Priority Health

MEDICAL POLICY No. 91601-R6

HIGH INTENSITY FOCUSED ULTRASOUND

Effective Date: June 1, 2025

Review Dates: 10/12, 10/13, 8/14, 8/15, 5/16, 5/17, 5/18, 5/19, 5/20, 5/21, 5/22, 5/23, 5/24, 5/25

Date Of Origin: October 10, 2012

Status: Current

Related medical policies:

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

Summary of Changes

Addition:

- I.B - Magnetic resonance-guided focused ultrasound (MRgFUS) is medically necessary for medication refractory essential tremor, and medication refractory, tremor dominant Parkinson's disease when InterQual criteria are met.
- II. New Government Regulations section listing applicable CMS NCDs or LCDs
  - Regions without an applicable LCD will follow NGS criteria for MRgFUS
- III. New FDA/Regulatory section
- V. New Medical/Professional Society Guidelines section

I. POLICY/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:

a. Medication refractory essential tremor
b. 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. GOVERNMENT REGULATIONS:

Centers for Medicare & Medicaid Services (CMS)

A. For services performed in MAC jurisdictions without a LCD, National Government Services, Inc coverage criteria for MRgFUS will be applied.

National Coverage Determinations (NCDs)	Not identified
Local Coverage Determinations	
First Coast Services Options, Inc	Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor: L38506
National Government Services, Inc	Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Tremor: L37421
Noridian Healthcare Solutions	Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor and Tremor Dominant Parkinson's Disease: L37729
Novitas Solutions, Inc.	Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor: L38495
Palmetto GBA	Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor: L37761
WPS	None identified

III. FDA/REGULATORY

Device	PMA Number	Notice Date	Indication
ExAblate Model 4000 Type 1.0 System (ExAblate Neuro) (Insightec Ltd.)	P150038	Original approval: July 25, 2016 Most recent supplement approval (S031): July 27, 2023	"[F]or the unilateral Thalamotomy treatment of idiopathic Essential Tremor patients with medication-refractory tremor. Patients must be at least age 22. The designated area in the brain responsible for the movement disorder symptoms (ventralis intermedius) must be identified and accessible for targeted thermal ablation by the ExAblate device" [capitalization *sic*] (p. 1).
Exablate Model 4000 Type 1.0 and 1.1 System ("Exablate Neuro") (Insightec Ltd.)	P150038 S014	October 29, 2021	"This device is indicated for use: "In the unilateral thalamotomy treatment of idiopathic essential tremor patients with medication refractory tremor. Patients must be at least age 22. The designated area in the brain responsible for the movement disorder symptoms (ventralis intermedius) must be identified and accessible for targeted thermal ablation by the Exablate device. "In the unilateral thalamotomy (ventralis intermedius) treatment of tremor-dominant Parkinson's disease with medication-refractory tremor. Patients must be at least age 30. "In the unilateral pallidotomy of patients with advanced, idiopathic Parkinson's disease with medication-refractory moderate to severe motor complications as an adjunct to Parkinson's disease medication treatment. Patients must be at least age 30. The designated area in the brain responsible for the movement disorder symptoms [globus pallidus (GPi)] must be identified and accessible for targeted thermal ablation by the Exablate device" (p. 1).
Exablate 4000 System Type-1 (i.e. Type 1.0/1.1) (Insightec Ltd.)	P150038 S022	December 8, 2022	"Approval for labeling changes to the indications for use of the device in idiopathic Essential tremor patients with medication-refractory tremor" [capitalization sic].

IV. DESCRIPTION

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). Ultrasound-guided 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 at (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 oof 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. Mortezasie 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.

V. GUIDELINES/POSITION STATEMENTS

High-intensity focused ultrasound (HIFU)	
American College of Radiology (ACR) Appropriateness Criteria®:	The 2017 Work Group's guideline on locally advanced (high-risk) prostate cancer does not mention the use of HIFU in the list of treatment options. The summary states that HIFU is currently an experimental therapy.
American Cancer Society (ACS): 2023	HIFU is mentioned as an ablative treatment for early-stage prostate cancer. The ACS states that new treatments could be used either as the first type of treatment for early-stage prostate cancer that are at low risk or after radiation therapy in cases where it was not successful. However, it's not yet clear how the long-term effectiveness of HIFU compares to surgery or radiation therapy. (ACS, 2023).
National Comprehensive Cancer Network ® (NCCN®	The 2025 NCCN Clinical Practice Guidelines in Oncology, Prostate Cancer, recommends HIFU and cryosurgery as options for secondary therapy for prostate cancer recurrence in the absence of metastatic disease.
National Cancer Institute (NCI):	In the 2024 Prostate Cancer Treatment health professional version Physician Data Query (PDQ) HIFU is not listed as a treatment option under clinical evaluation for patients with stage I and II prostate cancer.
Magnetic resonance-guided focused ultrasound (MRgFUS)	
American Society for Stereotactic and Functional Neurosurgery (Pouratian et al., 2020):	Position Statement on MR-Guided Focused Ultrasound for the Management of Essential Tremor

American Academy of Neurology Evidence-Based Guideline Update: Treatment of Essential Tremor (Zesiewicz et al., 2011)	Unilateral thalamotomy may be used to treat limb tremor in ET that is refractory to medical management (Level C), but bilateral thalamotomy is not recommended due to adverse side effects (Level C) MRI guided focused ultrasound is not specifically mentioned as a modality to accomplish thalamotomy in this guideline
Health Quality Ontario: Magnetic Resonance-Guided Focused Ultrasound Neurosurgery for Essential Tremor: A Health Technology Assessment (2018)	MRgFUS neurosurgery is an effective and generally safe treatment option for moderate to severe, medication-refractory [ET]. It provides a treatment option for people ineligible for invasive neurosurgery and offers a noninvasive option for all people considering neurosurgery.
International Essential Tremor Foundation: Essential Tremor in Adult Patients (Pocket Guide) (Lyons et al., 2021)	Focused ultrasound is listed as a later-stage treatment option for medication-refractory patients with comorbidities who are unable to undergo deep brain stimulation.
International Parkinson & Movement Disorder Society: Evidence-Based Review of Treatments for Essential Tremor (Ferreira et al., 2019)	For limb tremor associated w/ ET, "unilateral Ventralis intermedius (Vim)/thalamic DBS and thalamotomy (radiofrequency and MRI-guided focused ultrasound) were considered possibly useful … [D]ata available only allowed a conclusion of insufficient evidence for head tremor. None of the included studies specifically assessed voice tremor" (p. 952). Risk was considered "acceptable" with specialized monitoring
National Institute for Health and Care Excellence: Unilateral MRI-guided Focused Ultrasound Thalamotomy for Treatment-resistant Essential Tremor (2018)	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 (p. 2).

VI. CODING INFORMATION

ICD-10 Codes that 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 covered

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 (nonobstetrical)
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*

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VIII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, 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, please refer to the Priority Health Provider Manual.

IX APPLICATION TO PRODUCTS

Coverage is subject to 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) and/or the Evidence of Coverage (EOC); 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, 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.***
