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February 11, 2022

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 inclusion of thermal ablation as a treatment option for stage T1b tumors, and for changing the description of outcomes for ablation in the Principles of Surgery.

We furthermore request that the committee include an additional interventional radiologist. Given that biopsy, ablation, and follow-up imaging are crucial in the management of patients with renal cell carcinoma, the guidelines should be developed by individuals with expertise in diagnostic imaging and interventional radiology. Currently, the large, multidisciplinary committee includes only a single interventional radiologist. Increasing the number of diagnostic/interventional radiologists to the committee would add depth of knowledge and experience to the committee which would serve to provide a more balanced and inclusive perspectives to the committee's recommendations. An exception may be necessary to increase committee diversity/representation.

Specific Change 1: Add Thermal Ablation (in select patients) to diagram for T1b (below Active surveillance) on page KID-1.

FDA Clearance: Thermal ablation is FDA approved for renal ablation.

Rationale: As an active management strategy, thermal ablation should be conceptually included with surgical techniques rather than 3rd tier, following active surveillance. A recent meta-analysis demonstrates the efficacy of thermal ablation for T1b tumors.

The following articles are submitted in support of this proposed change:

Cazalas G, et al. Local recurrence and other oncologic outcomes after percutaneous image-guided tumor ablations on stage t1b renal cell carcinoma: a systematic review and network meta-analysis. *International Journal of Hyperthermia* 2021;38(1):295-1303.

Shapiro DD, et al. Comparing Outcomes for Patients with Clinical T1b Renal Cell Carcinoma Treated with Either Percutaneous Microwave Ablation or Surgery. *Urology* 2020; 135:88-94.

Specific Change 2: The comment that "Ablative techniques are associated with a higher local recurrence rate than conventional surgery and may require multiple treatments to achieve the same local oncologic outcomes" should be removed.

FDA Clearance: Thermal ablation is FDA approved for renal ablation.

Rationale: Whereas early experience with thermal ablation (upon which current NCCN guidelines are based) demonstrated high local recurrence rates, with refinement of techniques current literature reports local recurrence rates after thermal ablation with RFA and cryoablation to compare favorably with local recurrence rates following partial

nephrectomy. Furthermore, retreatment of local recurrence with repeat ablation is technically easier, quicker, and less morbid than repeat surgery. Compared to surgery, thermal ablation is associated with superior perioperative outcomes, including shorter hospital stay, fewer adverse events, and decreased cost. The incidence of local recurrence following renal ablation is very low: Using NCCN's threshold of 3cm, outcomes are much more favorable and approach that of partial nephrectomy. Multiple papers have shown that CSS is no different between treatment strategies.

The following articles are submitted in support of this proposed change:

Andrews J R, Atwell T, Schmit G et al. Oncologic outcomes following partial nephrectomy and percutaneous ablation for cT1 renal masses. *Eur Urol*. 2019;76(02):244–251.

Rivero J R, De La Cerda J, III, Wang H et al. Partial nephrectomy versus thermal ablation for clinical stage T1 renal masses: systematic review and meta-analysis of more than 3,900 patients. *J Vasc Interv Radiol*. 2018;29(01):18–29.

Larcher A, et al. Mortality, morbidity and healthcare expenditures after local tumour ablation or partial nephrectomy for T1A kidney cancer. *Eur J Surg Oncol*. 2017. 43(4):815.

Talenfeld AD, et al. Percutaneous Ablation Versus Partial and Radical Nephrectomy for T1a Renal Cancer: A Population-Based Analysis. *Ann Intern Med*. 2018. 169(2):69.

Uhlig J, et al. Ablation versus Resection for Stage 1A Renal Cell Carcinoma: National Variation in Clinical Management and Selected Outcomes. *Radiology*. 2018. 288(3):889-897.

Xing M, et al. Comparative Effectiveness of Thermal Ablation, Surgical Resection, and Active Surveillance for T1a Renal Cell Carcinoma: A surveillance, Epidemiology, and End Results (SEER)-Medicare-linked Population Study. *Radiology*. 2018. 288(1):81.

Pierorazio PM, et al. Management of Renal Masses and Localized Renal Cancer: Systemic Review and Meta-Analysis. *J Urol*. 2016. 196(4):989-99.

We thank the NCCN panel members for their time and effort in reviewing this submission on behalf of the Society of Interventional Oncology.

Respectfully,

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