

Submitted by:

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March 15, 2019

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: Move text related to thermal ablation to a position in front of surveillance

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:
Larcher A, et al. BJU Int, 2016. 118(4):541.

Specific Change 2: 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.
Thompson RH, et al. Eur Urol, 2015. 67(2):252.

Specific Change 3: 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.

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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 4: 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 articles are submitted in support of this proposed change:
Campbell S, et al. J Urol, 2011. 186(1):35.

Specific Change 5: Recommend the term “in selected patients” be removed below Ablative Techniques and Ablative Techniques be moved above Active Surveillance on page KID-1.

FDA Clearance: Thermal ablation is FDA approved for renal ablation

Rationale: The proposed change is supported by the references below and other literature in the NCCN guidelines demonstrating lower adverse events for ablative technologies with low rates of residual disease and recurrence and no difference in CSS for ablation versus partial nephrectomy.

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

Uhlig J, et al. Eur Radiol, 2019. 29(3):1293.
Uhlig J, et al. Radiology, 2018. 288(3):889.
Xing M, et al. Radiology, 2018. 288(1):81.

Specific Change 6: Recommend the following change be added to page Kid-B, 2-4, Follow-up after Partial or Radical Nephrectomy:

- **Biopsy or repeat biopsy:** New enhancement or enlarging nodularity along the surgical margin following partial nephrectomy or new enhancing mass in the surgical bed following radical nephrectomy.

FDA Clearance: Thermal ablation is FDA approved for renal ablation

Rationale: The proposed change is supported by the references below and other literature in the NCCN guidelines demonstrating recurrence rates and locoregional treatment options following partial or radical nephrectomy

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

Zhou W, et al. Cardiovasc Intervent Radiol, 2018. 41:1743.
Reiken M, et al. Clin Genitourin Can, 2018. 16(4):e903.

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

Sincerely,

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