Medicare Medical Policy

Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)

MEDICARE MEDICAL POLICY NUMBER: 348

Effective Date: 7/1/2025

Last Review Date: 6/2025

Next Annual Review: 8/2025

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes: Deep brain stimulation (DBS) is addressed in a separate policy. See Medical Policy Cross References below.

Service	Medicare Guidelines
Intracranial *Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor and Tremor Dominant Parkinson's (61715)*	Local Coverage Determination (LCD): Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor and Tremor Dominant Parkinson's (L37738) **NOTES:** 1. See *Policy Guidelines* below for a clarification received from Noridian regarding Criterion #2 of this LCD. 2. Intracranial MRgFUS for movement disorders is reported with CPT 0398T and is potentially medically necessary for essential tremor only (this includes Tremor Dominant Parkinson's disease [TDPD] patients). Other indications would **not** meet the medical necessity criteria in this LCD, and thus, CPT 0398T would be considered **not medically necessary** for indications other than idiopathic essential tremor or TDPD. 3. See row below for coverage criteria for MRgFUS reported with other CPT or HCPCS codes.
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*) • **Medicare Coverage Manuals:** Medicare does not have criteria for magnetic resonance-guided focused ultrasound Surgery (MRgFUS) in a coverage manual. • **National Coverage Determination (NCD):** There is no NCD which provides coverage criteria for MRgFUS. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** With the exception of the intracranial MRgFUS services noted above which are addressed by an LCD, as	

of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for focused ultrasound surgery or ablation. • Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available for these indications. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
MRgFUS NOT Reported with 0398T (e.g., 0071T, 0072T, etc., MRgFUS with Blood brain barrier disruption [BBBD] Using Microbubble Resonators [CPT 0947T], or other non-intracranial indications such as metastatic bone cancer, brain cancer, renal cancer, etc.)	Company medical policy for Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare when the Company medical policy criteria are not met. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Electrical Stimulation and Electromagnetic Therapies, MP333

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

The above LCD L37738 only addresses **intracranial** MRgFUS for movement disorders, which is reported with CPT 0398T. For focused ultrasound surgery or ablation procedures using magnetic resonance (MR) guidance for other indications, and reported with other CPT or HCPCS codes, these services would not fall into the scope of this LCD.

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Historically, the now-retired Noridian LCD for *Non-Covered Services* (L35008) considered all Category III codes to be non-covered, "unless specifically approved for payment by CMS or the Noridian Medical Directors and listed as approved" in the separate local coverage article (LCA) for *Additional Information Required for Coverage and Pricing for Category III CPT® Codes* (A55681).

Category III codes 0071T and 0072T used to report focused ultrasound ablation of uterine leiomyomata with MR guidance **were** included in LCA A55681 as "Group 1" codes since July 2017, as well as the LCA for Billing and Coding: Non-Covered Services (A57642), indicating this was a service which Noridian considered non-covered for several years. While the LCD L35008 and LCAs A57642 and A55681 were retired June 2020 to "align with Chapter 13 of the Program Integrity Manual (PIM)," this retirement does not mean these services became medically necessary, it only means the Medicare contractor does not choose to maintain a new LCD/LCA for this service.

Since there are not fully established coverage criteria for **non-intracranial** focused ultrasound surgery or ablation with MR guidance available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

Tremor Severity of the Dominant Hand

According to communication received from Noridian regarding Criterion #2 of LCD L37738, the "patient must meet criteria in the dominant hand." Noridian also states, "[a]ll other criteria mentioned in this section must also be met."

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See the associated local coverage article (LCA) for related billing and coding guidance:

- LCA: Billing and Coding: Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (A57513)

CODES*		
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 than or equal to 200 cc of tissue
	~~0398T~~	**TERMED 12/31/2024** ~~Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed~~
	0947T	Magnetic resonance image guided low intensity focused ultrasound (MRgFUS), stereotactic blood-brain barrier disruption using microbubble resonators to increase the concentration of blood-based biomarkers of target, intracranial, including stereotactic navigation and frame placement, when performed
	19499	Unlisted procedure, breast [when specified as destruction of breast tissue by magnetic resonance-guided focused ultrasound]
	20999	Unlisted procedure, musculoskeletal system, general [when specified as magnetic resonance-guided focused ultrasound for pain palliation for bone metastases]
	61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed
	76999	Unlisted ultrasound procedure (e.g. diagnostic, interventional)
HCPCS	C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
11/2022	New Medicare Advantage medical policy (converted to new format 2/2023)
11/2023	Annual review; no change to criteria, but language revision due to Company policy change from "Investigational" to "not medically necessary"
9/2024	Annual review; no change to criteria, add clarification information received from Noridian
1/2025	Q1 2025 code updates
7/2025	Interim update; added MRgFUS stereotactic blood-brain barrier disruption using microbubble resonators to this policy