MEDICAL POLICY	Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (Medicare Only)
Effective Date: 11/1/2022	Medical Policy Number: 348
 11/1/2022	Medical Policy Committee Approved Date: 8/2022
Medical Officer Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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

Service	Medicare Guidelines
Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (0398T)	Local Coverage Determination (LCD): Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L37738) **NOTE:** MRgFUS reported with CPT 0398T is potentially medically necessary for essential tremor only. Other indications would not meet the medical necessity criteria in this LCD, and thus, CPT 0398T would be considered not medically necessary for any indication other than essential tremor. See row below for coverage criteria for MRgFUS reported with other CPT or HCPCS codes.

MRgFUS For Other Indications (e.g., 0071T, 0072T, etc.)	Company medical policy for Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (All Lines of Business Except Medicare) I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.*

POLICY GUIDELINES

Medicare and Medical Necessity

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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, 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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

BILLING GUIDELINES

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)

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
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
Not Covered	
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
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
20999	Unlisted procedure, musculoskeletal system, general [when specified as magnetic resonance-guided focused ultrasound for pain palliation for bone metastases]
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be **denied as not covered.**	
19499	Unlisted procedure, breast [when specified as destruction of breast tissue by magnetic resonance-guided focused ultrasound]
76999	Unlisted ultrasound procedure (e.g. diagnostic, interventional)

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

MEDICAL POLICY CROSS REFERENCES

Electrical Stimulation and Electromagnetic Therapies (Medicare Only), MP333