Policy Name: High Intensity Focused Ultrasound (HIFU) Ablation Therapy
Current Policy Effective Date: 4/1/2015

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
High intensity focused ultrasound (HIFU) ablation therapy for uterine fibroids is investigative and therefore NOT COVERED.

HIFU ablation therapy is investigative and therefore NOT COVERED for all other indications including, but not limited to, benign prostatic hyperplasia, prostate cancer, or other tumors.

Note: See also related position statement, Surgical and Minimally Invasive Treatments for Benign Prostatic Hypertrophy/Hyperplasia (BPH).

Description
HIFU using magnetic resonance imaging guidance (also known as MRgFUS) has been proposed for the treatment of uterine fibroids (leiomyomata), cancer, and other tumor types. MRI guidance serves three functions: (1) precise targeting of treatment points within the tissue, (2) monitoring of therapy, and (3) assessment of treatment effects. Following MRI guidance, HIFU sound waves are applied, which produce intense heat at the identified focal point(s). This heat causes irreversible cell death to the tissue. Resulting necrotic tissue is sloughed off by normal processes. By delivering targeted treatment that avoids damaging intervening or surrounding tissue, normal organ function is purportedly maintained.

HIFU has been proposed as an alternative to surgery or minimally invasive procedures (e.g., hysterectomy, myomectomy, uterine artery embolization) for treatment of uterine fibroids. Uterine fibroids (leiomyomata) are benign growths of muscle and connective tissue which form from the smooth muscle tissue of the uterus. Fibroids are estimated to occur in 20 – 50% of women of childbearing age. Symptoms develop in a high proportion of these women and include, but are not limited to, heavy menstrual bleeding, anemia, pelvic pressure, reproductive disorders, or urinary frequency. HIFU is purported to alleviate symptoms while retaining uterine function.

HIFU has also been proposed as an alternative to surgery for treatment of cancer and other tumor types, including but not limited to prostate, breast, brain, and renal cancer. It is also being studied for palliation of pain (e.g., tumors
metastasis to bone). Currently, the most robust area of study is for use in the treatment of prostate cancer as either
(1) primary treatment of localized prostate cancer, (2) therapy adjunctive to transurethral resection of the prostate, or
(3) salvage therapy following prostatectomy or external beam radiation therapy.

FDA Approval
HIFU treatment is a procedure and, therefore, not subject to FDA approval. However, any medical devices and
equipment used as part of this procedure may be subject to FDA approval.
1. The ExAblate 2000 system received initial Premarket Approval (PMA) in October 2004 for ablation of uterine
fibroid tissue in pre-or peri-menopausal women with symptomatic uterine fibroids who desire a uterine sparing
procedure.
2. The ExAblate 2001, which features enhanced sonication and several other modifications, received FDA
approval in June 2009 for treatment of symptomatic fibroids in women with a uterine size of less than 24 weeks
and for those who have completed child bearing.
3. In October 2012, the ExAblate System, Models 2000, 2100, and 2100 V1, received PMA approval for use in
palliative treatment of pain due to bone metastases.

HIFU treatment for all other indications would be considered off-label use of this technology. Two HIFU devices,
the Sonablate® 500 system and Ablatherm®, are in late stage clinical trials for use in treatment of prostate cancer.

Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of
coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes
only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member
coverage or provider reimbursement.

CPT Codes:
- 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
- 76999 - Unlisted ultrasound procedure (e.g., diagnostic, interventional)
- C9734 - Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without
  magnetic resonance (MR) guidance
Medica Coverage Policy

Original Effective Date: 6/1/2006

Re-Review Date(s): 1/20/2009
12/20/2011
4/1/2015
1/4/2016 – Administrative update. Code 0389T added

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