

Subject:	Uterine Fibroid Ablation: Laparoscopic, or Percutaneous <u>or Transcervical</u> 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

Investigational and Not Medically Necessary:

The use of 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, cryotherapy, and radiofrequency ablation.

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

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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Laparoscopic ~~R~~adiofrequency volumetric thermal ablation (RFVTA)

In 2012, the U.S. Food and Drug Administration (FDA) cleared the Acesa System (Halt Medical, Inc., now Acesa Health) 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. Participants 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 cm³ 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

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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 including the Kramer RCT, discussed above, and 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%).

The ability to draw conclusions from case series results is limited due to lack of a control group with which to compare change in symptoms and adverse effects, and only one RCT has been published. Systematic reviews have presented outcomes only on RFVTA without comparing them to any other intervention or no intervention.

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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.

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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, 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.

Two-year findings of the SONATA trial were reported 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.

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 cm³ (SD: 21.4) at baseline to 8.0 cm³ (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 cm³ (SD: 20.6) at baseline to 5.8 cm³ (SD: 9.6) at 3 months and 6.6 cm³ (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.

Microwave ablation

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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.

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Cryomyolysis

Zreik and colleagues (2008) reported findings presented their experience with cryomyolysis 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.

Clinical guidelines

The American College of Obstetricians and Gynecologists (ACOG) guideline (2008, reaffirmed in 2019) entitled, *Alternatives to Hysterectomy in the Management of Leiomyomas*, stated that they do not recommend percutaneous techniques for myolysis as a treatment of uterine fibroids.

In 2015, an evidence-based guideline was published by the Journal of Obstetrics and Gynaecology Canada (JOGC) with the following recommendation, “Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients...Newer focused energy delivery methods are promising but lack long-term data.”

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.~~

Conclusion

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The published literature regarding the techniques for ~~myolysis~~uterine fibroid ablation is limited and of poor quality, even though some techniques, such as Nd:YAG laser myolysis, have been available since the early 1990s. There are no controlled clinical trials comparing ~~myolysis~~any of these techniques with hysterectomy. ~~Only, and one small RCT without long-term follow-up comparing a technique, -RFVTA, with laparoscopic myomectomy~~myolysis with myomectomy, which only reported interim results. The available ~~studies~~studies generally largely lack pertinent information such as uterine size, number and size of fibroids, location of fibroids (i.e., either subserosal, intramural or submucosal), and recurrence rates. ~~Clinical outcomes have been inconsistent or not reported.~~

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. ~~When radiofrequency ablation is used, the procedure may be referred to as the HALT (Hysterectomy Alternative) procedure.~~

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.

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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.

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

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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 are Investigational and Not Medically Necessary:

CPT

- 58578 Unlisted laparoscopy procedure, uterus [when specified as laparoscopic ablation by laser, bipolar electrodes, interstitial thermotherapy, cryotherapy]
- 58674 Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
- 58999 Unlisted procedure, female genital system (nonobstetrical) [when specified as image-guided percutaneous ablation by laser, bipolar electrodes, interstitial thermotherapy, cryotherapy, radiofrequency]
- [0404T](#) [Transcervical uterine fibroid\(s\) ablation with ultrasound guidance, radiofrequency](#)

ICD-10 Procedure

- 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

References

Peer Reviewed Publications:

1. [Alexander AL, Strohl AE, Rieder S, et al. Examining disparities in route of surgery and postoperative complications in black race and hysterectomy. Obstet Gynecol. 2019; 133\(1\):6-12.](#)
2. [Berman JM, Guido RS, Garza Leal JG, et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. J Minim Invasive Gynecol. 2014; 21\(5\):767-774.](#)
3. [Bongers M, Brölmann H, Gupta J, et al. Transcervical, intrauterine ultrasound-guided radiofrequency ablation of uterine fibroids with the VizAblate® System: three- and six-month endpoint results from the FAST-EU study. Gynecol Surg. 2015; 12\(1\):61-70.](#)

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Myolysis
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Document History

Status	Date	Action
<u>Revised</u>	<u>08/13/2020</u>	<u>Medical Policy & Technology Assessment Committee (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.</u>
Reviewed	05/14/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Rationale and References sections updated.
Reviewed	06/06/2019	MPTAC review. Rationale and References sections updated.

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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— <u>—</u> . 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
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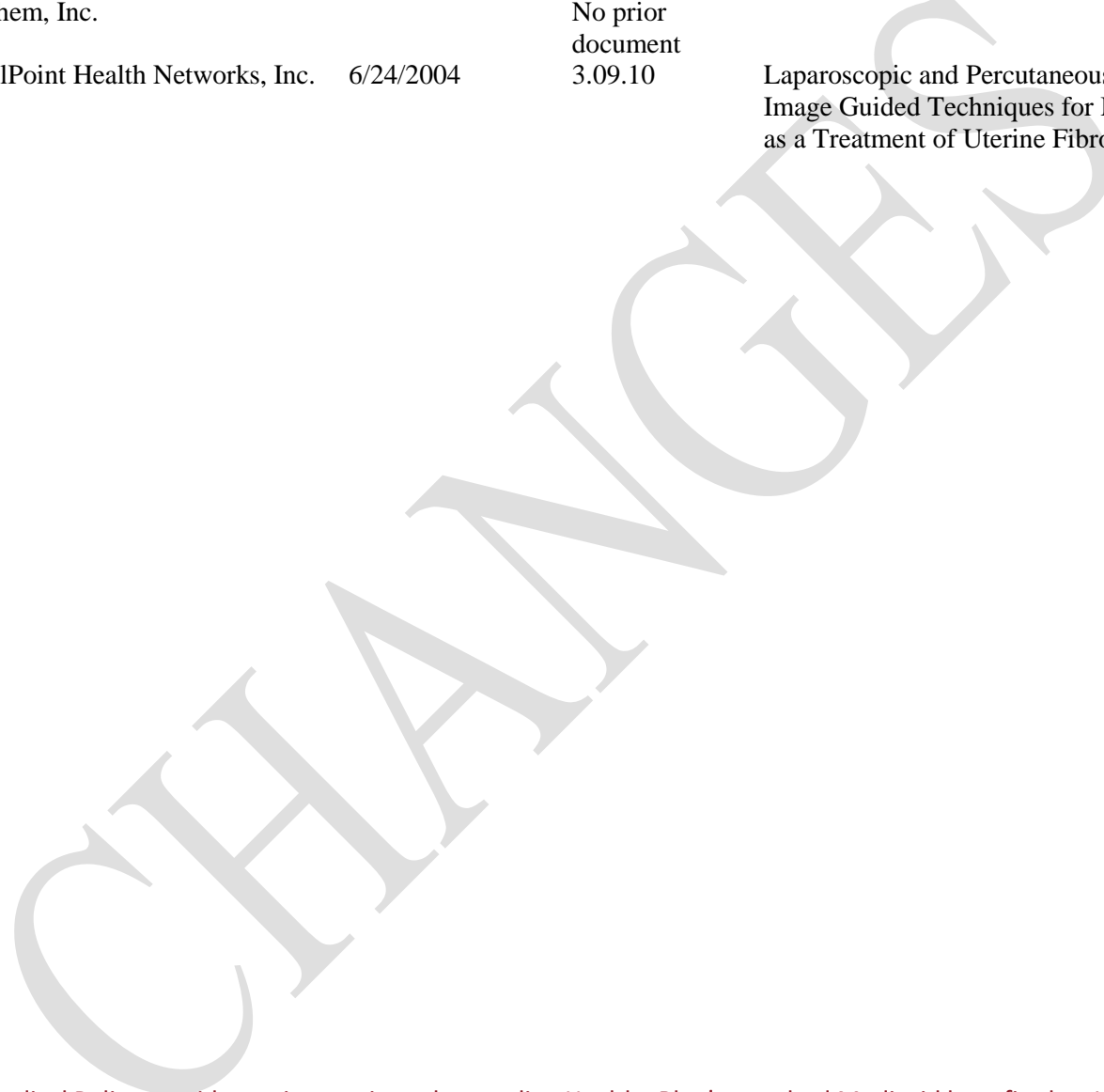
Anthem, Inc.

No prior document

WellPoint Health Networks, Inc. 6/24/2004

3.09.10

Laparoscopic and Percutaneous MRI-Image Guided Techniques for Myolysis as a Treatment of Uterine Fibroids



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