2022 CODING AND PAYMENT FOR TULSA-PRO® PROCEDURE

Payor policies vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. This information is presented for illustrative purposes only and does not constitute legal or reimbursement advice. It is always the provider's responsibility to determine medical necessity and submit appropriate codes, modifiers and charges for services rendered appropriate to the site of service in which the procedure is furnished. We recommend consulting relevant manuals for appropriate coding options and the payor for coding guidance.

HCPCS and CPT Codes

The TULSA-PRO® System uses a transurethral ultrasound applicator for focused ultrasound ablation of prostate tissue under continuous magnetic resonance (MR) guidance and control. This FDA cleared device is indicated for transurethral ultrasound ablation (TULSA) of prostate tissue.

The TULSA-PRO® procedure may be performed in sites of service that are paid under different payment systems by Medicare. The codes a provider uses to report the procedure may be different depending on whether the procedure is furnished in a hospital outpatient department or a facility that bills under the Medicare Physician Fee Schedule. Below are codes that may identify the procedure depending on the setting in which the service is provided and whether the claim is for the facility (hospital outpatient department) or physician service.

Hospital Outpatient Department

HCPCS/CPT Code	Description
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

Physician Service and Settings that Bill Under the Medicare Physician Fee Schedule

HCPCS/CPT Code	Description
53899	Unlisted procedure, urinary system
55899	Unlisted procedure, male genital system

TULSA-PRO®

ICD-10 CM Diagnosis Codes

The TULSA-PRO® System is indicated for transurethral ultrasound ablation (TULSA) of prostate tissue. The following diagnosis codes describe conditions for which TULSA may be prescribed. The final decision of billing for any procedure must be made by the provider of care considering the condition of the patient, the medical necessity of the service, federal and state laws, regulations and coding guidance, AMA/CPT coding rules, and requirements of insurers applicable to the patient.

Code	Description
C61	Malignant neoplasm of prostate
N40.0	Benign prostatic hyperplasia without lower urinary tract symptoms
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms
N40.2	Nodular prostate without lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms

ICD-10 MS-DRG definitions from the CMS ICD-10-CM/PCS MS-DRG v37.0 Definitions Manual. *Source:* https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0001.html.

Payment by Place of Service

HCPCS Code	Description	APC	Payment[1]	SI
Hospital Outpatient				
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance	5115	$12,593	J1[2]

[1] 2022 Medicare National Unadjusted OPPS Payment Rate.
[2] Status Indicator = J1 means that the payment rate covers all items and services for the hospital outpatient encounter.

PROFOUND

Unlisted Procedure Code Claims Submission Process

Although unlisted CPT codes may be accompanied initially by claims denials and inconsistent payment amounts, when reported with appropriate documentation, unlisted CPT codes should be reimbursed. This may require that the physician and their coding or billing staff follow-up with payors to facilitate reimbursement.

Reporting an unlisted procedure can require more steps than reporting a procedure that has a specific CPT or HCPCS code. To lessen the chance of payment denial, it is best to obtain prior authorization (for commercial insurance) in writing from the payor before performing an unlisted procedure. Most payors have a prior authorization form that allows the physician to describe the planned procedure and the medical necessity of the operation.

For Medicare and those instances where an unlisted procedure is performed without prior authorization, a copy of the operative report should be submitted, along with supporting information outlining the decision-making process and the medical rationale for performing the operation. For Medicare patients, this documentation should be submitted to the appropriate Medicare Administrative Contractor (MAC). Individual payors may have processes in place for submitting claims for unlisted codes. It is important to be familiar with your top payors' specific process to help expedite the claim.

When submitting an unlisted procedure, a concise description of the procedure must be included in Item 19 of the electronic media claim (EMC) CMS-1500 form. This concise statement must be 80 characters or less; below is a sample description:

Focused ultrasound ablation of the prostate, transurethral, with MR guidance

Even if the description can be summarized in this small space, it is best to send additional claim attachments. Common attachments include:

- Cover letter detailing request for reimbursement (including manufacturer invoice when applicable)
- Letter of Medical Necessity (LOMN)
- Operative report and/or discharge summary

These attachments are sent with the original claim, either electronically or by fax, e-mail, or hard copy based on the payor's rules.

TULSA-PRO®

Prior Authorization

While fee-for-service Medicare does not generally require prior authorization, many private payors require authorization before the physician performs the procedure. The following is provided to assist in the prior authorization process:

- TULSA-PRO® received FDA clearance in August 2019 for the indication of transurethral ultrasound ablation (TULSA) of prostate tissue.[1]
- A Pivotal study of prostate tissue ablation in 115 men with localized prostate cancer demonstrated that TULSA-PRO® was effective at reducing PSA and prostate volume, with low rates of side effects and residual disease:[2]
    - Median PSA decreased 95% to nadir of 0.34 ng/ml
    - Median prostate volume decreased significantly by 91%, and extensive biopsy sampling of the markedly reduced prostate demonstrated a benefit for nearly 80% of men
    - TULSA has a high degree of safety and maintenance of quality-of-life: to one year, no men had a rectal or bowel injury, 99% returned to baseline urinary continence, and 75% of potent men maintained or returned to erections sufficient for penetration
    - 7% rate of additional intervention by 2 years in intermediate-risk patients is comparable to accepted rates of relapse after standard prostate cancer treatments
- Systematic Review of TULSA-PRO demonstrates it to be safe and effective for prostate tissue ablation in men with primary PCa.[3]
- These benefits are comparable to those of commonly accepted interventions for localized prostate cancer, with a lower rate of serious or severe complications.
- Smaller clinical studies have also demonstrated the efficacy of TULSA-PRO® for prostate ablation in men seeking prostate ablation because of benign prostatic hyperplasia with lower urinary tract symptoms, and in men seeking prostate ablation because of recurrent localized prostate cancer after radiation therapy.

[1] https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191200.pdf

[2] Klotz, Pavlovich, Chin, Hatiboglu, et al, 'MRI-Guided Transurethral Ultrasound Ablation of Prostate Cancer,' *J Urology*, 2020: https://www.auajournals.org/doi/10.1097/JU.0000000000001362

[3] Dora, et al, 'MRI-Guided Transurethral Ultrasound Ablation of Prostate Cancer: A Systematic Review,' *J Endourology*, 2022: DOI: 10.1089/end.2021.0866

Reimbursement Support

For additional assistance, please contact Profound Medical's TULSA-PRO® reimbursement specialists at:

Phone (Toll-Free): 855-285-5724

Fax (Toll-Free): 833-557-0896

Email: Support@PROFOUNDReimbursement.com

TULSA-PRO®

Frequently Asked Questions

Q. IS TULSA® THE SAME AS HIGH INTENSITY FOCUSED ULTRASOUND (HIFU)?

A. No. HIFU uses standard transrectal ultrasound (TRUS) imaging to visualize the prostate and guide the ablation. There is no temperature measurement during a HIFU procedure.

TULSA-PRO uses a different approach (transurethral) and intraoperative MRI to guide the entire procedure, including imaging the prostate anatomy as well as measuring and monitoring in real-time the temperature changes in the prostate during ultrasound ablation, and controlling the ultrasound output. The imaging sequences are specific and unique to TULSA-PRO and are not performed with HIFU prostate procedures.

Q. WHAT CPT CODE IS USED TO BILL FOR THE TULSA PROCEDURE?

A. Currently, there is no CPT code that specifically describes the TULSA procedure. CMS has established a HCPCS code that describes ultrasound therapy under MRI guidance which is not specific to a particular part of the anatomy and can describe MR-guided ultrasound ablation of the prostate:

C9734 Focused ultrasound ablation/ therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance

CMS has confirmed that this code is not specific to a particular device and can be used to report MRI-guided ultrasound therapy other than for uterine leiomyomata.[1]

Medicare recognizes C9734 for services provided in the hospital outpatient department. Depending on payor preference, other payors may also use C9734 to describe TULSA.

Note: The codes for HIFU (a new CPT code effective January 1, 2021, *55880*: Ablation of malignant prostate tissue, transrectal, with high intensity focused ultrasound, including ultrasound guidance and the discontinued HCPCS code *C9747*: Ablation of prostate, transrectal, high intensity focused ultrasound, including imaging guidance) describe a transrectal procedure and therefore DO NOT describe TULSA.

Q. ARE OTHER PROCEDURES INCLUDED IN THE PAYMENT FOR HCPCS CODE C9734?

A. All items and services furnished by the hospital on the same day as the MR-guided ultrasound therapy, including any ancillary procedures, are bundled into the Medicare payment rate for C9734. Other procedures provided at the same time as the TULSA procedure may not be paid separately.

[1] E-mail from CMS to PROFOUND, January 6, 2020.