



FOCUS ... on you

APC Assignment of new CPT® 55880 Code

Advisory Panel on Hospital Outpatient Payment – Aug. 23, 2021

Prostate Cancer in the United States

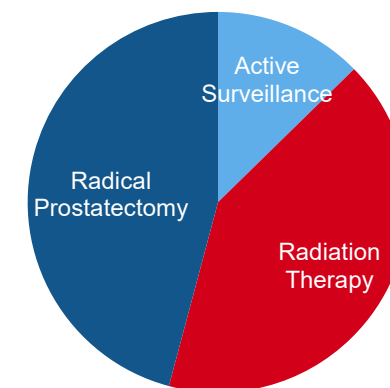
248,530 new cases diagnosed every year (#1 cancer in men)*

60% of diagnosed patients are 65 or older (average = 66y)*

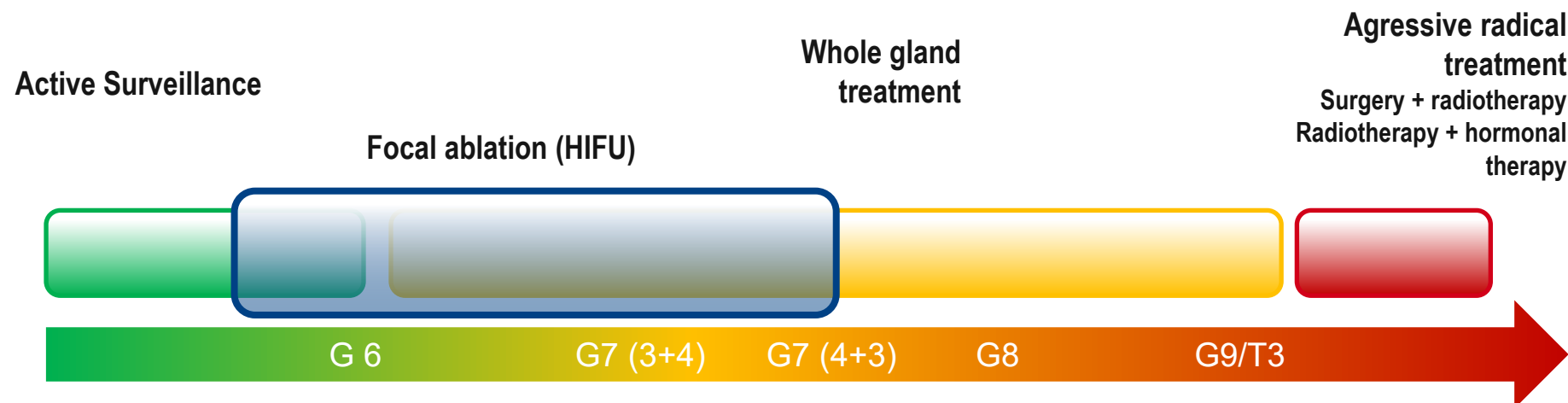
34,130 deaths every year (#2 cancer in men)*

3.1 Million American men living with prostate cancer*

Localized PCa Treatment patterns



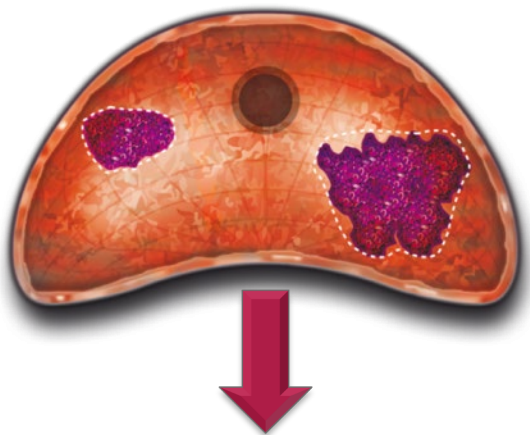
* Up to 35% over-treatment



Place for HIFU Ablation

130,000 patients need a local treatment every year in the US

Multifocal tumors (75%)

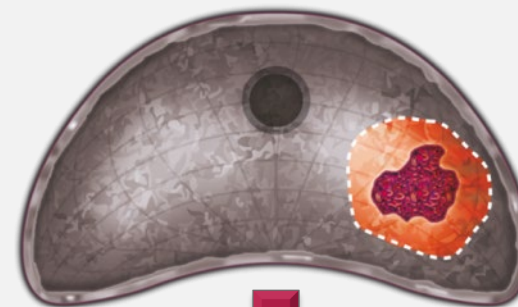


Whole-Gland therapy
(Surgery, radiotherapy)

Urinary and sexual morbidity

Unifocal tumors (25%)

30 000 / an

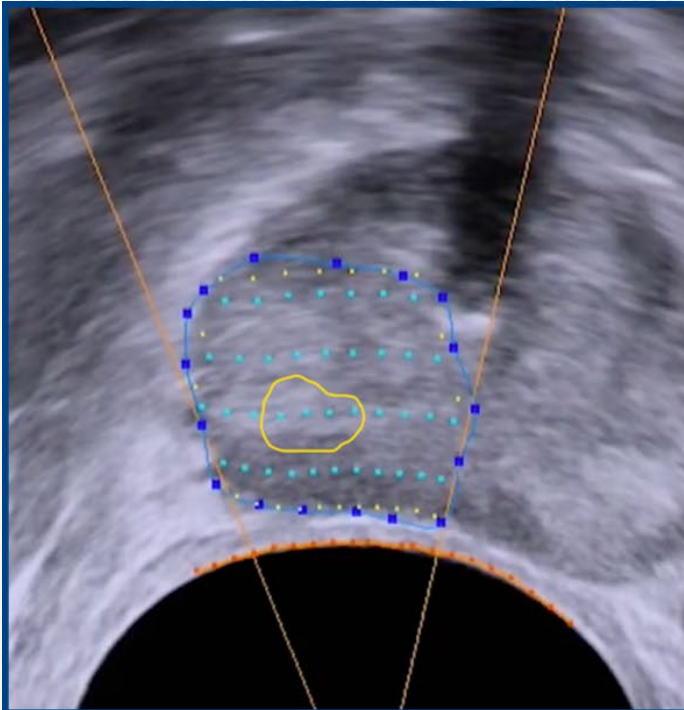


FOCAL Ablation

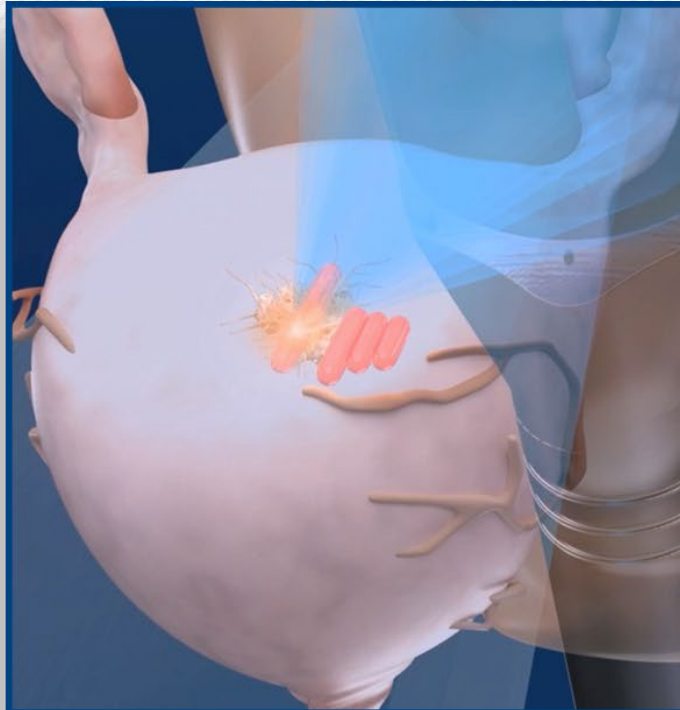
Treatment of the cancerous area only

No or few urinary and sexual morbidity

HIFU Procedure for Prostate Cancer



Localization



Ablation



Validation



70.000+

Treatments performed worldwide



300+

HIFU centers in the world



100+

Peer-reviewed publications

Status

- Approved in Europe (CE Marking), Canada, Brazil, Taiwan, etc. for Prostate Cancer Treatment
- 4 devices from 2 manufacturers are FDA-cleared
- Category I CPT Code effective January 1, 2021

November 2015



Sonablate[®] HIFU
Targeted Prostate Ablation

Ablatherm[®]
Robotic HIFU[®]

December 2017



Ablatherm[®] fusion

June 2018



Focal One[®]

Adoption in the US



Why we are here

**To discuss 2022 APC assignment
for new CPT® code 55880**



Request

Assign 55880 to either APC 5376 or
New Tech APC 1567 (\$6,001 - \$6,500)

Background: 55880 is not the same as C9747

- HCPCS C9747

Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance

- CPT® 55880

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

“High Intensity Focused Ultrasound (HIFU) was FDA approved in October 2015 for ablation of prostate tissue. Clinically, HIFU is used to ablate prostate cancer, and has been used for initial treatment or recurrence after prior therapy (radiation, laser, cryoablation, etc.). Ablation of prostate cancer using HIFU was not previously described in the CPT code set and an unlisted code (CPT 55899) was recommended to be used to report HIFU treatment. HIFU has had sufficient literature base and sufficient volume in the United States to warrant a new, separate CPT code. Starting January 1, 2021, HIFU procedures for prostate cancer will be reported using CPT code 55800”

Source: AUA Website: <https://community.auanet.org/blogs/policy-brief/2020/12/03/new-cpt-codes-for-2021>

HCPCS/APC History for HIFU for Prostate Ablation is Based Upon C9747



HIFU Prostate Ablation vs. Other Procedures in APCs 5375 and 5376

- By statute, procedures assigned to an APC must be “comparable clinically and with respect to the use of resources” Social Security Act sec. 1833(t)(2)(B).
- We believe 55880 is more comparable, clinically and with respect to the use of resources, to procedures in APC 5376 than to procedures in APC 5375

Other Prostate Ablation Procedures in APC 5375

Code	Description
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)
52630	Transurethral resection; residual or re-growth of obstructive prostate tissue including control of postoperative bleeding, complete
52647	Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance

55880 (HIFU) Compared to Prostate Ablation Procedures in APC 5375

Code	Indication	Access Method	Procedure Duration (minutes)	Imaging Required
52601	BPH	Urethral	60	No
52630	BPH	Urethral	45	No
52647	BPH	Urethral	60	No
52648	BPH	Urethral	60	No
52649	BPH	Urethral	60	No
55880	Prostate Cancer	Transrectal	120-240	Yes

55880 compared to other Prostate Ablation Procedures in APC 5375:

- Length of procedure is much longer
- Only code with required image guidance
- Only code to treat Prostate Cancer amongst all prostate ablation procedures
- Requires system accuracy and precision not required with other codes to remove all/only cancer

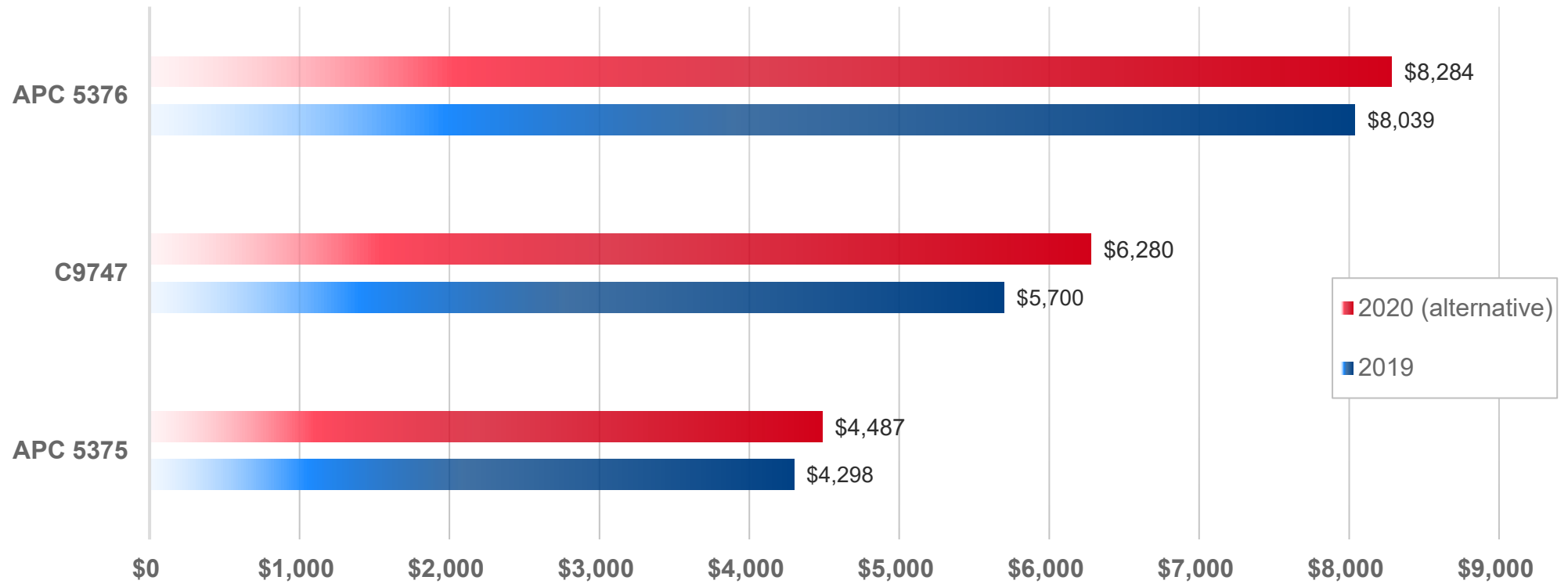
55880 (HIFU) Compares to Prostate Cancer Procedure in APC 5376

Code	Indication	Descriptor	Access Method	Procedure Duration (minutes)	Imaging Required
55873	Prostate Cancer	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)	Transperineal	100	Yes
55880	Prostate Cancer	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	Transrectal	120-240	Yes

55880 compared to only other Prostate Cancer Ablation Procedure

- Indication for Cancer is the same as 55873 (identical in NCCN Guidelines)
- Size and characteristics of Cancer treatable is the same
- Need for same precision and accuracy as 55873 to address cancer while sparing surrounding tissue
- Like 55873, there is a disposable
- Like 55873, treatment is required to be image guided
- Like 55873, target organ is prostate

Geo Mean Cost: HIFU (C9747) in middle of two APCs



Low payment has resulted in rationing/elimination of HIFU at US hospitals, limiting access to Medicare patients

- Robert Pugach, MD – Pacific Coast Urology Medical Center – Los Alamitos, CA
 - Large experience treating Prostate Cancer patients with HIFU
 - Chose HIFU to treat his own prostate cancer in 2017 – now cancer free and has no complications from his HIFU
 - Treated approximately 100 Medicare patients at local hospital in 2017-2018 under C9747 (renting from mobile service provider)
 - Hospital terminated his ability to treat after C9747 lowered to APC 5375
 - Can now only offer HIFU in a non-Medicare participating facility
- Mitchell R. Humphreys, MD - Chair, Department of Urology at Mayo Clinic – Scottsdale, AZ
 - Not-for-profit hospital purchased capital equipment for performing HIFU
 - Current running costs (OR time, maintenance, disposables, etc.) far exceeds current Medicare payment
 - There is a real disincentive to offer HIFU to a high number of patients at the below cost payment, affecting access to care
 - Patient's treatment options for prostate cancer are significantly impacted by hospital economics
 - *"The oncological and QoL results for HIFU are especially well-suited to the Medicare population, and these patients should be able to receive this treatment with institutional payment that, at least, covers the procedure's costs"*

Summary

- 55880 is a new code (effective since 1/1/2021)
- 2022 APC assignment of 55880 is based on C9747 GMN from 2019
- GMN for C9747 has significantly increased in 2020 from 2019 but is still underestimated (lack of reporting of device costs / mobile service cost apportionment issue)
- Inappropriately low payment is causing hospitals to ration / stop offering this option to prostate cancer patients under the Medicare program
- 55880 would be appropriate for assignment to 5376 based on 2020 claims data and clinical similarity with cryosurgery (55873)
- Alternatively, 55880 could be assigned to a New Tech APC in order to provide a more appropriate payment and allow for 2 years of claims data to emerge for 55880