



Submitted by:

David A. Woodrum, MD/PhD, Associate Professor of Radiology and Urology, Mayo Clinic
Vijay Ramalingam, MD, Assistant Professor of Radiology, Beth Israel Deaconess Medical Center/Harvard Medical School
Eric Walser, MD, Professor and Chair of Radiology, UTMB
Lance Mynderse, MD, MS, Associate Professor of Urology and Radiology, Mayo Clinic

Organization:

Society of Interventional Oncology
2025 M St NW #800, Washington, DC 20036
Phone: (202) 367-1164

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NCCN Guidelines Panel: Prostate Cancer

On behalf of The Society of Interventional Oncology, we respectfully request the NCCN Prostate Cancer Guideline Panel review the enclosed data for the following changes to be made to the NCCN Guidelines for Prostate Cancer Version 3.2025:

1. Include focused ultrasound ablation as an initial treatment option for very low risk, low risk, favorable intermediate-risk groups (PROS-3, PROS-4, PROS-5)
2. Include cryoablation as an initial treatment option for very low risk, low risk, favorable intermediate-risk groups (PROS-3, PROS-4, PROS-5)
3. Include laser ablation as an initial treatment option for very low risk, low risk, favorable intermediate-risk groups (PROS-3, PROS-4, PROS-5)

Specific Change 1: Include focused ultrasound ablation as an initial treatment option for very low risk, low risk, favorable intermediate risk groups (PROS-3, PROS-4, PROS-5)

Rationale: Specific change 1 would make the guidelines reflect the widespread use of focused ultrasound and would begin to acknowledge the growing body of literature for use of this technology in treating prostate cancer despite the relative lack of insurance coverage. The treatments and literature reflect good intermediate outcomes for treatment of low and favorable prostate cancer with low morbidity.

The following articles are submitted in support of Specific Change 1:

1. [MRI-guided focused ultrasound focal therapy for patients with intermediate-risk prostate cancer: a phase 2b, multicentre study.](#) Ehdaie B, Tempany CM, Holland F, Sjoberg DD, Kibel AS, Trinh QD, Durack JC, Akin O, Vickers AJ, Scardino PT, Sperling D, Wong JYC, Yuh B, Woodrum DA, Mynderse LA, Raman SS, Pantuck

2001 K Street NW, 3rd Floor North | Washington, DC 20006 | 1-202-367-1164
www.sio-central.org | info@sio-central.org

- AJ, Schiffman MH, McClure TD, Sonn GA, Ghanouni P. *Lancet Oncol.* 2022 Jul;23(7):910-918. doi: 10.1016/S1470-2045(22)00251-0. Epub 2022 Jun 14. PMID: 35714666
2. High Intensity Focused Ultrasound Hemigland Ablation for Prostate Cancer: Initial Outcomes of a United States Series. Abreu AL, Peretsman S, Iwata A, Shakir A, Iwata T, Brooks J, Tafuri A, Ashrafi A, Park D, Cacciamani GE, Kaneko M, Duddalwar V, Aron M, Palmer S, Gill IS. *J Urol.* 2020 Oct;204(4):741-747. doi: 10.1097/JU.0000000000001126. Epub 2020 Sep 8. PMID: 32898975
 3. Outcomes of partial gland ablation using high intensity focused ultrasound for prostate cancer. Hong SK, Lee H. *Urol Oncol.* 2022 May;40(5):193.e1-193.e5. doi: 10.1016/j.urolonc.2022.02.007. Epub 2022 Apr 2. PMID: 35379536
 4. Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Cancer. Klotz L, Pavlovich CP, Chin J, Hatiboglu G, Koch M, Penson D, Raman S, Oto A, Fütterer J, Serrallach M, Relle J, Lotan Y, Heidenreich A, Bonekamp D, Haider M, Tirkes T, Arora S, Macura KJ, Costa DN, Persigehl T, Pantuck AJ, Bomers J, Burtnyk M, Staruch R, Eggener S. *J Urol.* 2021 Mar;205(3):769-779. doi: 10.1097/JU.0000000000001362. Epub 2020 Oct 6. PMID: 33021440
 5. Magnetic resonance imaging-guided transurethral ultrasound ablation in patients with localised prostate cancer: 3-year outcomes of a prospective Phase I study. Nair SM, Hatiboglu G, Relle J, Hetou K, Hafron J, Harle C, Kassam Z, Staruch R, Burtnyk M, Bonekamp D, Schlemmer HP, Roethke MC, Mueller-Wolf M, Pahernik S, Chin JL. *BJU Int.* 2021 May;127(5):544-552. doi: 10.1111/bju.15268. Epub 2020 Nov 1. PMID: 33037765
 6. Cancer Control Outcomes Following Focal Therapy Using High-intensity Focused Ultrasound in 1379 Men with Nonmetastatic Prostate Cancer: A Multi-institute 15-year Experience. Reddy D, Peters M, Shah TT, van Son M, Tanaka MB, Huber PM, Lomas D, Rakauskas A, Miah S, Eldred-Evans D, Guillaumier S, Hosking-Jervis F, Engle R, Dudderidge T, Hindley RG, Emara A, Nigam R, McCartan N, Valerio M, Afzal N, Lewi H, Orczyk C, Ogden C, Shergill I, Persad R, Virdi J, Moore CM, Arya M, Winkler M, Emberton M, Ahmed HU. *Eur Urol.* 2022 Apr;81(4):407-413. doi: 10.1016/j.eururo.2022.01.005. Epub 2022 Feb 3. PMID: 35123819.
 7. Focal therapy with high-intensity focused ultrasound for prostate cancer: 3-year outcomes from a prospective trial. Kaufmann B, Raess E, Schmid FA, Bieri U, Scherer TP, Elleisy M, Donati OF, Rupp NJ, Moch H, Gorin MA, Mortezaei A, Eberli D. *Focal therapy with high-intensity focused ultrasound for prostate cancer: 3-year outcomes from a prospective trial.* *BJU Int.* 2024 Apr;133(4):413-424. doi: 10.1111/bju.16213. Epub 2023 Nov 14. PMID: 37897088.
 8. Focal high-intensity focused ultrasound therapy for localized prostate cancer: An interim analysis of the multinational FASST study. Ladjevardi S, Ebner A, Femic A, Huebner NA, Shariat SF, Krater S, Kubik-Huch RA, Ahlman RC, Häggman M, Hefermehl LJ. *Focal high-intensity focused ultrasound therapy for localized prostate cancer: An interim analysis of the multinational FASST study.* *Eur J Clin Invest.* 2024 Jun;54(6):e14192. doi: 10.1111/eci.14192. Epub 2024 Mar 6. PMID: 38445798.

Specific Change 2: Revise PROS-3 to include cryoablation as an initial treatment option for the >20 y category. Revise PROS-4 to include cryoablation as an initial treatment option for the ≥10 y category. Revise PROS-5 to include cryoablation as an initial treatment option for the >10 y and 5-10 y category.

Rationale: Specific change 2 would make the guidelines reflect the widespread use of cryoablation for prostate cancer treatment which is reflected in good overall insurance coverage of cryoablation for treatment of low and favorable prostate cancer which can be performed with low morbidity and good intermediate outcomes.

The following articles are submitted in support of Specific Change 2:

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) Version3.2024, Prostate Cancer.
1. **"Male lumpectomy"**: focal therapy for prostate cancer using cryoablation. Onik G, Vaughan D, Lotenfoe R, Dineen M, Brady J. *Urology*. 2007 Dec;70(6 Suppl):16-21. doi: 10.1016/j.urology.2007.06.001.PMID: 18194706
2. Comparing the Oncological Outcomes of **Cryoablation vs. Radical Prostatectomy** in Low-Intermediate Risk Localized Prostate Cancer. Guo XX, Liu SJ, Wang M, Hou HM, Wang X, Zhang ZP, Liu M, Wang JY. *Front Oncol*. 2020 Aug 26;10:1489. doi: 10.3389/fonc.2020.01489. eCollection 2020.PMID: 32983986
3. **Cryosurgery** would be An Effective Option for Clinically Localized Prostate Cancer: A Meta-analysis and Systematic Review. Gao L, Yang L, Qian S, Tang Z, Qin F, Wei Q, Han P, Yuan J. *Sci Rep*. 2016 Jun 7;6:27490. doi: 10.1038/srep27490.PMID: 27271239
4. Prospective trial of regional (hockey-stick) **prostate cryoablation**: oncologic and quality of life outcomes. Gregg JR, Borregales LD, Choi H, Lozano M, McRae SE, Venkatesan AM, Davis JW, Noguerras-Gonzalez GM, Pisters LL, Ward JF. *World J Urol*. 2021 Sep;39(9):3259-3264. doi: 10.1007/s00345-020-03575-4. Epub 2021 Jan 16.PMID: 33454813
5. Oncological and functional outcomes of men undergoing primary whole gland **cryoablation** of the **prostate**: A 20-year experience. Tan WP, Kotamarti S, Chen E, Mahle R, Arcot R, Chang A, Ayala A, Michael Z, Segulier D, Polascik TJ. *Cancer*. 2022 Nov 1;128(21):3824-3830. doi: 10.1002/cncr.34458. Epub 2022 Sep 15.PMID: 36107496
6. Oncological and Functional Outcomes of Patients Undergoing Individualized Partial Gland **Cryoablation** of the **Prostate**: A Single-Institution Experience. Tan WP, Chang A, Sze C, Polascik TJ. *J Endourol*. 2021 Sep;35(9):1290-1299. doi: 10.1089/end.2020.0740. Epub 2021 Mar 16.PMID: 33559527
7. **Hemigland Cryoablation** of Clinically Significant Prostate Cancer: Intermediate-Term Followup via Magnetic Resonance Imaging Guided Biopsy. Chuang R, Kinnaird A, Kwan L, Sisk A, Barsa D, Felker E, Delfin M, Marks L. *J Urol*. 2020 Nov;204(5):941-949. doi: 10.1097/JU.0000000000001133. Epub 2020 Sep 28. PMID: 32985924.
8. Five-year Oncologic Outcomes Following Primary Partial Gland Cryo-ablation Prospective Cohort Study of Men With Intermediate-risk **Prostate Cancer**. Lepor H, Rapoport E, Tafa M, Gogaj R, Wysock JS. Five-year Oncologic Outcomes Following Primary Partial Gland Cryo-ablation Prospective Cohort Study of Men With Intermediate-risk Prostate Cancer. *Urology*. 2025 Feb;196:189-195. doi: 10.1016/j.urology.2024.10.039. Epub 2024 Oct 22. PMID: 39447880.

Specific Change 3: Include laser ablation as an initial treatment option for very low risk, low risk, favorable intermediate-risk groups (PROS-3, PROS-4, PROS-5)

Rationale: Specific change 3 would make the guidelines reflect the use of laser ablation in treating low and intermediate prostate cancer. There are increasing amounts of procedures being performed with some insurance/Medicare coverage and increasing amounts of data to suggest that these treatments provide good focal treatment and low morbidity.



The following article is submitted in support of Specific Change 3:

1. Focal **Laser Ablation** of **Prostate Cancer**: Results in 120 Patients with Low- to Intermediate-Risk Disease. Walser E, Nance A, Ynalvez L, Yong S, Aoughsten JS, Eyzaguirre EJ, Williams SB. *J Vasc Interv Radiol*. 2019 Mar;30(3):401-409.e2. doi: 10.1016/j.jvir.2018.09.016.PMID: 30819483
2. 5-Year Outcomes Following Focal **Laser Ablation** of **Prostate Cancer**. Chao B, Lepor H. *Urology*. 2021 Sep;155:124-129. doi: 10.1016/j.urology.2021.03.054. Epub 2021 Jun 4.PMID: 34090887
3. A single-operator experience using EchoLaser SoractelLite™ for focal **laser ablation** of **prostate cancer**: One more arrow in the quiver for the conservative management of the disease. Meneghetti I, Giardino D, Morganti R, Marino V, Menchini Fabris F, Bartoletti R, Pinzi N. *Arch Ital Urol Androl*. 2022 Dec 27;94(4):406-412. doi: 10.4081/aiua.2022.4.406.PMID: 36576471
4. MRI-guided focal **laser ablation** for **prostate cancer** followed by radical prostatectomy: correlation of treatment effects with imaging. Bomers JGR, Cornel EB, Fütterer JJ, Jenniskens SFM, Schaafsma HE, Barentsz JO, Sedelaar JPM, Hulsbergen-van de Kaa CA, Witjes JA. *World J Urol*. 2017 May;35(5):703-711. doi: 10.1007/s00345-016-1924-1. Epub 2016 Aug 19.PMID: 27541586
5. 5-Year Outcomes Following **Focal Laser Ablation** of **Prostate Cancer**. Chao B, Lepor H. *Urology*. 2021 Sep;155:124-129. doi: 10.1016/j.urology.2021.03.054. Epub 2021 Jun 4. PMID: 34090887.
6. Transperineal laser ablation of the prostate as a treatment for benign prostatic hyperplasia and prostate cancer: The results of a Delphi consensus project. Cocci A, Pezzoli M, Bianco F, Blefari F, Bove P, Cornud F, De Rienzo G, Destefanis P, Di Trapani D, Giacobbe A, Giovanessi L, Laganà A, Lughezzani G, Manenti G, Muto G, Patelli G, Pinzi N, Regusci S, Russo GI, Salamanca JIM, Salvi M, Silvestri L, Verweij F, Walser E, Bertolo RG, Iacovelli V, Bertaccini A, Marchiori D, Davila H, Ditunno P, Gontero P, Iapicca G, M De Reijke T, Ricapito V, Pellegrini P, Minervini A, Serni S, Sessa F. *Transperineal laser ablation of the prostate as a treatment for benign prostatic hyperplasia and prostate cancer: The results of a Delphi consensus project.* *Asian J Urol*. 2024 Apr;11(2):271-279. doi: 10.1016/j.ajur.2023.07.001. Epub 2023 Jul 11. PMID: 38680587; PMCID: PMC11053328.

Respectfully submitted,

David A. Woodrum, MD/PhD
Vijay Ramalingam, MD
Eric Walser, MD
Lance Mynderse, MD, MS