I. Policy: High Intensity Focused Ultrasound

II. Purpose/Objective:
   To provide a policy of coverage regarding High Intensity Focused Ultrasound

III. Responsibility:
   A. Medical Directors
   B. Medical Management

IV. Required Definitions
   1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
   2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
   3. Devised – the date the policy was implemented.
   4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
   5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

   a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
   c. in accordance with current standards of good medical treatment practiced by the general medical community.
   d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
   e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

   (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
   (iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: High intensity focused ultrasound (HIFU) uses an acoustic lens to concentrate multiple intersecting beams of ultrasound on a target. High intensity ultrasound energy is focused at a specific location. At the focal point where the beams converge, HIFU destroys tissue with rapid heat elevation. HIFU is typically performed with real-time imaging via ultrasound or MRI to enable treatment targeting and monitoring. HIFU has been applied to treat a variety of solid malignant tumors, including the pancreas, liver, prostate, breast, uterine fibroids, and soft-tissue sarcomas. Magnetic Resonance Guided Focused Ultrasound (MRgFUS) combines focused ultrasound and magnetic resonance imaging to target and treat affected tissue.

INDICATIONS:
MRI-guided focused ultrasound (MRgFUS) is considered medically necessary if the following are met:

Diagnosis of metastatic bone cancer if ALL the following are met:
- Treatment is for palliation of cancer pain
- Member is eighteen years or older

Diagnosis of medication refractory essential tremor

(Medication refractory essential tremor is defined for the purposes of this policy as being refractory to a minimum of two trials of medical therapy to include the following unless contraindicated: beta blockers, anticonvulsants and/or benzodiazepines)

MEDICARE BUSINESS SEGMENT:
According to CMS coding updates, C9747 Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance is considered reimbursable in a hospital or ASC setting.

EXCLUSIONS: The long-term safety and efficacy data regarding the use of high intensity focused ultrasound (HIFU) in the treatment of various conditions is insufficient to show comparable or superior efficacy when compared to standard therapies. Therefore, unless mandated, high intensity focused ultrasound (HIFU) is considered experimental, investigational or unproven and NOT COVERED for all indications including but not limited to:

- Prostate cancer
- Benign prostatic hypertrophy
- Thyroid nodules and primary hyperparathyroidism
- Breast fibroadenoma
- Breast cancer
- Primary and secondary liver cancer
- Renal cell carcinoma
- Pancreatic cancer
- Brain cancer
- Osteosarcoma

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: High Intensity Focused Ultrasound
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

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

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)
C9734 - Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without magnetic resonance (MR) guidance
C9747 Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
National Comprehensive Cancer Network Clinical (NCCN) Prostate Cancer v4.2019

UpToDate Cyrotherapy and Other Ablative Techniques for the Initial Treatment of Prostate Cancer. September 12, 2016.


National Comprehensive Cancer Network (NCCN) Hepatobiliary Cancers, Hepatocellular v3.2019

UpToDate. Nonsurgical therapies for localized hepatocellular carcinoma: radiofrequency ablation, percutaneous ethanol injection, thermal ablation and cryoablation. October 16, 2015


UpToDate. Radiofrequency ablation and cyroablation for renal cell carcinoma. July 1, 2015

National Comprehensive Cancer Network (NCCN) Pancreatic Adenocarcinoma v 1.2019

National Comprehensive Cancer Network (NCCN) Breast Cancer v 3.2019


3.2018

National Comprehensive Cancer Network (NCCN) Central Nervous System Cancers v 3.2019


Duc NM, Keserci B. Emerging clinical applications of high-intensity focused ultrasound. Diagn Interv Radiol. 2019 Jul 9

Park YS, Jung NY, Na YC, Chang JW. Four-year follow-up results of magnetic resonance-guided focused ultrasound thalamotomy for essential tremor. Mov Disord. 2019;34(5):727-734


This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/18

Revised: 1/19 (added indication); 1/20 (added indication)

Reviewed: