

NO. 91601

HIGH INTENSITY FOCUSED ULTRASOUND

Effective: 06/01/2026**Committee Review:** 05/2026**Last Updated:** 05/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy establishes medical necessity criteria for high-intensity focused ultrasound (HIFU), including magnetic resonance-guided focused ultrasound (MRgFUS)

Related policies:

- Electrophysiology Testing & Catheter Ablation for Cardiac Arrhythmias # 91314
- Uterine Fibroid Treatment # 91573

I. MEDICAL NECESSITY CRITERIA

- A. High intensity focused ultrasound (HIFU), including magnetic resonance-guided focused ultrasound (MRgFUS), is experimental and investigational for the following indications because of insufficient evidence of its long term effectiveness (not an all-inclusive list):
1. Atrial fibrillation (See Electrophysiology Testing & Catheter Ablation for Cardiac Arrhythmias medical policy # 91314)
 2. Benign prostatic hypertrophy
 3. Central nervous system diseases/disorders (e.g., brain cancer and stroke)
 4. Fractures

5. Liver metastasis from colon and stomach cancer
 6. Osteosarcoma/bone tumors
 7. Palliation of bone metastases
 8. Pancreatic cancer
 9. Primary liver cancer
 10. Prostate cancer, primary therapy
 11. Renal cancer
 12. Thyroid nodules
 13. Vulvar dystrophy
- B. Magnetic resonance-guided focused ultrasound (MRgFUS) is medically necessary for the following indications when InterQual criteria are met:
1. Medication refractory essential tremor
 2. Medication refractory, tremor-dominant Parkinson's disease
- C. HIFU as secondary local therapy for recurrent prostate cancer after definitive radiotherapy, in the absence of metastatic disease, may be medically necessary according to NCCN guidelines.
- D. Other local therapies for the treatment of prostate cancer, including vascular targeted photodynamic therapy (VTP) are experimental and investigational.

For MRI-guided ultrasound ablation of uterine fibroids, see medical policy Uterine Fibroid Treatment #91573.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the [CMS Online Manual System \(IOMs\)](#) and Transmittals.

For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to [CMS Medicare Coverage Database](#).

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare [Coverage Database website](#) for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	LCD - Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L38506)

National Government Services, Inc.	LCD - Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Tremor (L37421)
Noridian Healthcare Solutions	LCD - Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor and Tremor Dominant Parkinson's Disease (L37729)
Novitas Solutions, Inc.	LCD - Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L38495)
Palmetto GBA	LCD - Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor (L37761)
WPS Insurance Corporation	None identified

III. BACKGROUND

High-intensity focused ultrasound (HIFU)

High-intensity focused ultrasound (HIFU) uses externally generated sonic waves to create a sharply delineated area of thermal energy that destroys the target tissue. In contrast to traditional ultrasound, which is mainly used for imaging and diagnostics, HIFU focuses high-energy sonic waves at a single point, leading to rapid temperature elevation in the targeted tissue (Hayes, 2023). Ultrasoundguided HIFU can be used for salvage treatment in patients with localized recurrence of prostate cancer after external beam radiotherapy or radical prostatectomy. HIFU can be used to thermally ablate either the entire prostate gland or the cancer-containing part of the gland, with the goal of achieving complete tumor control to improve survival. The role of ablation with HIFU as an alternative to radical prostatectomy or radiation therapy remains uncertain.

The French Urological Association initiated a prospective IDEAL multi-institutional study (2009-2015), to evaluate HIFU-hemiablation to evaluate the ability of HIFU to achieve local control of the tumor in patients with unilateral localized prostate cancer (Rischmann, 2017). The authors found at 1 year, HIFU-hemiablation was efficient with 95% absence of clinically significant cancer associated with low morbidity and preservation of quality of life. Radical treatment-free survival rate was 89% at 2 year.

HIFU also has been studied for treatment of radiation recurrence. Ahmed et al (2012) conducted a registry-based analysis of 430 patients who underwent HIFU. Thirty-nine patients received focal salvage therapy for localized recurrence after external beam radiotherapy. The actuarial progression-free survival rate (including PSA nonresponders) was 69% at 1 year and 49% at 2 years according to Phoenix criteria. Excluding PSA nonresponders, these rates were 74% and 58%, respectively (Phoenix criteria). In a retrospective registry analysis of 150 men who underwent focal salvage HIFU (FS-HIFU) (Sonablate 500), Kanthabalan et al (2017) concluded that focal salvage HIFU conferred a relatively low complication and side effect rate. CEFS and biochemical control in the short to medium term were reasonable, especially in this relatively high-risk cohort, but still low compared with current whole-gland salvage therapies.

Magnetic resonance-guided focused ultrasound (MRgFUS)

Approved by the FDA in July 2016, magnetic resonance imaging-guided focused ultrasound (MRgFUS) thalamotomy is an incisionless transcranial surgical procedure for the treatment of essential tremor (ET) and Parkinson's disease (PD). MRgFUS targets and ablates portions of the thalamus (i.e., thalamotomy), generally the ventral intermediate nucleus (VIM) (i.e., ventralis intermedius), a key brain structure for the regulation of motor signaling and control, among other sensory information (Agarwal and Biagioni, 2023).

In a pilot study, Elias et al (2016), enrolled medication refractory patients with moderate-to-severe essential tremor to undergo unilateral focused ultrasound thalamotomy or a sham procedure. 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 paresthesia or numbness in 38%; these adverse events persisted at 12 months in 9% and 14% of patients, respectively.

Currently, the only FDA approved MRgFUS system for the treatment of ET is the ExAblate Neuro (Insightec). The system integrates with standard magnetic resonance imaging (MRI) systems using a detachable treatment table. MR imaging and thermal mapping are used to plan, guide, and monitor treatment with the device during the procedure. Clinical alternatives to MRgFUS include deep brain stimulation (DBS), radiofrequency ablation, and gamma knife radiosurgery ablation.

The American Academy of Neurology guideline (2011; reaffirmed 2022) for treatment of ET states that thalamotomy is possibly effective; there are no recommendations regarding MRgFUS for treatment of essential tremors. International Essential Tremor Foundation: Essential Tremor in Adult Patients (2021) lists MRgFUS as a later-stage treatment option for medication-refractory patients with comorbidities who are unable to undergo deep brain stimulation. Mortezaie et al (2024) reviewed 43 studies comprising 1818 patients with ET who underwent MRgFUS in a systematic review and meta-analysis of MRgFUS in the treatment of ET. The authors found the mean total Clinical Rating Scale for Tremor (CRST) score significantly decreased at 3-, 6-, and 12-months post-MRgFUS. The mean hand tremor scores significantly mitigated at 3, 6, 12, 24, and 36 months post-MRgFUS. Furthermore, the mean Quality of Life in Essential Tremor Questionnaire scores were improved at 3 months (SMD -2.8, $p = 0.0025$), 6 months (SMD -4.1, $p = 0.04$), 12 months (SMD -1.57, $p = 0.0004$), 2 years (SMD -1.64, $p = 0.0003$), and 3 years (SMD -1.14, $p = 0.08$). The findings showed that sex ($p = 0.03$), unlike age, handedness, symptom duration, and peak energy levels at 3 months, was associated with a significantly higher mean difference in tremor severity.

Parkinson's disease (PD) is a neurodegenerative disorder that includes motor and nonmotor dysfunctions which may manifest clinically as tremors, muscle rigidity, bradykinesia, and postural instability. Tremor-predominant Parkinson's disease is characterized by prominent tremor of one or more limbs with a relative lack of significant rigidity and bradykinesia. Abbas et al (2024) conducted a systematic review of the effect

of MRgFUS pallidotomy on motor complications in PD patients and concluded it was effective, with a significant decrease in the Unified Parkinson's Disease Rating Scale (UPDRS) and the Unified Dyskinesia Rating Scale (UDysRS), reflecting improvement. The incidence of adverse events (headaches, pin-site pain, difficulty walking, and sonication-related head pain) of the FUS pallidotomy was not statistically significant, indicating its safety.

Guidera et al (2024) found that at present, limited data and heterogeneity in outcome reporting challenges comparisons of FUS and radiofrequency pallidotomy efficacy and safety. Available evidence suggests FUS pallidotomy may have broadly similar efficacy and a lower risk of cognitive impairment relative to RF pallidotomy. Standardized reporting of post-lesion outcomes in future studies would improve power and rule out potential confounders of these results

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American College of Radiology (ACR)	ACR Appropriateness Criteria® Management of Uterine Fibroids: 2023 Update
National Comprehensive Cancer Network (NCCN)	Clinical Practice Guidelines in Oncology: Prostate Cancer (2026)
American Society for Stereotactic and Functional Neurosurgery	Position Statement on Magnetic Resonance-Guided Focused Ultrasound for the Management of Essential Tremor (2020)
American Academy of Neurology	Update: Treatment of Essential Tremor (2011)
Health Quality Ontario	Magnetic Resonance-Guided Focused Ultrasound Neurosurgery for Essential Tremor: A Health Technology Assessment (2018)
International Essential Tremor Foundation	Essential Tremor in Adult Patients (Pocket Guide) (2021)
International Parkinson & Movement Disorder Society	Evidence-Based Review of Treatments for Essential Tremor (2019)
National Institute for Health and Care Excellence	Unilateral MRI-guided Focused Ultrasound Thalamotomy for Treatment-resistant Essential Tremor (2018)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See [U.S. Food & Drug Administration \(FDA\) Medical Device Databases](#) for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
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ExAblate Model 4000 Type 1.0 System (ExAblate Neuro) (Insightec Ltd.)	P150038	Original approval: 07/25/2016 Most recent supplement approval (S031): 07/27/2023
Exablate Model 4000 Type 1.0 and 1.1 System (“Exablate Neuro”) (Insightec Ltd.)	P150038 S014	10/29/2021
Exablate 4000 System Type-1 (i.e. Type 1.0/1.1) (Insightec Ltd.)	P150038 S022	12/08/2022

VI. CODING

ICD-10 Codes that may support medical necessity

C61 Malignant neoplasm of prostate
R97.21 Rising PSA following treatment for malignant neoplasm of prostate
Z92.3 Personal history of irradiation

CPT/HCPCS Codes

55880 Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
61715 Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed

Not medically necessary:

0950T Ablation of benign prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
27599 Unlisted procedure, femur or knee
47399 Unlisted procedure, liver
48999 Unlisted procedure, pancreas
50549 Unlisted laparoscopy procedure, renal
55899 Unlisted procedure, male genital system [*when specified as destruction of prostate tissue by high intensity focused ultrasound*]
58999 Unlisted procedure, female genital system (non-obstetrical)
60699 Unlisted procedure, endocrine system
64999 Unlisted procedure, nervous system
76999 Unlisted ultrasound procedure (eg, diagnostic, interventional) -
Explanatory notes must accompany claims billed with unlisted codes

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the [Priority Health Provider Manual](#).

To access Evicore guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

To access InterQual guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

To access EviCore, InterQual, or TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

VIII. APPLICATION TO PRODUCTS

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

- **HMO/EPO:** This policy applies to insured HMO/EPO plans.
- **POS:** This policy applies to insured POS plans.
- **PPO:** This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO:** For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL:** For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN:** For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the [Michigan Medicaid Fee Schedule](#). If there is a discrepancy between this policy and the [Michigan Medicaid Provider Manual](#), the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

General
in criteria section

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SUMMARY OF CHANGES

Clarifications:

- Updated references

Past committee review dates: 10/2012, 10/2013, 08/2014, 08/2015, 05/2016, 05/2017, 05/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023, 05/2024, 05/2025,05/2026

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