



Submitted by:

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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 inclusion in the management of T1a renal masses.

Specific Change 1: With respect to follow-up after ablative techniques, recommend abdominal CT or MRI without and with intravenous contrast at 1-6 months following ablation, then annually following ablation for 5 years or longer as clinically indicated. If patient is unable to receive intravenous contrast, MRI is the preferred imaging modality.

FDA Clearance: Thermal ablation is FDA approved for renal ablation Rationale: CT and MRI is the standard imaging technique for renal neoplasms, and new enhancement at the ablation site is consistent with tumor recurrence. Such enhancement can be difficult to discern from normal calcifying fat necrosis in the ablation bed, hence need for noncontrast images. The majority of ablation failures can be recognized within 1 year of the ablation procedure. There are inherent limitations of ultrasound in imaging a chronic ablation defect due to fat necrosis and secondary acoustic shadowing. Thus, there is a very limited role for isolated ultrasound surveillance.

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

Eiken, et al. *Abdom Radiol*, 2018. 43:2750-2755.

Matin, et al. *J Urol*. 2006. 176:1973-1977.

Specific Change 2: 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.

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

Gunn AJ, Joe WB, Salei A et al. *Cardiovasc Intervent Radiol*. 2019;42:970-978.

Hasegawa T, Yamanaka T, Gobara H et al. *Jpn J Radiol*. 2018;36:551-558.

Chang X, Zhang F, Liu T et al. *J Urol*. 2015;193:430-435.

Atwell TD, Vlaminck JJ, Boorjian SA et al. *J Vasc Interv Radiol*. 2015;26:792-799

Specific Change 3: When addressing relative incidence of local recurrence following thermal

ablation compared to surgery, qualification is needed to state that both techniques are very effective and the difference in treatment success is very small or absent (5% or less). For small renal tumors, cancer specific survival is also similar amongst treatment strategies.

FDA Clearance: Thermal ablation is FDA approved for renal ablation Rationale: The incidence of local recurrence following renal ablation is quite low, with historical worse outcomes following ablation of larger tumors using radiofrequency ablation. 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:

Johnson BA, et al. J Urol, 2019. 201(2):251.

Pierorazio PM, et al. J Urol, 2016. 196(4):989.

Andrews, et al. Eur Urol. 2019. 76(2):244.

Specific Change 4: Benefits of thermal ablation deserve mention in Principles of Surgery

FDA Clearance: Thermal ablation is FDA approved for renal ablation Rationale: Compared to surgery, thermal ablation is associated with superior perioperative outcomes, including shorter hospital stay, fewer adverse events, and decreased cost.

The following articles are submitted in support of this proposed change: Larcher A, et al. Eur J Surg Oncol. 2017. 43(4):815.

Talenfeld AD, et al. Ann Intern Med, 2018. 169(2):69.

Uhlig J, et al. Radiology, 2018. 288(3):889.

Xing M, et al. Radiology, 2018. 288(1):81.

Specific Change 5: When considering those patients appropriate for thermal ablation, please include “those patients willing to accept a potential very low increased incidence of local recurrence” and “those patients in whom partial nephrectomy is not possible and nephron preservation is imperative.”

FDA Clearance: Thermal ablation is FDA approved for renal ablation Rationale: Given the very low or absent difference in local tumor control rates, many patients are willing to accept this risk in favor of the more minimally invasive technique. Some patients may possess tumors that are technically not amenable to nephron sparing surgery (e.g. prior ipsilateral renal surgery) but can be treated with thermal ablation.

The following article is submitted in support of this proposed change:

Altunerende F, et al. J Urol, 2011. 186(1):35.

We would like to thank the NCCN panel members for their time and effort in reviewing this submission.

Sincerely,

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