	09/14/2006	MPTAC review. References updated. Removed CMS NCD, added November 2005 in error.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.		No prior document	

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.