



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Magnetic Resonance (MR)-
Guided Thermal Ablation of
Uterine Fibroids**

Effective Date 12/15/2010
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Coverage Policy Number 0274

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Hyperlink to Related Coverage Policies

Hysterectomy
 Leuprolide (Lupron[®], Lupron Depot[®], Lupron Depot-PED[®])
 Uterine Artery Embolization

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA does not cover magnetic resonance (MR)-guided thermal ablation of uterine fibroids because it is considered experimental, investigational or unproven.

General Background

Uterine leiomyomata, or fibroids, are benign tumors of the uterus that are composed of smooth muscle and the extracellular matrix proteins, collagen and elastin. Fibroids can lead to abnormal uterine bleeding, dysmenorrhea and noncyclic pelvic pain. As they increase in size, and depending on their location, they can also cause constipation, urinary frequency, and infertility. The current standards of care for the treatment of symptomatic fibroids include:

- nonsteroidal anti-inflammatory agents
- oral contraceptives
- pharmacological agents (gonadotropin-releasing hormone [GnRH]) for short-term therapy
- myomectomy (laparoscopic or open)
- uterine artery embolization
- hysterectomy

Myomectomy and uterine artery embolization are surgical options for patients who wish to preserve their fertility, since a hysterectomy would render these individuals permanently infertile.

Magnetic resonance (MR)-guided focused ultrasound (MRgFUS) has been proposed as a non-invasive technique used to ablate uterine fibroids in women who do not intend to become pregnant in the future. During this procedure, magnetic resonance imaging (MRI) is used to guide highly focused ultrasound energy directly to the fibroid, causing tissue temperature to rise. Thermal destruction of the fibroid is monitored to avoid damage to nearby tissue or structures. Although early studies showed that some fibroid symptoms decreased (n=71%) following the procedure, a high percentage of patients (n=21%) needed alternative surgical treatment for their fibroids within one year of having the procedure because their previous symptoms returned. Reported adverse effects of MRgFUS have included paresthesia, burns on the abdomen, excessive postoperative bleeding, and reactions to medication.

U.S. Food and Drug Administration (FDA)

In November 2004, the FDA granted premarket approval (PMA) for an MRgFUS system for the proposed targeting and destruction of symptomatic fibroids. The ExAblate[®] 2000 System (InSightec—North America, Dallas, TX) is indicated for the ablation of symptomatic fibroids in women who have completed childbearing, do not intend to become pregnant, and have a uterine gestational size of less than 24 weeks. The ExAblate 2000 is contraindicated for use in women who have:

- MRI-related issues, such as metallic implants or sensitivity to MRI contrast agents
- obstructions in the treatment beam path, such as a scar, skin folds or irregularity, bowel, pubic bone, intrauterine device (IUD), surgical clips, or any hard implants
- fibroids that are close to sensitive organs, such as the bowel or bladder, or are outside the image area

Literature Review

Studies in the published peer-reviewed scientific literature evaluating the safety and effectiveness of MRgFUS ablation of uterine fibroids consists primarily of case series. A comparative uncontrolled study (n=192) by Taran et al. (2009) reported a lower number of complications and adverse events for women who underwent MRgFUS (n=109). However, at six months of follow-up, most of the SF-36 subscale scores were significantly better for women in the hysterectomy group (n=83).

The results of a number of prospective and retrospective case series (n=35—359) suggest that MRgFUS may reduce fibroid volume and improve symptoms over the short term (Funaki, et al., 2009; Morita, et al., 2008; Fennessy, et al., 2007; Rabinovici, et al., 2007; Stewart, et al., 2007; Stewart, et al., 2006; Hindley, et al., 2004). However, limitations of these studies include short follow-up, lack of comparison of MRgFUS to other minimally invasive procedures intended to treat uterine fibroids and preserve uterine function, and for some trials, very small sample sizes.

An Emerging Technology evidence report by ECRI found the evidence on the safety and efficacy of MRgFUS using the ExAblate 2000 system to be weak because of its small quantity and low quality. The report stated that only one small nonrandomized controlled trial used for premarketing approval (PMA) was available, and that trial compares the procedure to hysterectomy, rather than to less invasive options (ECRI, 2007).

The Agency for Healthcare Research and Quality (AHRQ) published an updated evidence report on the management of uterine fibroids. The report evaluated two studies (Stewart, et al., 2006; Hindley, et al., 2004), and concluded that although the data demonstrated safety and preliminary efficacy of the procedure for improving symptoms, comparative trials and longer-term follow-up are needed for this fibroid treatment modality (AHRQ, 2007).

The National Institute for Clinical Excellence (NICE) guidance for MRI-guided percutaneous laser ablation of uterine fibroids states that the current evidence on the safety and efficacy is such that this procedure should only be used with special arrangements for consent and for audit or research. According to the NICE, further research on the procedure and publication of long-term outcomes would be useful. (NICE, 2007).

Professional Societies/Organizations

According to the American College of Obstetricians and Gynecologists (ACOG), “whereas 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).

Summary

Magnetic resonance (MR)-guided, focused ultrasound system (MRgFUS) treatment for symptomatic fibroids with the ExAblate® 2000 system remains unproven due to the lack of well-designed, randomized, controlled clinical trials with adequate follow-up. Published data are limited, and the long-term safety and efficacy of this procedure has not yet been demonstrated. Study population numbers have been low, and it is unknown what impact this treatment will have on patients’ safety or what adverse effects might occur during long-term follow-up. Although some limited preliminary data suggest that MRgFUS holds promise, the role of this procedure in the management of patients with fibroids has not been established at this time.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

| CPT* Codes | 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 |

| ICD-9-CM Diagnosis Codes | Description |
|--------------------------|----------------------------------|
| 218.0-218.9 | Uterine leiomyoma |
| 218.0 | Submucous leiomyoma of uterus |
| 218.1 | Intramural leiomyoma of uterus |
| 218.2 | Subserous leiomyoma of uterus |
| 218.9 | Leiomyoma of uterus, unspecified |
| | All other codes |

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

| Pre-Merger Organizations | Last Review Date | Policy Number | Title |
|-------------------------------------|-----------------------------|--------------------------|---|
| CIGNA HealthCare | 12/15/2007 | 0274 | Magnetic Resonance (MR)-Guided Thermal Ablation of Fibroids |
| Great-West Healthcare | 10/26/2006 | 06.346.01 | MRI Guided Focused Ultrasound of Uterine Fibroids (MRgFUS) |

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.