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Subject: Magnetic Resonance-Guided High Intensity Focused Ultrasound Ablation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Update			

DESCRIPTION:

Magnetic resonance-guided focused ultrasound (MGgFUS) (also known as magnetic resonance guided high intensity focused ultrasound ablation) is a noninvasive treatment that combines 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.

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in the reproductive years; symptoms include menorrhagia, pelvic pressure, or pain. Hysterectomy and various myomectomy procedures are considered the gold standard treatment.

Metastatic Bone Disease

Metastatic bone disease is one of the most common causes of cancer pain. Existing treatments include conservative measures (eg, massage, exercise) and pharmacologic agents (eg, analgesics, bisphosphonates, corticosteroids). For patients who fail the above treatments, the standard care is to use 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.

Other Tumors

Magnetic resonance-guided focused ultrasound of other tumors, including, but not limited to breast, prostate, and brain tumors are being studied.

Essential Tremors

Essential tremors (ET) are 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.

There are several ExAblate medical devices approved by the U.S. Food and Drug Administration (FDA) (e.g., ExAblate 2000 MRgFUS system (InSightec), ExAblate Model 4000 Type 1.0 System (ExAblate Neuro), ExAblate System (Insightec) Model 2000/2100/2100). The U.S. Food and Drug Administration (FDA) approved the ExAblate MRgFUS system (InSightec) for: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone.

The ExAblate System (Insightec) Model 2000/2100/2100) (2012) medical device is indicated for pain palliation of metastatic bone cancer in patients 18 years of age or older who are suffering from bone pain due to metastatic disease and who arc failures of standard radiation therapy, or not candidates for, or refused radiation therapy. The bone tumor to be treated must be visible on non-contrast MR and device accessible.

The FDA approved (2016) the ExAblate® Neuro System, Model 4000 Type 1.0 System (ExAblate Neuro) for the treatment of essential tremors in patients who have not responded to medication (β-blockers or anticonvulsant drugs). This device is indicated for use in the unilateral thalamotomy treatment of idiopathic essential tremor patients with medication-refractory tremor.

Summary of Evidence: Hurwitz et al 2014 reported the reults of a randomized control trial to assess the safety and efficacy of magnetic resonance-guided focused ultrasound surgery (MRgFUS). Patients with painful bone metastases were randomly assigned 3:1 to receive MRgFUS sonication or placebo. The primary endpoint was improvement in self-reported pain score without increase of pain medication 3 months after treatment and was analyzed by Fisher's exact test. Components of the response composite, Numerical Rating Scale for pain (NRS) and morphine equivalent daily dose intake, were analyzed by t test and Wilcoxon rank-sum test, respectively. Brief Pain Inventory (BPI-QoL), a measure of functional interference of pain on quality of life, was compared between MRgFUS and placebo by t test. Statistical tests were two-sided. One hundred forty-seven subjects were enrolled, with 112 and 35 randomly assigned to MRgFUS and placebo treatments, respectively. Response rate for the primary endpoint was 64.3% in the MRgFUS arm and 20.0% in the placebo arm ($P < .001$). MRgFUS was also superior to placebo at 3 months on the secondary endpoints assessing worst score NRS ($P < .001$) and the BPI-QoL ($P < .001$). The most common treatment-related adverse event (AE) was sonication pain, which occurred in 32.1% of MRgFUS patients. Two patients had pathological fractures, one patient had third-degree skin burn, and one patient suffered from neuropathy. Overall 60.3% of all AEs resolved on the treatment day. The authors conclude that this multicenter phase III trial demonstrated that MRgFUS is a safe and effective, noninvasive treatment for alleviating pain resulting from bone metastases in patients that have failed standard treatments.

Elias et al (2016) enrolled patients with moderate-to-severe essential tremor that had not responded to at least two trials of medical therapy and randomly assigned them in a 3:1 ratio to undergo unilateral focused ultrasound thalamotomy or a sham procedure. The Clinical Rating Scale for Tremor and the Quality of Life in Essential Tremor Questionnaire were administered at baseline and at 1, 3, 6, and 12 months. Tremor assessments were videotaped and rated by an independent group of neurologists who were unaware of the treatment assignments. The primary outcome was the between-group difference in the change from baseline to 3 months in hand tremor, rated on a 32-point scale (with higher scores indicating more severe tremor). After 3 months, patients in the sham-procedure group could cross over to active treatment (the open-label extension cohort). Seventy-six patients were included in the analysis. Hand-tremor scores improved more after focused ultrasound thalamotomy (from 18.1 points at baseline to 9.6 at 3 months) than after the sham procedure (from 16.0 to 15.8 points); the between-group difference in the mean change was 8.3 points (95% confidence interval [CI], 5.9 to 10.7; P<0.001). The improvement in the thalamotomy group was maintained at 12 months (change from baseline, 7.2 points; 95% CI, 6.1 to 8.3). Secondary outcome measures assessing disability and quality of life also improved with active treatment (the blinded thalamotomy cohort)as compared with the sham procedure (P<0.001 for both comparisons). Adverse events in the thalamotomy group included gait disturbance in 36% of patients and paresthesias or numbness in 38%; these adverse events persisted at 12 months in 9% and 14% of patients, respectively. MRI-guided focused ultrasound thalamotomy reduced hand tremor in patients with essential tremor. Side effects included sensory and gait disturbances. The authors concluded that MRI-guided focused ultrasound thalamotomy reduced hand tremor in patients with essential tremor.

The evidence is insufficient to determine the effects of magnetic resonance-guided high intensity focused ultrasound on health outcomes for all other indications (e.g., uterine fibroids, tumors, Parkinson disease) (Barnard et al 2017, Chen 2016, Otonkoski et al 2023, Abreu et al 2020, Pompe et al 2018, Merckel et al 2016, Ghai et al 2024, Pompe et al 2018, Bond et al 2017, Sinai et al 2022, Ko et al 2023, Momin et al 2024).

POSITION STATEMENT:

Magnetic resonance -guided high intensity focused ultrasound ablation using an FDA approved device **meets the definition of medical necessity** for pain palliation in adult members with metastatic bone cancer who failed or are not candidates for radiotherapy.

Magnetic resonance -guided high-intensity ultrasound ablation **meets the definition of medical necessity** for the treatment of medicine-refractory essential tremors.

Magnetic resonance-guided high intensity ultrasound ablation for all other indications, including, but not limited to the following is considered **experimental or investigational**.

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

The evidence is insufficient to determine the effects of magnetic resonance-guided high intensity focused ultrasound on health outcomes for all other indications.

BILLING/CODING INFORMATION:

CPT Coding

0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total lieomyomata volume less than 200cc of tissue (**Investigational**)
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200cc or tissue (**Investigational**)
61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Desmoid tumor: A type of soft tissue tumor that forms in fibrous (connective) tissue, usually in the arms, legs, or abdomen. It may also occur in the head and neck. Desmoid tumors are usually benign (not cancer). They often recur (come back) after treatment and spread to nearby tissue, but they rarely spread to other parts of the body. They may occur in adults or children. Also called aggressive fibromatosis and desmoid-type fibromatosis.

RELATED GUIDELINES:

None applicable.

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Other names used to report magnetic resonance-guided high intensity focused ultrasound:

Magnetic resonance guided focused ultrasound (MGgFUS)

Magnetic resonance imaging guided high intensity focused ultrasound (MRI-HIFU)
Magnetic resonance imaging-guided focused ultrasound (MRI-FUS)
MRI guided high intensity focused ultrasound

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

GUIDELINE UPDATE INFORMATION:

12/15/04	New Medical Coverage Guideline.
01/01/06	Scheduled review. No change in investigational status. Updated references.
01/01/07	Added investigational statement for other tumors. Updated references.
06/15/07	Reformatted guideline.
08/15/07	Annual review, investigational status maintained,references updated.
01/01/09	Scheduled review. No change in position statement. Updated references.
12/15/09	Annual review; no change in position statement. Updated references.
05/15/14	Revision; Program Exceptions section updated.
10/15/15	Review and revision; added position statement for pain palliation in adult members with metastatic bone cancer who failed or are not candidates for radiotherapy. Updated references.
11/15/17	Review; revised position statement. Added code 0398T.
09/15/18	Review; added treatment of medicine-refractory essential tremors. Updated description and references.
09/15/20	Review; no change to position statement. Updated references.

11/15/20	Code update; 0398T removed investigational.
01/01/21	Annual HCPCS code update. Added 55880.
09/15/21	Review; no change to position statement. Updated references.
10/15/22	Review and update. Added treatment of medication-refractory tremor dominant Parkinson disease. Deleted code 55880. Updated references.
05/25/23	Update to Program Exceptions section.
12/08/23	Review; no change to position statement.
09/15/24	Review; no change to position statement. Updated references.
01/01/25	Annual CPT/HCPCS coding update. Added 61715. Deleted 0398T.