Medical Coverage Policy | Magnetic Resonance Imaging-Guided Focused Ultrasound

EFFECTIVE DATE: 01|01|2023
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OVERVIEW

An integrated system providing magnetic resonance-guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for uterine fibroids and pain palliation of bone metastases. MRgFUS is also being investigated as a treatment of other benign and malignant tumors as well as essential tremors.

MEDICAL CRITERIA

Medicare Advantage Plans

For magnetic resonance-guided high-intensity ultrasound ablation using 0398T, Blue Cross & Blue Shield of Rhode Island (BCBSRI) follows the medical necessity criteria from Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations (NCD/LCD). Please use the online tool for participating providers. See the Related Policies section.

Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary for the following condition:

- Pain palliation in adults with metastatic bone cancer who have failed or are not candidates for Radiotherapy

Commercial Products

Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary when either of the following conditions are met:

- Pain palliation in adults with metastatic bone cancer who have failed or are not candidates for Radiotherapy
- Treatment of medicine-refractory essential tremors

PRIOR AUTHORIZATION

Medicare Advantage Plans & Commercial Products

Prior authorization is required for Medicare Advantage Plans for magnetic resonance-guided high-intensity ultrasound ablation using 0398T (via the online tool for participating providers. See the Related Policies section) and is recommended for Commercial Products.

POLICY STATEMENT

Medicare Advantage Plans & Commercial Products

Magnetic resonance-guided high-intensity ultrasound ablation for magnetic resonance-guided high-intensity ultrasound ablation using 0398T may be considered medically necessary for Medicare Advantage Plans via the online tool for participating providers.
Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary for Commercial Products when the medical criteria above has been met.

Medicare Advantage Plans

Magnetic resonance-guided high-intensity ultrasound ablation is not covered for Medicare Advantage Plans as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes in all other situations including but not limited to:

- treatment of uterine fibroids

- treatment of other tumors (e.g., brain cancer, prostate cancer, breast cancer, desmoid)

Commercial Products

Magnetic resonance-guided high-intensity ultrasound ablation is not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes in all other situations including but not limited to:

- treatment of uterine fibroids
- treatment of other tumors (e.g., brain cancer, prostate cancer, breast cancer, desmoid)
- treatment of medication-refractory tremor dominant Parkinson disease

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for the applicable surgery services benefits/coverage.

BACKGROUND

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain.

Treatment

Several approaches currently available to treat symptomatic uterine fibroids include 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 treatments.

Metastatic Bone Disease

Metastatic bone disease is one of the most common causes of cancer pain.

Treatment

Existing treatments include conservative measures (eg, massage, exercise) and pharmacologic agents (eg, analgesics, bisphosphonates, corticosteroids). For patients who do not respond to these treatments, standard care is external-beam radiotherapy. However, a substantial proportion of patients have residual pain after radiotherapy, and there is a need for alternative treatments for these patients.

Essential Tremors (ET)

ET is the most common movement disorder, with an estimated prevalence of 5% worldwide. ET most often affects the hands and arms, may affect head and voice, and rarely includes the face, legs, and trunk. ET is heterogeneous among patients, varying in frequency, amplitude, causes of exacerbation, and association with other neurologic deficits.

Treatment

The neuropathology of ET is uncertain, with some evidence suggesting that ET is localized in the brainstem and cerebellum. If patients with ET experience intermittent or persistent disability due to the tremors, initial therapy is with drugs (b-blockers or anticonvulsants). For medicine-refractory patients, surgery (deep brain stimulation or thalamotomy) may be offered, though high rates of adverse events have been observed.

Tremor-Dominant Parkinson Disease

The 3 cardinal features of Parkinson disease (PD) are tremor, bradykinesia, and rigidity. The tremor in PD is a resting tremor that occurs when the body part is not engaged in purposeful activities. Major subtypes of PD

include tremor-dominant, akinetic-rigid, and postural instability and gait difficulty. The progression of PD is highly variable and patients can change subtypes as the disease progresses.

Treatment

Dopaminergic therapy (ie, levodopa or a dopamine agonist) is the first-line treatment for PD, which improves tremor. Amantadine and anticholinergics (eg, trihexyphenidyl) can also be considered as initial treatment for tremor-dominant PD or as add-on therapy in patients who have persistent tremor despite dopaminergic therapy. For medication-refractory patients, surgery (deep brain stimulation or lesioning procedures) may be offered. Lesioning procedures include conventional unilateral thalamotomy and focused ultrasound thalamotomy. Deep brain stimulation is the most frequently performed surgical procedure for the treatment of PD.

Magnetic Resonance-Guided Focused Ultrasound

MRgFUS is a noninvasive treatment that combines 2 technologies: focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. Ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. Ultrasound waves from each sonication are directed at a focal point that has a maximum focal volume of 20 nm in diameter and 15 nm in height/length. This causes a rapid rise in temperature (ie, to 65°C-85°C), which is sufficient to ablate tissue at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging, a temperature "map", to 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) approved the ExAblate MRgFUS system (InSightec) for 2 indications: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specifically designed to be compatible with magnetic resonance magnets, and it is integrated into standard clinical MRI units; it also includes a patient table, which has a cradle that houses the focused ultrasound transducer in water or a light oil bath. Some models have a detachable cradle; only certain cradle types can be used for palliation of pain associated with metastatic bone cancer. For treating pain associated with bone metastases, the aim of MRgFUS is to destroy nerves in the bone surface surrounding the tumor.

MRgFUS is also being investigated for the treatment of other tumors, including breast, prostate, brain, and desmoid tumors as well as nonspinal osteoid osteoma.

Regulatory Status

In October 2004, the ExAblate® 2000 System (InSightec) was approved by the FDA through the premarket approval process 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 fewer than 24 weeks who have completed childbearing.

In October 2012, the ExAblate® System, Model 2000/2100/2100 VI, was approved by the FDA through the premarket approval process for pain palliation in adults with metastatic bone cancer who have 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.

In July 2016, the FDA approved the use of the ExAblate® Neuro System for the treatment of ET in patients who have not responded to medication (b-blockers or anticonvulsant drugs) through the premarket approval process.

For individuals who have uterine fibroids who receive MRgFUS, the evidence includes 2 small randomized controlled trials (RCTs), nonrandomized comparative studies, and case series. Relevant outcomes are

symptoms, quality of life, resource utilization, and treatment-related morbidity. One RCT (n=20) has 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 it did find lower fibroid volumes after active treatment. This trial did not have an active comparator, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. The second RCT (n=49) is ongoing; preliminary results at 6 weeks posttreatment, comparing MRgFUS with uterine artery embolization have shown that the 2 groups are comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the uterine artery embolization group, as measured by time to return to work and time to normal activities. In a separate 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. Long-term data on the treatment effects, recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with metastatic bone cancer who have failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a sham-controlled randomized trial and several case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvements after MRgFUS in a composite outcome comprised of a reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. A substantial proportion of patients in the treatment group experienced adverse events but most events were transient and not severe. The case series reported reductions in pain following MRgFUS treatment, consistent with the RCT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with other tumors (eg, breast cancer, brain cancer, prostate cancer, desmoid, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes small 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.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes 2 systematic reviews that identified an RCT and several observational studies. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The assessment did not pool study results but concluded that, overall, MRgFUS decreased tremor severity and improved quality of life. The sham-controlled randomized trial found significant improvements in the treatment group in tremor severity, functional improvement, and quality of life after 3 months of follow-up. The improvements in hand tremor score, function, and quality of life were maintained at the 2-year follow-up. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with medicine-refractory tremor dominant PD who receive MRgFUS, the evidence includes a pilot RCT. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The double-blind,sham-controlled, pilot randomized trial found significant improvements in the treatment group in tremor severity after 3 months of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) may be considered medically necessary for Medicare Advantage Plans via the online tool for participating providers and for Commercial Products when the medical criteria above has been met.

0398T Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed

The following CPT code(s) may be considered medically necessary for Medicare Advantage Plans and for Commercial Products when the medical criteria above has been met.

C9734 Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations
Prior Authorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, October 2023
Provider Update, November 2022
Provider Update, September 2021

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