PREMERA HMO

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MEDICAL POLICY – 7.01.109

Magnetic Resonance Imaging–Guided Focused Ultrasound

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Effective Date:	Oct. 1, 2024
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Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
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Introduction

Magnetic resonance-guided high-intensity ultrasound uses two technologies: magnetic resonance imaging (MRI) and ultrasound. It is a noninvasive procedure, which means the skin is not cut. MRI uses a magnetic field, radio frequency, and a computer to create detailed images of organs, tissues, and bones. Ultrasound uses sound waves at a higher frequency than a person can hear. Ultrasound is usually used to create images of body structures to help diagnose illnesses. But in this treatment, the ultrasound beams are at a different frequency and are focused on one area. Heat is created at the point where the high frequency beams meet, and the heat ablates (destroys) unhealthy tissue. The MRI is used to both guide the location of the ultrasound beams and to monitor treatment. This policy discusses when magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary and covered by the health plan.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Magnetic resonance-guided high-intensity ultrasound ablation	**Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary to help control pain in adults with bone metastases who have failed or are not candidates for radiotherapy.** **Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary for the treatment of medicine-refractory (such as beta-blockers or anticonvulsants) essential tremors.**

Service	Investigational
Magnetic resonance-guided high-intensity ultrasound ablation	**Magnetic resonance-guided high-intensity ultrasound ablation is considered investigational 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 tumors) (see **Related Policies**) • Treatment of medication-refractory tremor dominant Parkinson's disease

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Documentation that the requested service is for pain control that has failed for an individual with bone metastases, or an individual is not a candidate for radiotherapy

OR

- Documentation that the individual has essential tremors not responding to medication (such as beta-blockers or anticonvulsants)

Coding

Code	Description
CPT	
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
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 (code termed 12/31/2024)
51721	Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed (new code effective 01/01/2025)
53899	Unlisted procedure, urinary system
55881	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; (new code effective 01/01/2025)
55882	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed (new code effective 01/01/2025)
55899	Unlisted procedure, male genital system
58999	Unlisted procedure, female genital system (nonobstetrical)
61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed (new code effective 01/01/2025)
76999	Unlisted ultrasound procedure (e.g. diagnostic, interventional)
HCPCS	
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance (code termed 12/31/2024)

The procedure may be performed in a magnetic resonance imaging suite with an open magnetic resonance scanner, which might not be available at many institutions. The procedure is performed in an outpatient setting, with the individual under conscious sedation.

Related Information

Consideration of Age

Magnetic resonance–guided focused ultrasound (MRgFUS) is considered medically necessary for bone metastases in adult individuals, age 18 and older. This is based on the randomized controlled trial that studied the use of MRgFUS in individuals with bone metastases.

Evidence Review

Description

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.

Background

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. African American women have a greater lifetime incidence of uterine fibroids compared to other racial groups.[1] Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain.

Treatment

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 (e.g., massage, exercise) and pharmacologic agents (e.g., analgesics, bisphosphonates, corticosteroids). For individuals who do not respond to these treatments, standard care is external-beam radiotherapy. However, a substantial proportion of individuals have residual pain after radiotherapy, and there is a need for alternative treatments for these individuals. One option, radiofrequency ablation, is addressed in a **Related Policy**.

Essential Tremors

Essential tremor (ET) is the most common movement disorder, with an estimated prevalence of 5% worldwide. ET most often affects the hands and arms, may affect the head and voice, and rarely includes the face, legs, and trunk. ET is heterogeneous among individuals, 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 individuals with ET experience intermittent or persistent disability due to the tremors, initial therapy is with drugs (β-blockers or anticonvulsants). For medicine-refractory individuals, surgery (deep brain stimulation or thalamotomy) may be offered, though high rates of adverse events have been observed.

Tremor-Dominant Parkinson Disease

The three 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 individuals can change subtypes as the disease progresses.

Treatment

Dopaminergic therapy (i.e., levodopa or a dopamine agonist) is the first-line treatment for PD, which improves tremor. Amantadine and anticholinergics (e.g., trihexyphenidyl) can also be considered as initial treatment for tremor-dominant PD or as add-on therapy in individuals who have persistent tremor despite dopaminergic therapy. For medication-refractory individuals, 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

Magnetic resonance-guided focused ultrasound (MRgFUS) is a noninvasive treatment that combines two 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 (i.e., 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 US Food and Drug Administration (FDA) approved the ExAblate MRgFUS system (InSightec) for four indications: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone, medication refractory ET, and tremor-dominant PD. The

ultrasound equipment is specially designed to be compatible with magnetic resonance magnets and 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 treatment of other tumors, including breast, prostate, brain, and desmoid tumors as well as nonspinal osteoid osteoma.

Summary of Evidence

For individuals who have uterine fibroids who receive MRgFUS, the evidence includes systematic reviews, two randomized controlled trials (RCTs), nonrandomized comparative studies, and case series. The 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 one year. The second RCT (N=49) had preliminary results at six weeks posttreatment, comparing MRgFUS with uterine artery embolization (UAE), and demonstrated that the two groups are comparable in medication use and symptom improvement following treatments. Individuals in the MRgFUS group reported recovering significantly faster than individuals in the uterine artery embolization group, as measured by time to return to work and time to normal activities. Long-term follow-up results reported that there was lower reintervention rate and greater improvement in symptoms after UAE compared to MRgFUS. A 2021 meta-analysis reported that, comparatively, myomectomy had the lowest re-intervention rate of the 3 regimens (myomectomy vs UAE vs MRgFUS) in all time points assessed, while the MRgFUS had the highest re-intervention rate. Long-term data on the treatment effects, recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with metastatic bone cancer who failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a sham-controlled randomized trial, a systematic review of RCTs, observational studies, and case series. The 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 reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. A substantial proportion of individuals in the treatment group experienced adverse events but most events were transient and not severe. Pooled efficacy data from a systematic review reported a treatment response to MRgFUS of 79%. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with other tumors (e.g., breast cancer, brain cancer, prostate cancer, desmoid tumors, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes nonrandomized, uncontrolled phase II trials and several case series. The relevant outcomes are symptoms, health status measures, and treatment-related morbidity. A nonrandomized, uncontrolled phase II trial evaluating MRgFUS for prostate cancer reported a 93% success rate at five months and an 86% success rate at two years. Another nonrandomized, phase II trial in individuals with prostate cancer reported that at 24 months, 88% (78 out of 89) of individuals had no evidence of grade group 2 or higher prostate cancer in the treated area. Use of MRgFUS for the treatment of nonspinal osteoid osteoma consists of several larger case series, including a propensity score-matched retrospective study that reported similar reductions in pain with radiofrequency ablation and MRgFUS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes a technology assessment, meta-analyses, and a double-blind, sham-controlled randomized trial. The 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. One meta-analysis reported significant improvements in hand tremor scores from baseline up to 24 months post-treatment, with evidence of a diminishing treatment benefit over time. Another meta-analysis found similar improvements in tremor severity with MRgFUS to unilateral DBS, but improvements in both were inferior to bilateral DBS. The sham-controlled randomized trial found significant improvements in the treatment group in tremor severity, functional improvement, and quality of life after three months of follow-up. The improvements in hand tremor score, function, and quality of life were maintained at the two-year follow-up. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with medicine-refractory tremor dominant Parkinson disease (PD) who receive MRgFUS, the evidence includes a pilot RCT. The relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The double-blind, sham-controlled, pilot randomized trial (N=27) found significant improvements in the treatment group

in tremor severity after three months of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01473485[a]	A Study to Evaluate the Safety and Feasibility of Transcranial MRI-Guided Focused Ultrasound Surgery in the Treatment of Brain Tumors	10	Dec 2022
NCT03998657	A Continued Access Study to Evaluate Focal MR-Guided Focused Ultrasound Treatment of Localized Intermediate Risk Prostate Lesions	14	Dec 2022
NCT02923011	Phase III Study to Compare the Effectiveness of Magnetic Resonance Guided Focused Ultrasound With Computed Tomography Guided Radiofrequency Ablation for Treatment of Osteoid Osteomas	56	Dec 2024
NCT03948789	Multicenter, Randomized Phase III Study of MR-Guided Focused Ultrasound Surgery for the Treatment of Uterine Fibroids (MRgFUS TUF) Compared to Myomectomy in Symptomatic Medication and Not Sufficiently Treatable Uterine Fibroids	127	Jun 2025
NCT03100474[a]	Global Registry: ExAblate 4000 Transcranial MR Guided Focused Ultrasound (TcMRgFUS) of Neurological Disorders	500	Jan 2024
NCT02252380[a]	A Feasibility Clinical Trial of the Magnetic Resonance Guided Focused Ultrasound (MRgFUS) for the Management of Treatment-Refractory Movement Disorders	10	Dec 2023
Unpublished			
NCT02260752	Comparing Options for Management: Patient Centered Results for Uterine Fibroids	3,094	Apr 2020

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01833806[a]	A Phase IV Post Approval Clinical Study of ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain	32	Jan 2022
NCT01285960[a]	A Clinical Study to Evaluate Safety of the ExAblate Model 2100 Type 1.1 System in the Treatment of Symptomatic Uterine Fibroids	108	Apr 2016 (completed)
NCT01620359[a]	Study of ExAblate Focused Ultrasound Ablation of Breast Cancer under MR Guidance and MRI Evaluation of Ablation	14	Jul 2016 (completed)
NCT02794558[a]	A Clinical Study to Evaluate the Safety and Effectiveness of MR Guided Focused Ultrasound Surgery in the Treatment of Early Breast Carcinomas	100	Mar 2019

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology

In 2018, the American College of Radiology published appropriateness criteria for the radiological management of uterine leiomyomas (fibroids).[35] The clinical guidance states that "MR-guided high-intensity focused US [ultrasound] (MRgFUS) is another uterine-sparing option to treat focal leiomyomas. It is noninvasive, though each treatment may take several hours to complete. Its use currently is restricted to patients with fewer than six leiomyomas or leiomyoma volume < 900 cm^3," and "although a reasonable alternative for patients unable or unwilling to tolerate sedation or anesthesia, long-term data and viability results are still lacking."

These appropriateness criteria were most recently updated in 2023, with evidence summaries provided for each reviewed clinical scenario.[36] **Table 2** summarizes the appropriateness category for specific populations with uterine fibroids.

Table 2. ACR Appropriateness Criteria: Management of Uterine Fibroids

Clinical situation	MRgFUS Appropriateness Category[a]
Reproductive age patient with uterine fibroids, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms), and a desire to preserve fertility. Initial therapy.	Usually appropriate
Reproductive age patient with uterine fibroids, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bowel, or bladder symptoms), and no desire for future fertility. Initial therapy.	Usually appropriate
Reproductive age patient with uterine fibroids and concurrent adenomyosis, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms), and no desire for future fertility. Initial therapy.	Usually not appropriate
Reproductive age patient with pedunculated submucosal uterine fibroids, symptomatic with heavy uterine bleeding. Initial therapy.	May be appropriate
Postmenopausal patient with uterine fibroids, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms). Negative endometrial biopsy. Next step.	Usually not appropriate
Reproductive age patient with uterine fibroids desiring pregnancy and experiencing reproductive dysfunction. Initial therapy.	May be appropriate

ACR: American College of Radiology; MRgFUS: magnetic resonance-guided focused ultrasound. [a]Usually appropriate: the imaging procedure or treatment is indicated in teh specified clinical scenarios at a favorable risk-benefit ratio for patients; May be appropriate: The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal; Usually not appropriate: The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

American Society for Radiation Oncology et al

In 2017, the American Society for Radiation Oncology (ASTRO) published guidelines on palliative radiotherapy for bone metastases, which stated that external-beam radiotherapy continues to be the primary therapy for treating painful uncomplicated bone metastases.[37] The guidelines did not mention MRgFUS. If patients experience persistent or recurrent pain more than one month

after initial treatment, the guidelines recommended retreatment with external-beam radiotherapy. As for advanced radiotherapy such as stereotactic body radiotherapy for retreatment of recurrent pain in spine bone lesions, these "may be feasible, effective, and safe, but the panel recommends that this approach should be limited to clinical trial participation or on a registry given limited data supporting routine use."

In 2022, the American Urological Association (AUA)/ ASTRO published guidance on the management of clinically localized prostate cancer.[38] The guidance states that "there is a lack of data to date to support the use of whole gland or focal ablation for the treatment of clinically localized prostate cancer."

National Comprehensive Cancer Network

Guidelines from the National Comprehensive Cancer Network (NCCN) on bone cancer (v.2.2024),[39] breast cancer (v.2.2024),[40] brain cancer (v.1.2023),[41] do not mention magnetic resonance-guided ultrasound as a treatment option.

The NCCN guideline for prostate cancer (v.3.2024) states that "Cryotherapy or other local therapies are not recommended as routine primary therapy for localized prostate cancer due to lack of long-term data comparing these treatments to radiation. At this time, the panel recommends only cryosurgery and high-intensity focused ultrasound (HIFU; category 2B) as local therapy options for RT [radiotherapy] recurrence in the absence of metastatic disease". [42]

National Institute for Health and Care Excellence

Guidance from the NICE (2018) on unilateral MRgFUS for treatment-resistant essential tremor states "the evidence on the safety of unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor raises no major safety concerns. However, current evidence on its efficacy is limited in quantity. Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research."[43]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In October 2004, the ExAblate 2000 System (InSightec) was approved by 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 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 postapproval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

In July 2016, FDA approved the use of the ExAblate Neuro System for the treatment of ET in patients who have not responded to medication (β-blockers or anticonvulsant drugs) through the premarket approval process. In December 2018, the FDA approved the use of the ExAblate Model 4000 (Neuro) for the treatment of tremor-dominant PD with medication-refractory tremor through the premarket approval process.

In November 2021, the FDA approved the use of the Exablate Prostate System for prostate tissue ablation through the premarket approval process.

FDA product codes: NRZ, POH, PLP.

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History

Date	Comments
09/14/04	Add to OB/GYN Section - New Policy
08/09/05	Replace Policy - Policy updated with June 2005 TEC Assessment; references added; policy statement unchanged.
06/23/06	Update Scope and Disclaimer - No other changes.
09/12/06	Replace Policy - Policy updated with literature review; title expanded to include, "and Other Tumors" reflecting indications other than uterine fibroids; "MRI-guided high intensity ultrasound ablation of other tumors…is considered investigational" added to policy statement; references added.
03/13/07	Replace Policy - Policy moved from OB/GYN to Surgery section and assigned a new number (previously BC.4.01.20).
04/08/08	Replace Policy - Policy updated with literature search; no change to the policy statement. References added.
03/10/09	Replace Policy - Policy updated with literature search; no change to the policy statement. Title updated to remove "High-intensity" and "ablation of". References added.
04/13/10	Replace Policy - Policy updated with literature search. Policy statement updated to include palliative treatment of bone metastases added to the investigational statement regarding treatment of conditions other than uterine fibroids. References added.
05/10/11	Replace Policy - Policy updated with literature review through December 2010. Reference numbers 10, 21, 22 and 25 added; other references reordered or removed. No change to policy statements. ICD-10 codes added to policy.

Date	Comments
04/25/12	Replace policy. Policy updated with literature review through December 2011. Reference numbers 7, 8 and 10 added; other references reordered or removed. No change to policy statements.
09/25/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
11/20/12	Code update: CPT codes 19499, 55899 and 58999 added to the policy to support policy information and tumors.
02/15/13	Update Related Policies, add 7.01.548.
04/08/13	Replace policy. Policy updated with literature review. Policy changed to single investigational statement; no change to intent of policy. Policy title changed to MRI-Guided Focused Ultrasound (MRgFUS). References 10 and 17 added; other references renumbered or removed. CPT code 58999 corrected; it previously appeared as 55899, which is not the correct code.
05/05/14	Annual Review. Policy updated with literature review through January 6, 2014; references 2, 6, and 14 added; other references renumbered or removed. Coding update: add CPT code 55899 and remove 55999 (wrong code); update descriptor for 58999.
04/14/15	Annual Review. Policy updated with literature review through January 6, 2015. Statement added that MRgFUS may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer. (Previously considered Investigational). References 12, 21-22 added; others renumbered or removed. Policy statement changed as noted.
08/25/15	Update Related Policies. Remove 7.01.548 as it was archived and add 8.01.61.
05/01/16	Annual Review, approved April 12, 2016. Policy updated with literature review through December 15, 2015; references 2 and 23 added. Policy coverage unchanged. Global change to policy to remove "imaging" (e.g., title, policy statement) to standardize terminology to magnetic resonance–guided focused ultrasound (MRgFUS). Coding update; CPT codes 47999 and 55899 removed from policy; these are moving to review by AIM.
06/24/16	Minor update. Removed codes 77299 and 77499 from information in the coding section that discusses radiation oncology unlisted codes. Correction to 05/01/16 History note: AIM is not reviewing 47999 and 55899.
09/30/16	Coding update. Added CPT code 55899.
11/08/16	Minor update. Language added to Rationale section to indicate that MRgFUS is considered medically necessary only in those age 18 and older based on randomized controlled trials.
07/01/17	Annual Review, approved June 22, 2017. Policy moved into new format. Reference to policy 8.01.61 added for prostate cancer diagnosis. No changes to policy statement.

Date	Comments
09/01/17	Interim review, approved August 22, 2017. Policy updated with literature review through June 2, 2017; references 2, 12, 18, 23, and 27-29 added. Removed CPT code 19499. Policy statements unchanged.
10/01/18	Annual Review, approved September 11, 2018. Policy updated with literature review through May 2018; references 23-26 and 28 added. A policy statement added that MRgFUS ablation may be considered medically necessary for the treatment of medicine-refractory essential tremors. Added CPT codes 0398T, 53899, 55899, and 76999.
05/10/19	Coding update. Added CPT code 58999 to policy (inadvertently removed). Removed verbiage in the coding section that is no longer applicable.
10/01/19	Annual Review, approved September 5, 2019. Policy updated with literature review through May 2019; references on NCCN updated. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
7/1/20	Coding update. Remove CPT codes 0071T & 0072T.
10/01/20	Annual Review, approved September 17, 2020. Policy updated with literature review through May 2020; no references added. Policy statements unchanged.
08/01/21	Coding update. Added CPT codes 0071T & 0072T.
10/01/21	Annual Review, approved September 14, 2021. Policy updated with literature review through May 24, 2021; references added. Added policy statement that l MRgFUS for treatment of tremor-dominant Parkinson disease is considered investigational.
09/01/22	Annual Review, approved August 22, 2022. Policy updated with literature review through June 3, 2022; references added. Policy statements unchanged.
10/01/23	Annual Review, approved September 11, 2023. Policy updated with literature review through May 22, 2023; references added. Policy statements unchanged. Updated title to Magnetic Resonance Imaging-Guided Focused Ultrasound. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/01/24	Annual Review, approved September 9, 2024. Policy updated with literature review through May 15, 2024; references added. Policy statements unchanged.
01/01/25	Coding update. Added new CPT codes 51721, 55881, 55882 and 61715 and removed termed CPT code 0398T.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and

local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.