

Corporate Medical Policy

MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids

File Name: mri_guided_high_intensity_ultrasound_ablation_of_uterine_fibroids
Origination: 11/2004
Last CAP Review: 6/2011
Next CAP Review: 6/2012
Last Review: 6/2011

Description of Procedure or Service

Description

An integrated system providing magnetic resonance imaging (MRI)-guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for uterine fibroids. MRgFUS is also being investigated for the treatment of other benign and malignant tumors, including palliative treatment of painful bone metastases.

Background

Uterine fibroids are one of the most common conditions affecting women in the reproductive years; symptoms include menorrhagia, pelvic pressure, or pain. There are several approaches that are currently available to treat symptomatic uterine fibroids: hysterectomy; abdominal myomectomy; laparoscopic and hysteroscopic myomectomy; hormone therapy; uterine artery embolization; and watchful waiting. Hysterectomy and various myomectomy procedures are considered the gold standard treatment.

Recently, there has been interest in using high-intensity focused ultrasound (HIFU) treatment that is guided by magnetic resonance imaging (MRI; MRgFUS) as a totally noninvasive approach to the ablation of uterine fibroids. The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. The ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. The ultrasound waves from each sonication can be focused into a maximum tissue volume of 4.3 cm³, causing a rapid rise in temperature sufficient to achieve tissue ablation at the focal point. In addition to providing guidance, the associated MRI can provide on-line thermometric imaging that provides a temperature “map” that can further confirm the therapeutic effect of the ablation treatment and allow for real-time adjustment of the treatment parameters.

The ultrasound equipment is specially designed to be compatible with MR magnets and is integrated into standard clinical MRI units. The ExAblate® 2000 System (InSightec, Inc., Dallas, TX) consists of a focused piezoelectric phased-array transducer, a computer-controlled positioning system, and a multichannel radiofrequency amplifier system. The array is located within a specially designed table in a water bath; imaging is performed with a custom receive-only pelvic coil. The ExAblate® 2000 System has received FDA approval for treatment of uterine fibroids. MRI-guided high-intensity focused ultrasound ablation of other tumors, including breast, prostate, and brain tumors and for the treatment of tumors metastatic to bone for the palliation of pain is also being studied. However, the device approved by the U.S. Food and Drug Administration (FDA) for MRI-guided ultrasound ablation is only for uterine fibroids.

Regulatory Status

In October 2004, the U.S. Food and Drug Administration (FDA) approved via the Premarket Application (PMA) process, the ExAblate® 2000 System for “ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure.” Treatment is indicated for women with a uterine gestational size of less than 24 weeks who have

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completed childbearing. In the initial safety and efficacy studies, the FDA limited MRI-guided focused ultrasound to 33% of fibroid volume with a maximum treatment time of 120 minutes. Guidelines were modified on April 30, 2004, to allow up to 50% treatment volume, 180-minute maximum treatment time, and a second treatment, if within a 14-day period. The ExAblate® 2000 treatment 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 fold, or irregularity, bowel, pubic bone, intrauterine device, surgical slips, or any hard implants; and fibroids that are close to sensitive organs such as the bowel or bladder, or are outside the image area. In December 2009, the ExAblate® 2100 System received premarket approval. It includes several modifications to the previous system including enhanced sonication and a detachable cradle. Approval remains limited to treatment of symptomatic uterine fibroids and is indicated in women with a uterine size of less than 24 weeks and those who have completed child bearing.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids is covered

Not applicable.

When MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids is not covered

MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids is considered investigational.

Policy Guidelines

A technology assessment from the Agency for Healthcare Research and Quality (AHRQ) on the management of uterine fibroids was published in July 2007. The AHRQ report concluded that the strength of the evidence about MRI-guided ultrasound ablation of fibroids is weak, and that the one carefully conducted prospective case series ranks as poor for informing clinical decision making. The National Institute for Health and Clinical Excellence (NICE) also conducted a review of this technology and issued their guidance in September 2007. They concluded the current evidence on the safety and efficacy of MRI-guided transcatheter focused ultrasound for uterine fibroids is such that this procedure should only be used with special arrangements for consent and for audit or research.

MRgFUS is only FDA-approved for the treatment of uterine fibroids. To date, there are no randomized controlled trials and only one non-randomized study comparing MRgFUS to a different treatment. Other than the lack of randomization, this study was limited in that data on the comparison group was not published until 5 years after data on the treatment group, the clinical significance of the primary outcome is unclear and there was only one-year follow-up. There is

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insufficient evidence on the long-term treatment effects, recurrence rates and impact on future fertility and pregnancy. Thus, MRgFUS is investigational for treatment of uterine fibroids.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0071T, 0072T

These CPT codes should not be used in conjunction with 51702 or 77022, since 0071T and 0072T describe the comprehensive service.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Funaki K, Fukunishi H, Sawada K. Clinical outcomes of magnetic resonance-guided focused ultrasound surgery for uterine myomas: 24-month follow-up. *Ultrasound Obstet Gynecol* 2009; 34(5): 584-9.

Taran FA, Tempany CM, Regan L, et al. Magnetic resonance-guided focused ultrasound (MRgFUS) compared with abdominal hysterectomy for treatment of uterine leiomyomas. *Ultrasound Obstet Gynecol* 2009; 34(5):572-8

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Policy Implementation/Update Information

- 11/11/04 New Policy issued. Reference added.
- 11/27/06 References updated. Specialty Matched Consultant Advisory Panel review 10/23/06. No changes to policy coverage criteria
- 6/16/08 References updated. Specialty Matched Consultant Advisory Panel review 5/15/08. No change to policy statement. (adn)
- 6/22/10 Policy Number(s) removed (amw)
- 9/28/10 Description section revised. Investigational statement reworded but intent remains unchanged. Policy Guidelines updated. Coding information added to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 8/25/10. Draft approved as written. (adn)
- 7/19/11 Statement added to Description section regarding FDA status. Specialty Matched Consultant Advisory Panel review 6/29/11. Policy accepted as written. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.