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Clinical UM Guideline

Subject:	**High Intensity Focused Ultrasound (HIFU) for Oncologic Indications**		
Guideline #:	**CG-MED-81**	**Publish Date:**	**05/09/2019**
Status:	**New**	**Last Review Date:**	**03/21/2019**

Description

This document addresses the use of high intensity focused ultrasound (HIFU) or magnetic resonance-guided focused ultrasound (MRgFUS) for the treatment of oncologic conditions. HIFU involves the use of a focused high-intensity convergent ultrasound beam to destroy targeted tissue.

Note:

- **See the following related document for HIFU treatment non-oncologic indications:**
  - **MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications**
- **For information regarding other palliative treatments of metastatic bone lesions, please see the following:**
  - **CG-SURG-62 Radiofrequency Ablation to Treat Tumors Outside the Liver**

Clinical Indications

Medically Necessary:

The use of high intensity focused ultrasound (HIFU) is considered medically necessary for pain palliation in individuals with localized metastatic bone pain when all the following criteria are met:

A. Age 18 years or older; and
B. Metastatic lesions located 1 centimeter (cm) or greater from skin and major nerve bundles; and
C. Individual does not present an increased risk of fracture from the procedure (for example, a score of 7 or less on Mirel's fracture risk score); and

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D. Individual does not require surgical stabilization or have clinically significant comorbidities; and
E. Individual is not a candidate for other therapies as evidenced by pain refractory to previous radiation therapy.

~~Investigational and~~ Not Medically Necessary:

High intensity focused ultrasound (HIFU) is considered ~~investigational and~~ not medically necessary when the above criteria are not met and for all other indications, including but not limited to, the treatment of prostate cancer.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Bone metastases
~~When Services may be Medically Necessary when criteria are met:~~

CPT	
20999	**Unlisted procedure, musculoskeletal system, general [when specified as high intensity focused ultrasound for pain palliation for bone metastases]**
HCPCS	
C9734	**Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance**
ICD-10 Diagnosis	
C79.51	**Secondary malignant neoplasm of bone**

~~When Services are Investigational and Not Medically Necessary:~~

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Treatment of other oncologic indications ~~**When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.**~~

CPT

	Note: the following services are considered not medically necessary:
19499	**Unlisted procedure, breast [when specified as destruction of breast tissue by high intensity focused ultrasound]**
55899	**Unlisted procedure, male genital system [when specified as destruction of prostate tissue by high intensity focused ultrasound]**

HCPCS

C9734	**Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance**
C9747	**Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance**

ICD-10 Diagnosis

C00.0-C79.49	**Malignant neoplasms**
C79.52-C80.2	**Malignant neoplasms**
D00.00-D09.9	**In situ neoplasms**

Discussion/General Information

Ultrasound, the use of low-intensity sound waves to produce images, is long established as a diagnostic tool. When high-intensity ultrasound waves are used in place of low-intensity, body tissue absorbs, rather than reflects the energy and produces heat and cavitation that destroys the targeted tissue. Temperatures within the targeted area increase to 60-95°C, which destroys the targeted tissue without damaging the adjacent tissue. HIFU treatment is combined with a visualization method, frequently MR guidance, to better guide treatment in real time. Ultrasound is currently being used as a therapeutic treatment in some cases, such as lithotripsy to disintegrate kidney stones. HIFU or MRgFUS has been studied as a potential treatment of various cancers. During the procedure, individuals are typically placed under conscious sedation with or without epidural anesthesia, although general anesthesia may be used. Proposed advantages of HIFU include

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the noninvasive nature of the procedure that spares surrounding tissue, reducing postoperative morbidity, and hastening recovery.

Pain palliation for localized metastatic bone pain

Bone pain is a common complaint for individuals with metastatic cancer to the bone. The current standard treatment is external beam radiation therapy (EBRT). However, EBRT has been shown to be ineffective in approximately 20-30% of cases and pain recurs in 27% of the treated population (Liberman, 2009). In addition, there are limitations on tissue tolerance at sites previously irradiated. Those who fail, are not eligible for, or refuse radiation therapy may be pharmacologically managed, or other therapies such as surgery or percutaneous cryoablation may be attempted. These options carry their own risks and side effects.

Although the exact mechanism of analgesic action of MRgFUS in pain palliation is unknown, studies have pointed to a few explanations. As the bone cortex absorbs high ultrasound energy, periosteal denervation may ensue, resulting in pain relief. Alternatively, the reduced tumor mass caused by thermal ablation may have an analgesic effect. It is likely that both of these treatment effects contribute to pain relief.

Early prospective studies evaluating MRgFUS reported promising results. In a 2009 study by Liberman and associates, 31 individuals with painful bone metastases who had exhausted or refused all other pain palliation methods were treated with MRgFUS. Researchers used the visual analog pain score (VAS) to measure pain levels. In those 25 participants that were able to tolerate a complete treatment, 72% (18/25) reported significant pain reduction of at least 2 points on the VAS scale, 24% (6/25) reported no reduction in pain and 4% (1/25) reported an increase in pain levels. In those individuals who reported a decrease in pain levels, 50% (9/18) reported complete relief of pain. In addition, 52% of these individuals reported significant pain relief beginning 3 days post treatment. There were no reported treatment related severe adverse events (AEs). In 2013, Napoli and colleagues treated 18 individuals with painful bone metastases with MRgFUS. Participants included those who could not undergo or refused all other available options for pain palliation. Pain severity was measured using a 10-point pain scale questionnaire. The pain severity score was significantly reduced from a baseline mean of 7.1 (SD ± 2.08) (4-10; 95% confidence interval [CI], 6.07-8.15), to 2.5 (SD ± 1.4) (0-5; 95% CI, 1.81-3.2) at 1 month. This further reduced at the 3 month follow-up to 1 (SD ± 1.1) (0-3; 95% CI, 0-1.85) (p=0.001). At 3 months, 72.2% (13/18) reported no pain without the use of pain

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medication, and 16.7% (3/18) reported a drop of at least 2 points on pain scale without an increase in pain medication. The remaining 11.1% (2/18) reported pain reoccurrence which required pharmacological care. There were no treatment-related AEs. In a recent, small prospective, non-randomized single arm trial, MRgFUS was used on 5 individuals with painful bone metastatic lesions with a pain rating of 4 or higher. At 2 weeks follow-up, all individuals experienced a decrease in VAS pain scores from baseline (1.5-5). A complete resolution of pain at 1 year follow-up was shown in 2 participants. While this study suggested that MRgFUS can be an effective palliative treatment, this was a small study with no comparison group (Joo, 2015).

In the first phase III study published to date, Hurwitz and colleagues (2014) conducted a randomized, placebo-controlled, single-blind, multicenter, pivotal trial which included 147 participants. Eligibility included those at least 18 years old with at least a 3-month life expectancy with bone metastases which were painful despite previous radiation therapy (RT) but unsuitable for further RT. In addition, eligible participants reported a numerical rating scale (NRS) pain score of 4 or greater in spite of maximal pain medication therapy, and a score of 7 or less on the Mirel's fracture risk scale. Participants received either MRgFUS (n=112) or placebo (n=35) treatment. The identified primary endpoint was the improvement in self-reported pain score without an increase in pain medication utilization at 3 months. The difference in response rates between MRgFUS and placebo at 3 months was significant (64.3% versus 20.0%; p<0.001). In addition, 21% of individuals in the MRgFUS group reduced their morphine equivalent daily dose (MEDD) intake and another 26% completely stopped their MEDD consumption. Of note, 65.7% (23/35) of individuals in the placebo group did not complete the 3-month follow-up compared to approximately 21% (26/112) of the MRgFUS group. After excluding the drop-out groups the results remained similarly statistically significant. The study also included a crossover component; 17 of the 23 individuals in the placebo group who did not complete follow-up chose to receive rescue MRgFUS after a lack of response to placebo. A statistically significant pain response was reported in 70.7% of this group. These results were not included in the primary efficacy analysis. Participants were not followed beyond 3 months. While the overall primary endpoint was met, this endpoint, a composite of the change from baseline in the worst numerical rating scale (NRS) pain score and the MEDD intake, was not comprised of entirely statistically significant components. The mean reduction in the NRS score was significant between MRgFUS and placebo (3.6 ± 3.1 versus 0.7 ± 2.4; p<0.001). However, the change from baseline in MEDD intake was not statistically significant, although the authors noted a trend towards a statistically significant change. The treatment group reported an AE

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frequency of 76.2% versus 23.8% in the sham group. The majority of events were minor and reversible. The authors noted these results compared well to the radiation therapy complication rate.

While the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines (CPG) in Oncology for Adult Cancer Pain (V1.20198) document notes that the palliative effects of HIFU have been demonstrated in several small studies, no recommendation for or against the use of HIFU for pain palliation was given.

In 2012, the FDA approved via the Premarket Application (PMA) process the use of the ExAblate® System (InSightec, Ltd, Dallas, TX) for pain palliation in individuals 18 years and older who have metastatic bone cancer pain who have failed, are not candidates for or have refused standard radiation therapy.

Prostate Cancer

Prostate cancer is the most commonly diagnosed cancer in men, accounting for 19% of all new cancer cases. Prostate cancer is the second leading cause of death with approximately 39,430 deaths in 2018 (Bekelman, 2018).

HIFU has been evaluated as a minimally invasive treatment of whole gland or a focal treatment of prostate cancer, both in clinically localized prostate cancer and following recurrence. The available peer-reviewed published literature addressing the use of HIFU to treat prostate cancer consists of nonrandomized studies. There is a lack of comparative studies which evaluate the long term safety and efficacy outcomes compared to standard treatment options.

There are a number of uncontrolled case series and prospective studies which address HIFU for prostate cancer (Ahmed, 2009, 2011, 2012; Beerlage, 1999b; Blana, 2004; Chaussy, 2001; Gelet, 2000; Gelet, 2004; Guillaumier; 2018; Lawrentschuk, 2011; Muto, 2008; Napoli, 2013; Poissonnier, 2007; Shoji, 2010; Thuroff, 2003; Uchida, 2002; Uchida, 2005; Uchida, 2006a; Uchida, 2006b; Zacharakis, 2008). One of the largest of these studies was conducted by Ganzer and colleagues (2011). This study was a retrospective case series involving 804 subjects who underwent HIFU and were included in an industry-sponsored registry. The focus of this study was the use of prostate specific antigen (PSA) as a predictor of disease-free survival after HIFU, not the outcomes related to HIFU treatment. The study has several methodological flaws, including lack of a

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comparison group, and uncertainty regarding the percentage of subjects who completed the follow-up period.

Crouzet and colleagues (2014) conducted the largest prospective case series (n=1002) to evaluate rates of survival and morbidity over the long term in subjects treated with HIFU (Ablatherm) for localized disease. The mean follow-up period was 6.4 years (range, 0.2-13.9). Approximately 98% of subjects received 1 (60%) or 2 treatments (38%). Post-treatment biopsies were available in 77% of subjects. The overall survival (OS) rate was 80%, the progression-free survival (PFS) rate was 94%, and the disease-specific survival rate was 97%. The most commonly reported complications included "Stress 1" urinary incontinence (18.7%), followed by obstruction of the bladder outlet (16.6%), and acute urinary retention (7.6%). Late complications included occurrences of stenosis (9%) and fistula (0.4%). This prospective case series did not compare HIFU long-term survival and morbidity rates with the rates of other standard treatments.

The NCCN Prostate Cancer CPG (V4.2018) includes a recommendation for individuals with tumor recurrence following radiation therapy to include HIFU as a treatment option (2A recommendation). Individuals must be transrectal ultrasound (TRUS) biopsy positive with negative studies for distant metastases. This recommendation is based upon prospective and retrospective studies (Ahmed, 2012; Baco, 2014; Crouzet, 2012; Crouzet, 2017; Kanthabalan, 2017; Palermo, 2017; Rischmann, 2017; Shah, 2016; Siddiqui, 2016; Uddin 2012). The American Urological Association (AUA) 2007 guideline on prostate cancer notes that conclusions on the outcomes of HIFU cannot be determined as there is minimal data available on this treatment. This guideline was reviewed and validated in 2011. The 2018 American Urological Association/American Society for Radiation Oncology/Society of Urologic Oncology (AUA/ASCO/SUO) notes that high intensity focused ultrasound treatment is not a standard care option for low, intermediate or high risk or localized prostate cancer. There is a lack of evidence which supports that HIFU outcomes are comparable to standard treatment options.

In 2015, The U.S. Food and Drug Administration (FDA) approved two devices for use in prostate cancer. On October 9, the FDA granted *de novo* clearance to SonaCare Medical, LLC (Charlotte, NC) to market the Sonablate® 450 for prostate tissue ablation. Sonablate was classified as a class II device. In November, the FDA approved the use of Ablatherm® (Maple Leaf; Toronto, Canada) to treat prostate cancer in individuals who previously failed radiation therapy.

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Other Oncologic Indications

Peek and associates (2015) conducted a systematic review of the use of HIFU in breast cancer. The authors reviewed 9 studies with a total of 167 participants. Following treatment, no residual tumor was found in 46.2% of cases. However, residual tumors of less than 10% were found in 29.4% of cases and residual tumors between 10-90% were found in 22.7% of cases. The authors noted that incomplete tumor ablation could be related to poor accuracy in determining the target area or movement during the procedure. The use of HIFU in the setting of breast cancer treatment may not allow for an adequate collection of tumor specimens to evaluate the tumor histopathology. The limited examination of small biopsies as well as the lack of a reliable means of assessing some prognostic factors, such as potential lymphovascular invasion, may not provide adequate information for the determination of adjuvant systemic therapies.

In a systematic review, Li and colleagues (2014) performed a meta-analysis on the use of HIFU in combination with radiotherapy or chemotherapy in the treatment of pancreatic cancer. A total of 23 studies comprised of 1157 individuals were included. While the analysis showed superior survival rates at 6 and 12 months in the groups which included HIFU in combination therapy, the authors noted that the overall quality of the studies was poor. A second systemic review in which HIFU was compared to other ablative therapies in the treatment of locally advanced pancreatic cancer was done by Rombouts and colleagues (2015). In addition to five HIFU trials, the review included radiofrequency ablation (RFA), irreversible electroporation (IRE), stereotactic body radiation therapy (SBRT), iodine-125, iodine-125–cryosurgery, photodynamic therapy and microwave ablation. Results indicated that median survival in RFA, IRE and SBRT was more favorable compared to HIFU. HIFU was comparable to the median survival in standard chemotherapy. The five HIFU trials included a total of only 136 individuals. While some trials using HIFU to treat pancreatic or liver cancer have shown some promising results, these trials have lacked a comparator group (Chen, 2015; Dupré, 2015; Shi, 2015; Sofuni, 2014). Similar to prostate cancer, there is a lack of randomized trials comparing HIFU to standard treatment options. There is a lack of evidence which supports that HIFU improves clinical outcomes over the standard treatment options. .

Definitions

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Bone metastasis: When cancer cells have broken off from the primary tumor and have settled and started growing on bones.

High intensity focused ultrasound (HIFU): A surgical procedure that uses focused high energy sound waves to destroy target tissues in the body.

Mirel's scoring system: A scoring system based upon lesion characteristics and pain levels used to classify pathologic fracture risk.

Score	Site of Lesion	Size of Lesion	Nature of Lesion	Pain
1	Upper limb	<1/3 of cortex	Blastic	Mild
2	Lower limb	1/3-2/3 of cortex	Mixed	Moderate
3	Trochanteric region	>2/3 of cortex	Lytic	Functional

*** From Jawad MU, Scully SP. In brief: classifications in brief: Mirels' classification: metastatic disease in long bones and impending pathologic fracture. Clin Orthop Relat Res. 2010; 468(10):2825-2827.**

Palliative treatment: Treatment given for relief of symptoms and pain rather than attempting to cure.

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Index

Ablatherm®
Sonablate 450
ExAblate

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	03/21/2019	Medical Policy & Technology Assessment Committee (MPTAC) review.
New	03/20/2019	Hematology/Oncology Subcommittee review. Moved content of MED.00119 High Intensity Focused Ultrasound (HIFU) for Oncologic Indications to new clinical utilization management guideline document with the same title.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. ~~Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.~~

~~Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.~~

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