BlueCross BlueShield of Alabama

Name of the Blue Advantage Policy:

Magnetic Resonance Guided Focused Ultrasound (MRgFUS)

Policy #: 178
Latest Review Date: August 2024
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service on or after September 16, 2024:

For **magnetic resonance-guided high-intensity ultrasound ablation for the treatment of medicine-refractory essential tremors**, refer to **L37761/A56690**.

Blue Advantage will treat **magnetic resonance-guided high-intensity ultrasound ablation** as a **covered benefit** for pain palliation in adults with metastatic bone cancer who have failed or are not candidates for radiotherapy.

Blue Advantage will treat **high-intensity focused ultrasound (HIFU)** as a **covered benefit** for:

- Initial treatment of localized prostate cancer.
- Treatment for recurrent local prostate cancer following failure of radiation therapy.

Blue Advantage will treat **magnetic resonance imaging (MRI)-guided high-intensity ultrasound ablation** as a **non-covered benefit** and **investigational for all other situations, including but not limited to:**

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

Blue Advantage will treat **transurethral ultrasound ablation of the prostate (TULSA)** as a **non-covered benefit** and as **investigational. This includes, but is not limited to, its use in the following situations:**

- Treatment of prostate cancer.
- Treatment of benign prostatic hypertrophy (BPH).

For coverage information regarding radiofrequency ablation of bone tumors, refer to medical policy #119-** ***Radiofrequency Ablation of Solid Tumors Excluding Liver Tumors.

For coverage information regarding cryosurgical ablation of bone tumors, refer to medical policy #429-** ***Cryosurgical Ablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors.

For dates of service prior to September 16, 2024:

For **magnetic resonance-guided high-intensity ultrasound ablation for the treatment of medicine-refractory essential tremors**, refer to **L37761/A56690**.

Blue Advantage will treat **magnetic resonance-guided high-intensity ultrasound ablation** as a **covered benefit** for pain palliation in adults with metastatic bone cancer who have failed or are not candidates for radiotherapy.

Blue Advantage will treat **magnetic resonance imaging (MRI)-guided high-intensity ultrasound ablation** as a **non-covered benefit** and **investigational for all other situations, including but not limited to:**

- Treatment of uterine fibroids;

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

Blue Advantage will treat **transurethral ultrasound ablation of the prostate (TULSA)** as a **non-covered benefit** and as **investigational. This includes, but is not limited to, its use in the following situations:**

- Treatment of prostate cancer.
- Treatment of benign prostatic hypertrophy (BPH).

For coverage information regarding radiofrequency ablation of bone tumors, refer to medical policy #119-** ***Radiofrequency Ablation of Solid Tumors Excluding Liver Tumors.

For coverage information regarding cryosurgical ablation of bone tumors, refer to medical policy #429-** ***Cryosurgical Ablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors.

For coverage information regarding focal treatments of the prostate, refer to medical policy 596-** ***Focal Treatments for Prostate Cancer.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in their reproductive years. African American women have a greater lifetime incidence of uterine fibroids compared to other racial groups. 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 treatment.

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 patients who do not respond to these treatments, the standard care is to use external beam radiotherapy. However, a substantial proportion of patients have residual pain after radiotherapy.

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 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 (beta-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.

Magnetic Resonance-Guided Focused Ultrasound
MRgFUS is a noninvasive treatment that combines two technologies, focused ultrasound and MRI. 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 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 approximately 65°C to 85°C), which is sufficient to achieve tissue ablation at the focal point. In addition to providing guidance, the associated MRI can provide online 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 for two indications: treatment of uterine fibroids 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 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, and brain tumors.

KEY POINTS:

The most recent literature search was performed through May 15, 2024.

Summary of Evidence

For individuals who have uterine fibroids who receive magnetic resonance-guided focused ultrasound (MRgFUS), the evidence includes 2 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); had preliminary results at 6 weeks posttreatment, comparing MRgFUS with uterine artery embolization (UAE), and demonstrated 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 (UAE) 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 have failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a randomized trial, a systematic review of RCTs and observational studies, and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found 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. 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 (eg, breast cancer, brain cancer, prostate cancer, desmoid, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes nonrandomized, uncontrolled phase II trials and several case series. 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 5 months and an 86% success rate at 2 years. Another nonrandomized, phase II trial in patients with prostate cancer reported that at 24 months, 88% (78 out of 89) of patients had no evidence of grade group 2 or higher prostate cancer in the treated area. The 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 medication-refractory essential tremors who receive MRgFUS, the evidence includes a technology assessment, meta-analyses, and a double-blind, sham-controlled randomized trial. 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 deep brain stimulation (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 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 an improvement in the net health outcome.

For individuals with medicine-refractory tremor dominant Parkinson's disease (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 (N=27) 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.

Practice Guidelines and Position Statements
American College of Radiology
In 2018, The American College of Radiology published appropriateness Criteria for the radiological management of uterine leiomyomas (fibroids). The clinical guidance states that "MR[magnetic resonance]-guided high-intensity focused US [ultrasound] (MRgFUS) is another uterine-sparing option to treat focal leiomyomas. It is non-invasive, 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 cm3," 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. Table 1 summarizes the appropriateness category for specific populations with uterine fibroids.

Table 1. ACR Appropriateness Criteria: Management of Uterine Fibroids

Clinical situation	MRgFUS Appropriateness Category
Reproductive age patient with uterine fibroids, symptomatic with heavy uterine bleeding or bulk symptoms (eg, 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 (eg, 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 (eg, 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 (eg, 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.

Usually appropriate: the imaging procedure or treatment is indicated in the 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
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. The guidelines did not mention magnetic resonance-guided focused ultrasound. If patients experience persistent or recurrent pain more than 1 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. The guidelines state 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), breast cancer (2.2024), brain cancer (v.1.2023), do not mention magnetic resonance-guided ultrasound as a treatment option. The NCCN guideline for prostate cancer (~~v 3.2024~~) (v 4.2024) 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".

National Institute for Health and Care Excellence
Guidance from NICE (2018) on unilateral magnetic resonance-guided ultrasound for treatment-resistant essential tremor states "The evidence on the safety of unilateral MRI [magnetic resonance imaging]-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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Fibroids, ultrasound ablation, MRI-guidance, ultrasound ablation of uterine fibroids, ExAblate 2000, high-intensity ultrasound ablation; uterine, leiomyoma; uterine; high-intensity ultrasound ablation (HIFU), ExAblate, ultrasound ablation of breast tumors, ultrasound ablation of brain tumors, ultrasound ablation of prostate cancer, ultrasound ablation of bone metastasis, transrectal high intensity focused ultrasound for prostate cancer, Ablatherm, Sonablate 500; MRgFUS, essential tremors, TULSA, TULSA-PRO, Transurethral Ultrasound Ablation of the Prostate

APPROVED BY GOVERNING BODIES:

In October 2004, the U.S. Food and Drug Administration (FDA) approved via the premarket application (PMA) process, the ExAblate 2000 System (Insightec, Inc., Haifa, Israel) 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 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 radiation therapy. 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 essential tremors in patients who have not responded to medication (beta-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 tremors 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.

BENEFIT APPLICATION:

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

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
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume of 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
20999	Unlisted procedure, musculoskeletal system, general

There is no specific code for MRgFUS in reference to bone cancer. This code may come in on unlisted code 20999 along with the appropriate radiology guidance code.
These CPT codes should not be used in conjunction with 51702 (insertion of temporary indwelling bladder catheter, simple) or 77022 (magnetic resonance imaging guidance for, and

monitoring of, visceral tissue ablation). Prior to the introduction of the above codes, the procedure may have been coded for using several codes describing the individual components of the procedure. CPT codes 0071T-0072T describe the comprehensive service.

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, June 2006
Medical Policy Group, August 2006
Available for comment August 30-October 13, 2006
Medical Policy Group, August 2007
Medical Policy Group, October 2007
Medical Policy Group, April 2009
Medical Policy Group, February 2010
Available for comment February 23-April 8, 2010
Medical Policy Group, March 2011
Available for comment April 4 – May 18, 2011
Medical Policy Group March 2012
Medical Policy Group, May 2013
Available for comment May 22 through July 5, 2013
Medical Policy Group, February 2014
Medical Policy Group, April 2015
Medical Policy Group, December 2015
Medical Policy Group, February 2016
Medical Policy Group, July 2017
Medical Policy Group, February 2018
Medical Policy Group, September 2020: Reinstated effective March 24, 2020. Refer to LCD L34555 for dates of service from February 26, 2018 and prior to March 24, 2020. L34555 (Non-Covered Category III CPT Codes) retired effective March 23, 2020.
Medical Policy Group, November 2020: 2021 Annual Coding Update. Added CPT code 55880 to the Current Coding section.). Updated policy statement to include: Transurethral Ultrasound Ablation of the Prostate (TULSA) is considered investigational. This includes, but is not limited to its use in the following situations: Treatment of prostate cancer and Treatment of benign prostatic hypertrophy (BPH).
Medical Policy Group, July 2021
Medical Policy Group, July 2022
Medical Policy Group, July 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, August 2024: Added coverage statement for high-intensity focused ultrasound. On draft and open for comment August 15, 2024, through September 15, 2024.
UM Committee, August 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review)in Blue Cross and Blue Shield's administration of plan contracts.