Medical Policy
MRI-Guided Focused Ultrasound - MRgFUS

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Policy Number: 243
BCBSA Reference Number: 7.01.109

Related Policies
- Occlusion of Uterine Arteries Using Transcatheter Embolization #242

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Magnetic resonance imaging (MRI)-guided high-intensity ultrasound ablation is INVESTIGATIONAL. This includes, but is not limited to, its use in the following situations:
- Treatment of uterine fibroids;
- Pain palliation for patients with metastatic bone cancer;
- Treatment of other tumors e.g., brain cancer, prostate cancer and breast cancer.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO BlueSM
This is NOT a covered service.

Medicare Members: PPO BlueSM
This is NOT a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Code Description</th>
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<tr>
<td>0071T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue</td>
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<tr>
<td>0072T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue</td>
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ICD-9 Diagnosis Codes

Investigational for all diagnoses.

Description

Uterine fibroids (leiomyomata) 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 treatments.

An integrated system providing magnetic resonance imaging guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for uterine fibroid ablation. 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.

MRgFUS is also being investigated for the treatment of other benign and malignant tumors, including palliative treatment of painful bone metastases.

An example of an MRgFUS treatment device for ablation of uterine fibroids is the ExAblate® 2000 System from InSightec, Inc. All MRgFUS devices for ablation of uterine fibroids are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

Summary

There is insufficient evidence from randomized controlled trials or nonrandomized controlled trials that magnetic resonance-guided focused ultrasound (MRgFUS) improves the net health outcome for any clinical application. Additional well-designed studies with sufficient numbers of patients, high rates of follow-up and sufficient lengths of follow-up are needed. Thus, MRgFUS is considered investigational for treatment of uterine fibroids, pain palliation in patients with bone metastases and other applications.

Policy History

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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/2014</td>
<td>New references from BCBSA National medical policy</td>
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<tr>
<td>8/2013</td>
<td>BCBSA National medical policy review. Policy changed to single investigational statement; no change to intent of policy. Policy</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References