

---

## Magnetic resonance-guided focused ultrasound therapy for symptomatic uterine fibroids

*BlueCross Blue shield Association*

---

### Record Status

This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

The BlueCross BlueShield Association Technology Evaluation Center website ([www.bcbs.com/tec](http://www.bcbs.com/tec)) includes the most recent 3 years of TEC Assessments. To request older reports, please use the "contact us" feature on the website.

### Citation

BlueCross Blue shield Association. Magnetic resonance-guided focused ultrasound therapy for symptomatic uterine fibroids. Chicago: BlueCross BlueShield Association (BCBS). TEC Assessment 20(10). 2005

### Authors' objectives

The objective of this assessment is to evaluate the available evidence to determine the effect on health outcomes of using magnetic resonance imaging (MRI) -guided, focused ultrasound (MRgFUS) therapy as a treatment for symptomatic uterine fibroids. This assessment will compare MRgFUS with alternative interventions, including hysterectomy, myomectomy, and uterine artery embolization (UAE).

### Authors' conclusions

Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether MRgFUS for the treatment of uterine fibroids meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental bodies.

On October 22, 2004, the U.S. Food and Drug Administration (FDA) approved via the Premarket Application (PMA) process, the ExAblate 2000 System (InSightec, Inc., Dallas, TX) for "ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure." The FDA approval letter states that patients must have a uterine gestational size of less than 24 weeks and that patients must have completed childbearing. The device meets the first TEC criterion.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The available evidence on MRgFUS is insufficient to permit conclusions regarding the effect on health outcomes. One multicenter study including 109 subjects treated with MRgFUS was designed as a comparative trial including 83 subjects treated with hysterectomy, but comparative data on the hysterectomy group are largely missing in the reporting of results. It is unclear what represents a clinically meaningful change in the primary outcome measure for the FDA study (i.e., the Uterine Fibroid Symptom Quality of Life Symptom Severity Score; UFS-QOL SSS). A threshold of greater than 10 points was selected for the analysis, but this is not substantiated by other research.

At 6 months' follow-up, 70.6% of the MRgFUS group achieved a 10-point or greater reduction in SSS, but this decreased to 38.5% at 12 months. SSS results for the hysterectomy group were not reported, but presumably they would be normal. The proportions of women in the MRgFUS group at 6 months that were satisfied with their therapy or felt that they had an adequate treatment effect were 76 or 72%, respectively, but these values were not reported for the hysterectomy group, nor were they reported for either group at 12 months. In addition, 21% of those treated by MRgFUS needed additional surgical treatment and 4% underwent repeat MRgFUS by 12 months.

InSightec recently submitted its semi-annual report to the FDA (unpublished material shared with permission by InSightec). While not yet peer reviewed, some data are relevant to the evidence in support of MRgFUS. The report

includes 24-month follow-up of the study population originally presented to the FDA. Sixty-two patients continued on from the 12-month follow-up. By 24 months, a total of 40 (of the original 109) patients underwent an alternative treatment or repeat procedure (36.5%). For the 40 patients not already considered treatment failures or lost to follow-up at 24 months, the SSS efficacy measure was essentially unchanged at 24 months from the 6- and 12-month scores. Of 19 patients with imaging at 24 months, the percent shrinkage of the treated fibroid is 4.3% (from 15.3% at 6 months).

The available evidence is limited, which raises concerns about the reliability and validity of the reported findings. Considering the prevalence of fibroids in the general population, the number of patients in the published outcomes studies is relatively small. Also, the length of reported follow-up is insufficient because of the potential for regrowth of treated fibroids. At least, 1- to 2-year follow-up results are necessary to understand the durability of any early treatment effect. If complete infarction/ablation of the fibroid is required to prevent regrowth, then it is of concern that the current treatment protocol for MRgFUS, which allows treatment of only up to 50% of the fibroid, might not provide durable symptom relief. Limitations in quality of the existing evidence include significant loss to follow-up at longer follow-up intervals, lack of adequate well-controlled comparison studies, and lack of comparability between treatment groups in the available nonrandomized comparisons.

3. The technology must improve the net health outcome, and
4. The technology must be as beneficial as any established alternatives.

The evidence is insufficient to determine whether the use of MR-guided, focused ultrasound improves net health outcome or whether it is as beneficial as any established alternatives. The few available comparisons suggest that MR-guided focused ultrasound surgery may not be as effective as available alternatives. The InSightec study performed for the FDA PMA report does not provide sufficient information to directly compare results of hysterectomy with MRgFUS. Focused ultrasound surgery does offer a noninvasive treatment compared to hysterectomy, with substantially reduced recovery time and procedure-related morbidity. Patient satisfaction from the procedure is higher with hysterectomy, as is the degree of symptom relief. No direct comparisons of MRgFUS to either UAE or myomectomy are available in the literature; however, this does not preclude general and preliminary comparisons. Durability of the procedure is a major concern; a substantially greater proportion of women undergo other (or repeat) procedures after MRgFUS compared to either UAE or myomectomy. Available data suggest that MRgFUS fibroid volume reduction is much lower than with comparison procedures. When the change in SSS is used as the outcome measure, UAE appears to produce a more profound improvement in symptom severity scores than MRgFUS. For fertility preservation, myomectomy is the treatment of choice. Neither UAE nor MRgFUS is recommended if a woman is not family complete.

The data are inadequate to make fair and valid comparisons between procedures. Current protocols for MRgFUS allow for treating greater fibroid volumes than in the single available study. Further study of the procedure and its durability, especially in light of other available treatments, is needed.

5. The improvement must be attainable outside the investigational settings.

Whether the use of MR-guided, focused ultrasound improves health outcomes is not established in the investigational settings.

Therefore, the use of MR-guided, focused ultrasound for treatment of symptomatic uterine fibroids does not meet the TEC criteria.

### **Project page URL**

<http://www.bcbs.com/blueresources/tec/contact-tec.html>

### **Indexing Status**

Subject indexing assigned by CRD

### **MeSH**

Embolization, Therapeutic; Hysterectomy; Leiomyoma /ultrasonography; Magnetic Resonance Imaging; Ultrasonic

Therapy

**Language Published**

English

**Country of organisation**

United States

**Address for correspondence**

BlueCross BlueShield Association, Technology Evaluation Center, 225 North Michigan Ave, Chicago, Illinois, USA.  
Tel: 888 832 4321 Email: tec@bcbsa.com

**AccessionNumber**

32005001203

**Date bibliographic record published**

01/11/2005

**Date abstract record published**

01/11/2005