



February 08, 2021

Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop: C4-01-26
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via email to Larry.Chan@cms.hhs.gov

RE: Public Nomination of CPT Code 55880 as Potentially Misvalued for CY 2022

55880 Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance.

Dear Ms. Richter:

In accordance with the procedures for public nomination of potentially misvalued CPT codes, SonaCare Medical, LLC wishes to propose to CMS that CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance) is potentially misvalued (85 FR 84614 - 84615).

In particular, there are no separate Non-Facility inputs for Practice Expense (the Facility rate is used for both settings). It is SonaCare's understanding that when CPT 55880 was initially created, the RUC did not recommend separate pricing in the Non-Facility setting on the basis that this procedure would take place in the Facility setting. Thus, the RUC, did not propose or finalize separate Non-Facility pricing for this code.

Due to the similarity in HIFU procedures and cryoablation procedures, advances in HIFU technology, and concerns from physicians regarding the ability to treat HIFU patients in a Non-Facility setting, we would like to nominate CPT 55880 as potentially misvalued. CMS doing so would allow an opportunity for public discussion to determine whether it would be appropriate to establish separate Non-Facility pricing for the code.

The basis of our nomination is outlined below:

Cryoablation of prostate tissue (55873) and HIFU (55880) are comparable minimally invasive procedures used to treat prostate disease and performed on an outpatient basis. Cryoablation has been safely performed in non-facility settings for approximately 10 years and has had Non-facility RVU valuation since 2001. According to NCCN guidelines prostate cryoablation and HIFU have the same indication. From a clinical point of view, these two procedures require similar resources, such as general anesthesia, transrectal ultrasound guidance, intra-procedure physician and nursing resources, to treat



the same disease. Cryoablation of the prostate is typically a 1–2-hour procedure with approximately 1 hour of post-procedure recovery. HIFU ablation of the prostate is typically a 2-3 hour procedure with approximately 1 hour of post-procedure recovery.

By assigning Non-facility RVUs for 55880, CMS and payors would also be decreasing healthcare costs by encouraging this procedure to be performed within offices instead of more costly hospitals and ASCs. Additionally, right now with the COVID pandemic, this is an ideal solution for finding a balance to providing care in a safe, effective manner while offering this minimally invasive procedure without further taxing already overstretched hospitals.

In summary, we believe that 55880 should be designated as potentially misvalued for Non-Facility inputs for practice expense for purposes of further action. Additionally, if there is a way to address the Non-Facility valuation of CPT 55880 more expeditiously than having CPT 55880 added to the misvalued code list, we welcome the opportunity to work with CMS to do so.

Thank you for your attention to this issue. If you require any further information, please contact our consultant V. Bitoy at v@vbitoy.com or (415) 789-5101.

Sincerely,

A handwritten signature in black ink, appearing to read "Brad Snow", with a long horizontal flourish extending to the right.

Brad Snow, CEO
SonaCare Medical, LLC

ATTACHMENTS



Overview

55880 Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance.

DETAILED TECHNOLOGY DESCRIPTION:

High intensity focused ultrasound (HIFU) is a noninvasive technique for the ablation of prostate tissue that induces coagulative necrosis in targeted tissue without surgical exposure or insertion of instruments into the tissue. A HIFU probe, inserted in the rectum, contains both imaging and therapy transducers both using ultrasound energy focused by a curved transducer. The energy, concentrated at the focal point of the transducer, decreases sharply outside the focal zone, thus creating a sharp border between the targeted and non-targeted tissue. Transrectal HIFU is well suited for the anatomic position of the prostate because the transducer can be introduced into the rectum and brought within 5 cm of the target, no intervening structures are present between the rectum and the prostate, and both can be visualized on ultrasonography included as part of the therapy probe. In addition, the prostate is located in the pelvic space so that respiratory movement is minimal.

The technology consists of a transrectal probe, console containing the computers, electronics, and amplifiers required to provide the energy source for ablation, process imaging data, and plan and guide the treatment. A treatment planning program is used to identify, target, and monitor the treatment. Probe and transducer movement once the probe is placed manually in the rectum is controlled by computer. The ablation is achieved by placing a series of cylindrical ablations in the prostate each approximately 3mm x 10 - 20mm in size.



DETAILED PROCEDURE DESCRIPTION:

NOTE: According to FDA requirements, the probe and all patient associated components must be sterilized prior to use.

The procedure is performed on an outpatient basis. The patient is anesthetized by general, epidural or spinal anesthesia and placed in a supine and open-leg position or a lateral decubitus position. A suprapubic or foley catheter may be placed prior to at the end of the procedure. A condom or sheath is placed over the probe head and a fluid coupling medium is used to inflate the condom covered with ultrasound gel for close coupling of the ultrasound probe to the rectal wall. The probe is inserted into the rectum and locked in position. The probe is used to image the prostate and a treatment

plan is created designed to cover the region of interest with elemental ablation lesions. Optionally, multiparametric MRI data can be imported into the planning system that is

coregistered with the ultrasound data obtained from the transrectal probe in order to identify on the ultrasound images regions of cancer more easily identified on the MpMRI. The ablation proceeds with monitoring to pause the procedure should evidence of excessive heat buildup in none targeted tissue become apparent. Once the entire treatment is delivered, the probe is removed, the patient awakened and taken to the recovery room for several hours of monitoring, at the end of which he is sent home.



RESOURCES: The resources commonly used to furnish the prostate ultrasound ablation

NOTE: HIFU treatment disposables/supplies described are a per-patient estimate. This is not an all-inclusive list as each facility's requirements may vary:

- A. HIFU Ablation System including energy source, chiller, patient position adjustment device, treatment planning system, coupling medium, and sterile sheath.
- B. Anesthesia machine and related gases and drugs
- C. Anesthesiologist
- D. Two OR Nurses (one nonsterile to circulate, one sterile to support equipment and physician)
- E. One surgical technologist (nonsterile to operate equipment)
- F. Disposables
 - 1. Ultrasound gel (3cc per patient)
 - 2. 60cc catheter tip syringe (2 per patient)
 - 3. 10cc syringe (2 per patient)
 - 4. Betadine (3cc per patient)
 - 5. Sterile 4x4 inch gauze (12 per patient)
 - 6. Tape-gentle/paper tape type (1 roll per patient)
 - 7. Sterile gloves (2 pair per patient various sizes should be available)
 - 8. Non-sterile clean gloves (6 pair per patient)
 - 9. Leg catheter bag (1 small leg urine collection bag per patient)
 - 10. Large catheter bag for night time use (1 large urine collection bag per patient)
 - 11. Physician prescribed antibiotic coverage (1 dose per patient IV)
 - 12. Spray disinfectant to clean/wipe down equipment
 - 13. Foley catheter to fill bladder prior to SP tube introduction (1 per patient size #16 or #18)
 - 14. Scalpel (1 per patient for use in introduction of suprapubic catheter unless included in SP kit)
 - 15. Disposable razor or electric clippers (1 per patient)
 - 16. Sterile saline/irrigation solution of physician choice (estimated 500ml per patient)
 - 17. IV tubing and IV solutions (3000ml per patient approximate)
 - 18. Medical gases and medications for general anesthesia or epidural anesthesia with IV sedation for 2-3 hour procedure
 - 19. Small sterile kidney basin to pour saline into (1 available per procedure)
 - 20. Sterile/Distilled water (1 liter per patient)
 - 21. Suprapubic Catheter 16F
- G. OR



A standard procedure room/treatment room/operating room with dimensions of at least 12' x 12' can be used to perform as a HIFU procedure room. The treatment room must accommodate the following essential equipment and needs:

1. Surgical table able to achieve lithotomy position with attachment rails for Yellofin or Allen type stirrups
2. Anesthesia machine that has been inspected by and cleared for use by anesthesiologist and has medical gas availability and vitals monitor with pulse oximetry
3. Rolling patient stretcher for transport of patient to recovery room
4. Recovery room (2-3 hour recovery is usual per patient) with vitals monitoring equipment including pulse oximetry
5. Crash cart/Cardiac emergency cart with current medications required for patient management during an emergency/cardiac event
6. Mayo tables (2)
7. Rolling stools (2)
8. Patient warming blanket (forced air warming system) or equivalent normothermia system
9. Sequential compression devices/pumps for lower extremity DVT prevention
10. Electrical outlets for standard 110V connection x 3 outlets not on same circuit as the anesthesia machine
11. UPS battery back-up such as APC SUA300 or similar equivalent