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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Magnetic Resonance Guided Focused Ultrasound for Treatment of Uterine Fibroids (MRgFUS)

- ExAblate 2000 Technology for Ablation of Uterine Fibroids

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"*Magnetic Resonance Guided Focused Ultrasound for Treatment of Uterine Fibroids (MRgFUS)*"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Uterine fibroids (or leiomyoma) are benign tumors of the uterus with a rich blood supply that may cause excessive bleeding and pelvic pain. The prevalence of uterine fibroids is estimated to be 20-40% in women older than 35. Hysterectomy is the standard permanent treatment for women who do not have a strong desire to retain their uterus. Other treatments include watchful waiting, medical management with hormonal therapy, myomectomy (local surgical removal) and uterine artery embolization (UAE). UAE is covered for GHC members when recommended by a GHC physician.

The ExAblate 2000 system (Insightec Ltd., Israel) is a minimally invasive, uterine-sparing treatment for uterine fibroids. The system is used in conjunction with a commercially available MRI scanner, the GE Signa 1.5T MR imaging system. A special coil is required to use the GE device with the ExAblate system. The MRI is used for planning, and also for monitoring during the procedure. The treatment is also known as MR guided focused ultrasound (MRI-FUS or MRgFUS).

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During the procedure, focused ultrasound waves heat the targeted fibroid tissue to approximately 65-85o C. causing cell necrosis. Over time, the necrotic tissue is absorbed by the body. The treatment can take several hours, and it requires collaboration between a gynecologist and a radiologist.

The ExAblate system was approved by the FDA in October 2004 for ablation of uterine fibroid tissue in pre- or peri- menopausal women with symptomatic uterine fibroids who want a uterine sparing procedure. Patients must have a uterine size of <24 weeks' gestation and have completed child-bearing. Prior to commercial availability in the U.S., the ExAblate system was used in Europe (since 2002) and, to a limited extent, in Japan.

The ExAblate 2000 technology for ablation of uterine fibroids has not been reviewed previously by MTAC.

Medical Technology Assessment Committee (MTAC)

Magnetic Resonance Guided Focused Ultrasound in the Treatment of Uterine Fibroids

06/04/2008: MTAC REVIEW

Evidence Conclusion: In the FDA pivotal study in which 109 women were treated using the ExAblate 2000 technology (Stewart et al., 2006), there was a statistically significant improvement in self-reported symptoms pre- and post-treatment. The Funaki et al. (2007) case series did not report pre- and post-comparisons. 25 out of 69 women (53%) reported improving a great deal or being symptom-free 3 months after being treated. An additional 17 women (28%) said their symptoms were somewhat improved. In both studies, the main outcomes were self-report measures. A sham or comparison group is needed in this type of study to evaluate the extent to which treatment with ExAblate had a placebo effect on women's perception of their symptoms. None of the published studies focused on objective health outcomes such as bleeding or anemia. There is insufficient evidence to draw conclusions about the safety and effectiveness of the ExAblate 2000 technology for ablation of uterine fibroids. The empirical literature consists of case series. There are no studies comparing this technology to sham treatment or other accepted treatments such as UAE and myomectomy.

Articles: The Medline search yielded 35 articles. There was also an unpublished FDA document from October 2004, entitled, "Summary of safety and effectiveness data". The pivotal study submitted by InSightec to the FDA was a cohort study with n=109 receiving MRI-FUS with ExAblate and n=83 receiving hysterectomy. The FDA document describes pre- and post-treatment findings in each group but does not present statistical comparisons comparing results in the two groups. Several subsequent published articles described subjective treatment effects in the 109 patients who received ExAblate in the FDA pivotal study. These include Hindley et al., 2004 (short-term outcomes) and Stewart et al., 2006 (6- and 12- month outcomes). No published articles were identified that compared the ExAblate and hysterectomy groups in the FDA pivotal study. No published randomized or non-randomized controlled studies were identified that compared ExAblate to sham or to a less invasive alternative treatment such as uterine artery embolization or myomectomy. Two studies were identified that compared different protocols of MRI-FUS. One was a small study in which one of the two groups received a GnRh agonist pre-treatment and the other evaluated compared a standard and slightly modified treatment guideline with the ExAblate system. Stewart et al. also published an article in 2007 that combined and re-evaluated data from the FDA study and other case series sponsored by Insightec. This article included selected data and post-hoc analyses which can be misleading and thus was not evaluated further. The Stewart et al., 2006 study reporting the clinical outcomes from the FDA pivotal trial was critically appraised. In addition, a case series from Japan with a reasonably large sample size was critically appraised. References are: Stewart EA et al. Clinical outcomes of focused ultrasound surgery for treatment of uterine fibroids. Fertil and Steril 2006; 85: 22-29. See Evidence Table.

The use of Magnetic resonance guided focused ultrasound in the treatment of uterine fibroids does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Magnetic Resonance-Guided Focused Ultrasound (MRgFUS)

07/25/2016: Medical Technology Assessment Team (MTAT) Review

Evidence Conclusion:

The studies identified in this assessment have limitations that make it difficult to have confidence in the estimates regarding efficacy and safety of MRgFUS or MR-HIFU for treatment of uterine fibroids. Given the small sample sizes of most of the studies, the lack of evidence on long-term health and pregnancy outcomes, and a substantial concern about the existence of confounding in study design:

1. There is low quality evidence that MRgFUS or MR-HIFU is as efficacious as hysterectomy and UAE for treating symptomatic uterine fibroids. The available evidence suggests MRgFUS or MR-HIFU is *less efficacious* than hysterectomy and UAE for treating symptomatic uterine fibroids.
2. There is very low-quality evidence that MRgFUS or MR-HIFU is as safe as hysterectomy and UAE for treating symptomatic uterine fibroids**.**

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The potential benefits of MRgFUS or MR-HIFU for treating uterine fibroids should be weighed against the potential harms (e.g., need for re-intervention following treatment). Additional large, high quality longitudinal studies are needed to assess the long-term efficacy and safety of MRgFUS or MR-HIFU for treating uterine fibroids.

Articles: Two systematic reviews (Clark, 2014; Canadian Agency for Drugs and Technologies in Health (CADTH), 2016 (Chen, Pitre, Kaunelis, & Singh, 2016)) and one technology assessment (Hayes, Inc., 2014) addressing efficacy and/or safety of MRgFUS or MR-HIFU were identified. The most comprehensive systematic review of comparative studies involving any type of MRgFUS versus hysterectomy, myomectomy, or UAE is from CADTH. We therefore used the CADTH report as our primary evidence source. Our update search identified one pilot randomized controlled trial (PROMISe Trial; Jacoby, et al., 2016) that assessed the efficacy and safety of MRgFUS compared to a sham procedure. Therefore, a total of three comparative studies (two from the CADTH report and one from our update search) were selected for inclusion in the SCPMG EBM assessment. CADTH (2016) found that MRgFUS (or MR-HIFU) was associated with more re-interventions but also fewer complications compared with hysterectomy and UAE. The review included RCTs, non-randomized studies, and economic evaluations assessing the clinical effectiveness and safety of uterine-preserving interventions in women with symptomatic uterine fibroids. Interventions of interest included myomectomy, myolysis, UAE, uterine artery occlusion (UAO), or endometrial ablation. They were compared with each other or with hysterectomy. The search for health technology assessments, systematic reviews, meta-analyses, and guidelines was limited to documents published since January 1, 2005, while the search for randomized controlled trials (RCTs), controlled clinical trials, cohort studies, and economic studies was not limited by publication year. A total of two non-randomized observational studies comparing MRgFUS versus hysterectomy and UAE (Taran et al., 2009 and Ikink et al., 2014, respectively) were reviewed and appraised (last CADTH search date: November 24, 2015).

The use of Magnetic resonance guided focused ultrasound in the treatment of uterine fibroids does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered not medically necessary:

CPT® or HCPC 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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/17/2008	06/04/2008[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	06/04/2008

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
02/13/2017	Added KP MTAT Review

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