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NCCN Guidelines Panel: Kidney Cancer

On behalf of The Society of Interventional Oncology, we respectfully request the NCCN Kidney Cancer Guideline panel review the enclosed data for the following changes to be made to the NCCN Guidelines for Kidney Cancer Version 4.2023:

1. Include microwave ablation as a thermal ablation option (bullet #6, page KID-A);
2. Remove the line “Ablation in masses > 3 cm is associated with higher rates of local recurrence/persistence and complications” page KID-A;
3. Revise the recommendations for imaging follow-up after thermal ablation to included contrast-enhanced CT, contrast-enhanced MRI, or contrast-enhanced US @ 1-3 months, 6 months, 12 months after ablation then annually thereafter;
4. Include thermal ablation as a treatment option for stage T1b tumors, along with Radical nephrectomy (in select patients), Partial Nephrectomy or Active surveillance (in select patients).

Specific Change 1: Revise Principles of Surgery bullet #6 on page KID-A to include microwave ablation as a treatment option, as follows: “Thermal ablation (e.g., cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of patients with clinical stage T1a renal lesions.”

Rationale: Specific change 1 would make the guidelines consistent with Primary Treatment options as indicated on page KID-1. It is generally accepted among interventional radiologists that all energy modalities have essentially equivalent technical and oncologic outcomes in patients with T1a disease. Many physicians have experienced issues with pre-authorization and payment when using microwave ablation due to its exclusion in the guidelines.

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

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Version 4.2023, Kidney Cancer, page KID-1.
2. Zhou W, Herwald S, McCarthy C, Uppot R, et al., Radiofrequency Ablation, Cryoablation, and Microwave Ablation for t1a Renal Cell Carcinoma: A Comparative Evaluation of Therapeutic and Renal Function Outcomes. J Vasc Interv Radiol. 2019 Ju;30(7):1035-1042.
3. Zhou W, Arellano RS. Thermal Ablation of T1c Renal Cell Carcinoma: A Comparative Assessment of Technical Performance, Procedural Outcome, and Safety of Microwave Ablation, Radiofrequency Ablation and Cryoablation. J Vasc Interv Radiol. 2018 Jul;29(7):943-951.
4. Maciolek K, Abel E, Posielski N, Hinshaw J, et al., Tumor location does not impact oncologic outcomes for percutaneous microwave ablation of clinical T1a renal cell carcinoma. Eur Radiol. 2019 Nov;29(11):6319-6329.

Specific Change 2: Remove from Principles of Surgery #6 bullet, the sub-bullet point which reads, “Thermal ablation is an option for masses < 3 cm but may also be an option for larger masses in select patient. Ablation in masses > 3 cm is associated with higher rates of local recurrence/persistence and complications.”

Rationale: Removing the sentence, “Thermal ablation is an option for masses < 3 cm but may also be an option for larger masses in select patient.” brings consistency of the guidelines with Primary Treatment options as indicated on page KID-1. Further, when considering repeat ablations, local disease control between ablation and partial nephrectomy are equivalent.

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

1. Abdelsalam ME, Awad A, Baiomy A, Irwin D, et al., Outcomes of Radiofrequency Ablation for Solitary T1a Renal Cell Carcinoma: A 20-year Tertiary Cancer Center Experience. *Cancers (Basel)*. 2023 Jan 31;15(3):909.
2. Lucignani G, Rizzo M, Ierardi A, Piasentin A, et al., Percutaneous Microwave Ablation is Comparable to Cryoablation for the Treatment of T1a Renal Masses: Results From a Cross-Sectional Study. *Clin Genitourin Cancer*. 2022 Dec;20(6): e506-e511.
3. Duus L, Junker T, Rasmussen B, Bojsen J, et al., Safety, efficacy, and mid-term oncologic outcomes of computed tomography-guided cryoablation of T1 renal cancer. *Acta Radiol*. 2023 Feb;64(2):814-820.
4. Zangiaco RN, Martins G, Viana P, Horvat N, et al., Percutaneous thermoablation of small renal masses (T1a) in surgical candidate patients: oncologic outcomes. *Eur Radiol*. 2021 Jul;31(7):5370-5378.

Specific Change 3: Revise FOLLOW-UP (category 2B), Follow-up After Ablative Techniques, KID-B 1 OF 5.

Request revision of bullet #3 “Abdominal Imaging” as follows:

- Abdominal Imaging:
 - Abdominal CT, MRI with and without IV contrast (unless otherwise contraindicated) or contrast-enhanced US @ 1-3 months, 6 months, 12 months after ablation then annually thereafter. If patient is unable to receive IV contrast, MRI or contrast enhanced US are the preferred imaging modalities.
 - If there is imaging or clinical concern for residual or recurrent disease, then renal mass biopsy or further treatment may be indicated.

Rationale: The requested revision is that frequent follow-up imaging after ablation allows earlier detection of recurrent disease or delayed complications.

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

1. Andrews JR, Atwell T, Schmit G, et al., Oncologic outcomes following partial nephrectomy and percutaneous ablation for cT1 renal masses. *Eur Radiol*. 2019; 76:244-51.
2. Kowalczyk KJ, Harbin AC, Choueiri TK, et al. Use of surveillance imaging following treatment of small renal masses. *J Urol* 2013; 190:1680-5.
3. Lokken PR, Gervais DA, Arellano RS, et al., Inflammatory Nodules Mimic Applicator Track Seeding After Percutaneous Ablation of Renal Tumors. *AJR Am J Roentgenol*. 2007 Oct;189(4):845-8.
4. Zhou W, Herwald SE, Arellano RS. Inflammatory Pseudotumor Mimics Local Recurrence following a Microwave Ablation of Renal Cell Carcinoma. *J Vasc Interv Radiol*.

Specific Change 4: Include Ablative techniques as a treatment option for T1b renal cancer treatment on page KID-1 and KID-A.

Rationale: Patients with T1b tumors who are poor surgical candidates should be offered thermal ablation as an alternative active surveillance. Current data demonstrates comparable RCC-related survival and disease-free survival



rates between ablation and nephrectomy in this patient population. While surgery should remain the primary option for these patients, more patients are ineligible for surgery due to medical co-morbidities. In this specific scenario, physicians and patients should have the option of thermal ablation within the guidelines.

The following articles are submitted in support of Specific Change 4:

1. Aikawa K, Yanagisawa T, Fukuokaya W, Shimizu K, et al., Percutaneous cryoablation versus partial nephrectomy for cT1b renal tumors: An inverse probability weight analysis. *Urol Oncol.* 2023 Mar;41(3): 150.e11-150.e19.
2. Cazalas G, Jambon E, Coussy A, et al., Local recurrence and other oncologic outcomes after image-guided tumor ablations on stage T1b renal cell carcinoma: a systematic review and network meta-analysis. *Int J Hyperthermia.* 2021;38(1):1295-1303.
3. Shapiro D, Wells S, Best S, Hedican S, et al., Comparing Outcomes for Patients with Clinical T1b Renal Cell Carcinoma Treated with Either Microwave Ablation or Surgery. *Urology.* 2020 Jan; 135:88-94.
4. Shimizu K, Enoki K, Kameoka Y, Motohashi K, et al., Image-guided percutaneous cyroablation of T1b renal cell carcinomas in patients with comorbidities. *Jpn J Radiol.* 2021 Dec;39(12):1213-1222.
5. Caputo P, Zargar H, Ramirez D, et al., Cryoablation versus Partial Nephrectomy for Clinical T1b Renal Tumors: A Matched Group Comparative Analysis. *Eur Urol.* 2017 Jan;71(1):111-117

Respectfully submitted,

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