CLINICAL MEDICAL POLICY	
Policy Name:	Magnetic Resonance-Guided Focused Ultrasound (MRgFUS)
Policy Number:	MP-094-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	03/01/2025; 06/01/2024; 03/01/2023; 05/01/2022; 03/19/2021; 04/20/2020; 05/06/2019
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Next Annual Review:	01/2026
Revision Date:	01/15/2025; 01/17/2024; 01/18/2023; 01/19/2022; 01/20/2021; 01/15/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
04/01/2025	Provider Effective date
02/07/2025	PARP Approval
01/15/2025	QI/UM Committee review
01/15/2025	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
07/01/2024	Provider Effective date
05/13/2024	PARP Approval
01/17/2024	QI/UM Committee review
01/17/2024	Annual Review: No changes to clinical stance. Updated 'Summary of Literature,' 'Governing Bodies Approval' and 'Reference Sources' sections.
04/01/2023	Provider Effective date
02/14/2023	PARP Approval
01/18/2023	QI/UM Committee review
01/18/2023	Annual Review: No changes to clinical stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
06/01/2022	Provider Effective date
04/11/2022	PARP Approval
01/19/2022	QI/UM Committee Review

01/19/2022	Annual Review: Updated Summary of Literature and Reference Sources sections. Per DHS recommendation, added Program Exception statement to 'Governing Bodies Approval' section.
01/02/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage under the medical-surgical benefits of the Company's Medicaid products for Magnetic Resonance (MRI)-Guided Focused Ultrasound (MRgFUS) for any indication.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval, and denial of all PH-MCO Prior Authorization policies and procedures.

Essential Tremors (ET) - A chronic, incurable condition with unknown cause, characterized by involuntary, rhythmic tremor of a body part, most typically the hands and arms.

Uterine Fibroids (also called leiomyomata or myomas) - Benign tumors of the myometrium, the smooth muscle layer of the uterus.

Procedures

1. Magnetic Resonance (MR)-Guided Focused Ultrasound (MRgFUS) is considered experimental/investigational and not medically necessary for all indications, including but not limited to, treatment of the following indications:
    - Medicine-refractory essential tremors
    - Uterine fibroids
    - All tumors, including but not limited to, brain, breast, prostate, and/or renal
    - Bone metastases for palliation of pain

    Note: Approval for MRgFUS may be reviewed on a case-by-case basis by a Medical Director, and would require a Program Exception. The request must include supporting statement indicating why the request is medically necessary, and that all other options are likely to be ineffective.

2. Post-payment Audit Statement
    The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

Governing Bodies Approval

MRgFUS was initially FDA-approved for unilateral application in medically-intractable patients with ET as an alternative to thalamotomy and deep brain stimulation. MRgFUS received a second FDA indication in 2021 as a supplement to medication treatment for unilateral pallidotomy in medication-resistant Parkinson's disease patients with moderate to severe motor complications. In December 2022, MRgFUS received a third FDA indication (and second in ET) for staged, bilateral treatment of medication-refractory essential tremor, permitting contralateral treatment at least nine months after initial therapy in patients with bilateral tremors from ET (Penn Medicine, 2023).

There are several devices that have received U.S. FDA approval via De Novo and Premarket Application (PMA) processes:

- The ExAblate® 2000 System (InSightec, Inc.) was approved for two indications: “ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure” and for palliation of pain associated with tumors metastatic to bone.
- The ExAblate® 2100 System also received approval through the PMA process. Approval remains limited to treatment of patients with metastatic bone cancer who failed or are not candidates for radiation therapy or in patients with symptomatic uterine fibroids with a uterine size of less than 24 weeks and those who have completed childbearing.
- In October 2012, the FDA approved the ExAblate® System, Model 2000/2100/2100 VI for pain palliation via the PMA process. For pain palliation, the intended use of the device is 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, but the FDA required a post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.
- The Sonablate® 450 (SonaCare Medical) is the first high-intensity ultrasound system for prostate tissue ablation to receive FDA approval, and therefore underwent the de novo application process, obtaining clearance in 2015.

- Shortly thereafter, Ablatherm Integrated Imaging® (EDAP TMS) received PMA approval.
- The ExAblate® Neuro System for the treatment of essential tremors in patients who have not responded to medication (beta blockers or anticonvulsants) through the premarket approval process.

CMS
The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- Local Coverage Determination (LCD) Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L38495)
- Local Coverage Article (LCA) Billing and Coding: Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (A57839)

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

The TAG workgroup has assigned Magnetic Resonance (MR)-Guided Focused Ultrasound an Option # 4, specifically for CPT codes 0398T, 0071T, and 0072T.

Program Exception
MRgFUS may be reviewed for approval on a case-by-case basis. The ordering physician must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

Summary of Literature

Magnetic Resonance-Guided Focused Ultrasound (MRgFUS) is a noninvasive treatment that combines focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through the soft tissues, and the beam can be focused on targeted sites. This causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. Broadly, the MRgFUS uses an integrated imaging system to take measurements, confirm the treatment area, and monitor thermal destruction in real time. The procedure is proposed as a less invasive approach, rather than surgery, for the treatment of localized tumors (e.g., prostate cancer), uterine fibroids, pain palliation on bone metastases, and medicine-refractory essential tremors (ET).

Essential Tremors
The MRgFUS thalamotomy may be indicated for patients with medically refractory ET. MRgFUS creates a thalamic lesion which can reduce tremor but can also result in permanent neurologic deficits. While creation of a lesion does reduce tremor, and larger lesions can result in more enduring efficacy, larger lesions have a higher incidence of side effects. In July 2016, MRgFUS (i.e., ExAblate Neuro) was FDA-

approved for patients with severe, chronic, and medically intractable ET as an alternative to deep brain stimulation or surgical interventions (e.g., thalamotomy and pallidotomy) (InSightec, Inc., Dallas, TX). Preliminary uncontrolled studies have shown improvement compared with baseline scores for contralateral hand tremor, disability, and quality of life. However, large, randomized, controlled trials are needed to determine the proper patient populations that may benefit from this therapy and assess the long-term efficacy and safety of MRgFUS for this indication. Adverse effects included transient sensory and cerebellar symptoms, and persistent paresthesia (Elias, 2016).

According to Tarsy et al. (2018), unilateral thalamotomy with MRgFUS is a newer technique that may be a reasonable alternative for treating contralateral limb tremor associated with ET. This is the only form of thalamotomy approved for ET by the U.S. Food and Drug Administration (FDA), although long-term studies are currently lacking.

Surgical treatment of ET should be considered a viable option in patients who have had adequate trials of at least two first-line therapies. Surgical options currently include deep brain stimulation and unilateral thalamotomy for patients who have undergone a multidisciplinary team evaluation at a specialized center. Unilateral thalamotomy with MRgFUS may be a reasonable alternative if deep brain stimulation is not practical. However, it is noted that long-term studies are currently lacking (UpToDate, 2021).

A 5-year, single center experience was documented regarding MRgFUS thalamotomy treatment for ETs. Forty-four ET patients treated with unilateral MRgFUS ventral intermediate nucleus (VIM) thalamotomy were assessed using the Clinical Rating Scale for Tremor (CRST) score and the Quality of Life in Essential Tremor Questionnaire (QUEST). The results showed that tremor was significantly improved immediately following MRgFUS in all patients and ceased completely in 24 patients. CRST scores in the treated hand at baseline improved by a median of 16 at 1 month, 17 at 6 months, 15 at 1 year, 18 at 2 years, 19 at 3 years, 21 at 4 years, and 23 at 5 years. Return of tremor that impacted activities of daily living was reported in 5 patients. MRgFUS thalamotomy for ET is an effective and safe procedure that provides long-term tremor relief and improvement in quality of life even in patients with medication-resistant disabling tremor. However, additional studies with a larger group of patients is needed to substantiate these favorable results (Sinai, et al., 2019).

In an initial pilot investigation, Bond and associates (2017) evaluated the safety and efficacy of focused ultrasound thalamotomy for the treatment of medically refractory, tremor-dominant Parkinson disease (TDPD). The investigation concluded MRgFUS as a promising new treatment approach for ET, but additional long-term effectiveness and safety data were needed to make a conclusion.

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. Several approaches currently available to treat symptomatic uterine fibroids include hysterectomy, abdominal myomectomy, laparoscopic and hysteroscopy myomectomy, hormone therapy, uterine artery embolization, and watchful waiting. Hysterectomies and various myomectomy procedures are considered the standard treatment. All current surgical treatments are invasive, and all treatments have limitations. MRgFUS is indicated to ablate uterine fibroid tissue in premenopausal or perimenopausal women with symptomatic uterine fibroids who desire a uterine-sparing procedure and whose uterine size is less than 24 weeks gestation size.

In 2015, the Society of Obstetricians and Gynaecologists of Canada (SOGC) published practice guidelines on the management of uterine fibroids in women with otherwise unexplained infertility. The guidelines found no studies comparing MRgFUS with myomectomy or in women with fibroids who have infertility as their primary complaint, and thus additional data would be needed before the treatment could be offered to this patient population (SOGC, 2015).

The Agency for Healthcare Research and Quality (AHRQ) issued a comparative effectiveness review on management of uterine fibroids. The review noted that hysterectomy and myomectomy by a variety of routes are frequently used for the management of symptomatic fibroids. However, the range of fibroid-specific treatments including interventions like extended medical management with ulipristal acetate, MRgFUS, uterine artery embolization, radiofrequency volumetric thermal ablation, and techniques for myolysis are increasingly generating comparative effectiveness data. As the literature evolves, including larger studies of stronger design with longer follow-up, a clearer picture of anticipated outcomes is likely to emerge (AHRQ, 2017).

A 2020 study was conducted in regard to MRgFUS as treatment for symptomatic uterine fibroids. This study explored the experiences after treatment of 339 patients, and included patients with symptomatic uterine fibroids who qualified for and were treated with MRgFUS using the ExAblate 2100 UF V2 between 2012 and 2017. Associations of patient-related characteristics and primary success (defined as non-perfused volume (NPV) above 80%) and association of NPV and symptom control were analyzed. The report found that a careful selection process is key for successful treatment of uterine fibroids with MRgFUS. Although the study's results are important for daily practice, prospective studies are needed to develop more robust selection scores (Wilms, et al., 2020).

Palliative Treatment of Bone Metastases

In 2011, the American Society for Radiation Oncology (ASTRO) published guidelines on palliative radiotherapy for bone metastases, which states that external-beam radiotherapy continues to be the primary therapy for treating painful uncomplicated bone metastases. The guidelines did not mention MRgFUS and did not offer specific recommendations for patients who fail or are not candidates for radiotherapy (ASTRO, 2017).

Image-guided ablation of skeletal metastases has an advantage of being completely noninvasive, however, drawbacks include the high cost of the equipment, inability to treat claustrophobic patients, or for patients in which MRI is contraindicated. Overall, this treatment has shown to be effective for palliation of symptomatic skeletal metastases. However, there are no randomized trials comparing MRgFUS with other ablative treatments (ASTRO, 2017).

Other Tumors

MRI-guided high-intensity focused ultrasound (MRgFUS) ablation is also being studied as a treatment of other tumors including breast, prostate, brain, and desmoid tumors.

Only small case series have been published on the safety and/or efficacy of MRgFUS for treating tumors related to breast cancer, brain cancer, prostate cancer, and nonspinal osteoid osteoma. Randomized controlled trials are needed to evaluate the long-term efficacy and safety of MRgFUS for these indications.

The most recent case series on the use of MRgFUS for breast cancer ablation was published in 2016 (Merckel, 2016). Ten patients with early-stage invasive breast cancer underwent MRgFUS prior to surgical resection. Ablation was confirmed histopathologically in six of these patients. It was concluded that

MRgFUS is safe and feasible with a noted limitation of long procedure times (average, 145 minutes), due to waiting time after contrast injection and time to find a proper magnetic resonance navigator signal. The evidence is insufficient for the treatment of tumors, to determine the effects of the technology on net health outcomes.

Coding Requirements

Non-Covered Procedure Codes
These procedure codes will not be reimbursed without Medical Director approval.

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

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

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