MRI-Guided Focused Ultrasound (MRgFUS)

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 and for pain palliation of bone metastases. MRgFUS is also being investigated for the treatment of other benign and malignant tumors.

Background

Magnetic resonance-guided focused ultrasound (MRgFUS) is a non-invasive treatment that combines two technologies, focused ultrasound and magnetic resonance imaging. 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 are focused at a focal point which has a maximum focal volume of 20 nm in diameter and 15 nm in height/length. This causes 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 U.S. Food and Drug Administration (FDA) has approved the ExAblate® MRgFUS system (InSightec, Inc., Haifa, Israel) for two indications; treatment of uterine fibroids (leiomyomata) and for palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specially designed to be compatible with MR magnets and is integrated into standard clinical MRI units. It includes a patient table, which includes a cradle housing the focused ultrasound transducer in a water or light oil bath. Some models of the device have a detachable cradle; only certain cradle types can be used for the palliation of pain associated with metastatic bone cancer.

To date, the primary clinical application of MRgFUS has been treatment of uterine fibroids (leiomyomata), one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids 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 criterion standard treatment.

For treating pain associated with bone metastases, the aim of MRgFUS treatment is to destroy nerves in the bone surface surrounding the tumor. Metastatic bone disease is one of the most common causes of cancer pain. Existing treatments include conservative measures (e.g., massage, exercise) and pharmacologic agents (e.g., analgesics, bisphosphonates, corticosteroids). For patients who fail the above treatments, standard care is use of external beam radiotherapy (EBRT). However, a substantial proportion of patients have residual pain after radiotherapy, and there is a need for alternative treatments for these patients.

MRgFUS is also being investigated for treatment of other tumors, including breast, prostate, and brain.
MRI-Guided Focused Ultrasound (MRgFUS)

tumors.

**Regulatory Status**

In October 2004, FDA approved via the Premarket Application (PMA) process, the ExAblate® 2000 System for “ablation of uterine fibroid tissue in pre- or peri-menopausal 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 completed childbearing.

In October 2012, the FDA approved the ExAblate® System, Model 2000/2100/2100 VI via the PMA process. The intended use of the device is for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy. The device was evaluated through an expedited review process. The FDA required a post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

**Related Policies**

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

***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 may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy.

**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 Focused Ultrasound is covered**

Magnetic resonance imaging (MRI)–guided high-intensity ultrasound ablation may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy.

**When MRI-Guided Focused Ultrasound is not covered**

MRI-Guided High Intensity Ultrasound Ablation is considered investigational in all other situations, including:

- Treatment of uterine fibroids;
- Treatment of other tumors e.g., brain cancer, prostate cancer and breast cancer.

**Policy Guidelines**

The evidence for MRgFUS in individuals who have metastatic bone cancer who failed or are not candidates for radiotherapy includes a sham controlled randomized controlled trial (RCT) Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life and treatment related morbidity. The RCT found statistically significant improvement after MRgFUS in a composite outcome comprised of reduction in pain and morphine use, and in painreduction as a stand alone outcome. A substantial proportion of patients in the treatment group experienced adverse events, but most of these
MRI-Guided Focused Ultrasound (MRgFUS)

were not severe and were transient. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for MRgFUS in individuals who have uterine fibroids includes a pilot RCT, nonrandomized comparative studies and case studies. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment related morbidity. The pilot RCT (N=20 patients) reported some health outcomes but its primary purpose was to determine the feasibility of a larger trial. It did not find statistically significant differences in quality of life outcomes between active and sham treatment groups, but did find lower fibroid volumes after active treatment. The pivotal Food and Drug Administration trial was not randomized, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. In the 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. There are insufficient data on the long term treatment effects, recurrence rates and impact on future fertility and pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for MRgFUS in individuals who have miscellaneous tumors (eg. Brain, prostate, breast cancer) includes case series. Relevant outcomes are symptoms, health status measures, and treatment related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

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, 0398T, C9734

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

There are no specific CPT codes for the use of MRI-guided high-intensity ultrasound ablation in metastatic bone cancer. An unlisted code would be used based on the anatomic location of the metastasis being treated (eg, 23929 for the clavicle) or perhaps one of the radiation oncology unlisted codes (eg, 77299 or 77499).

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


MRI-Guided Focused Ultrasound (MRgFUS)


Specialty Matched Consultant Advisory Panel review 6/2015


Policy Implementation/Update Information

### MRI-Guided Focused Ultrasound (MRgFUS)

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<tr>
<td>11/27/06</td>
<td>References updated. Specialty Matched Consultant Advisory Panel review 10/23/06. No changes to policy coverage criteria</td>
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<td>6/16/08</td>
<td>References updated. Specialty Matched Consultant Advisory Panel review 5/15/08. No change to policy statement.</td>
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<td>7/19/11</td>
<td>Statement added to Description section regarding FDA status. Specialty Matched Consultant Advisory Panel review 6/29/11. Policy accepted as written.</td>
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<td>6/29/12</td>
<td>Policy title changed to include “Other Tumors.” Related Guideline added to Description section. “Magnetic resonance imaging (MRI)-guided ablation of other tumors, including but not limited to breast, brain, prostate cancer, and palliative treatment of bone metastases, is considered investigational” added to When Not Covered section. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/20/12.</td>
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**For Policy Re-named: MRI-Guided Focused Ultrasound (MRgFUS)**

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<tr>
<td>4/16/13</td>
<td>References added. Policy title changed from MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids and Other Tumors to MRI-Guided Focused Ultrasound (MRgFUS). Description and Background sections updated to include information on palliative treatment of bony metastases. Regulatory Status section updated to include FDA information from 2012. HCPCS code C9734 added to Billing/Coding section. No change to policy statement.</td>
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<td>3/31/15</td>
<td>Reference added. “Magnetic resonance imaging (MRI)-guided high-intensity ultrasound ablation may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy” added to the When Covered section. Policy guidelines updated. Billing/Coding section updated. Senior Medical Director review.</td>
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<td>Added CPT code 0398T to Billing/Coding section for effective date 1/1/2016.</td>
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<td>Updated Policy Guidelines section. No change to policy intent. Reference added.</td>
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<td>Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement.</td>
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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.