**Subject: Magnetic Resonance-Guided High Intensity Focused Ultrasound Ablation**

**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 are 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.

**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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Investigational Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>0071T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200cc of tissue</td>
<td>Investigational</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 200cc or tissue</td>
<td>Investigational</td>
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<tr>
<td>0398T</td>
<td>Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed</td>
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</table>

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

REFERENCES:


5. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.109 Magnetic Resonance-Guided Focused Ultrasound, 08/22.


**COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/22/22.

**GUIDELINE UPDATE INFORMATION:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>12/15/04</td>
<td>New Medical Coverage Guideline.</td>
</tr>
<tr>
<td>01/01/06</td>
<td>Scheduled review. No change in investigational status. Updated references.</td>
</tr>
<tr>
<td>01/01/07</td>
<td>Added investigational statement for other tumors. Updated references.</td>
</tr>
<tr>
<td>06/15/07</td>
<td>Reformatted guideline.</td>
</tr>
<tr>
<td>08/15/07</td>
<td>Annual review, investigational status maintained, references updated.</td>
</tr>
<tr>
<td>01/01/09</td>
<td>Scheduled review. No change in position statement. Updated references.</td>
</tr>
<tr>
<td>12/15/09</td>
<td>Annual review; no change in position statement. Updated references.</td>
</tr>
<tr>
<td>05/15/14</td>
<td>Revision; Program Exceptions section updated.</td>
</tr>
<tr>
<td>10/15/15</td>
<td>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.</td>
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<tr>
<td>11/15/17</td>
<td>Review; revised position statement. Added code 0398T.</td>
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<tr>
<td>09/15/18</td>
<td>Review; added treatment of medicine-refractory essential tremors. Updated description and references.</td>
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<tr>
<td>09/15/20</td>
<td>Review; no change to position statement. Updated references.</td>
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<td>11/15/20</td>
<td>Code update; 0398T removed investigational.</td>
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<tr>
<td>01/01/21</td>
<td>Annual HCPCS code update. Added 55880.</td>
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<tr>
<td>09/15/21</td>
<td>Review; no change to position statement. Updated references.</td>
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<tr>
<td>05/25/23</td>
<td>Update to Program Exceptions section.</td>
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