

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	ABSTAIN	ABSENT
<p>External request: Submission request from Pfizer, Inc to recommend the use of sunitinib malate, as a treatment option, for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy.</p> <p>Appended submission from Pfizer, Inc to [consider] deferring a formal category of evidence and consensus for sunitinib as an adjuvant treatment option for adult patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy until after the September 19th ODAC meeting where additional information will be addressed and debated, greater insights and understandings will undoubtedly be achieved.</p>	<p>The panel consensus was to defer the decision to include sunitinib malate, as a treatment option, for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy until after the ODAC meeting.</p> <p>See Submission for References.</p>	21	0	0	0
<p>External request: Submission request from Merck & Co, Inc to recommend the addition of pembrolizumab as a systemic treatment option for adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors that has progressed following prior treatment and who have no satisfactory alternative treatment options or with colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.</p>	<p>Based on the panel discussion, the consensus was not to include pembrolizumab as a treatment option for kidney cancer due to limited available data.</p> <p>See Submission for References.</p>	0	21	0	6

NCCN Guidelines for Kidney Cancer V.1.2018 – Web teleconference on 06/21/17

<p>KID-1 External request: Submission request from the American Society for Radiation Oncology (ASTRO) to have more radiation oncology representation.</p>	<p>Based on panel discussion, the consensus was to have a radiation oncologist added to the panel.</p>	21	0	0	6
<p>KID-1 External request: Submission request from the American Society for Radiation Oncology (ASTRO): On page KID-1, stereotactic body radiotherapy (SBRT) is not included for primary treatment. SBRT should be listed as a treatment option for T1a disease in patients who are not surgical candidates or failed any ablative treatment. It should also be included for T1a disease if there is local relapse after probe-based ablative procedures and, after multidisciplinary group discussion, for selected patients with stage I-III kidney cancer who are not fit for open surgery.</p>	<p>Based on panel discussion, the consensus was not to include SBRT as a primary treatment due to limited available data. See Submission for References.</p>	0	21	0	6
<p>KID-1 External request: Submission request from the American Society for Radiation Oncology (ASTRO): There is no mention on page KID-1 of post-operative radiation as primary treatment, especially for advanced stage disease. Radiation after nephrectomy for high-risk patients should be added to the algorithm.</p>	<p>Based on panel discussion, the consensus was not to include post-operative radiation as primary treatment due to limited available data. See Submission for References.</p>	0	21	0	6
<p>KID-2 External request: Submission request from the American Society for Radiation Oncology (ASTRO): On page KID-2, SBRT is not offered as an option for primary treatment for stage IV. SBRT should be listed as an alternative to “nephrectomy + surgical metastasectomy” for patients</p>	<p>Based on panel discussion, the consensus was not to include SBRT as primary treatment for stage IV kidney cancer due to limited available data. However, “Ablative techniques of metastases in selected patients who are not candidates for surgery” was added as a primary treatment option. See Submission for References.</p>	0	21	0	6

NCCN Guidelines for Kidney Cancer V.1.2018 – Web teleconference on 06/21/17

<p>with stage IV disease and a solitary metastasis depending on the site of the metastasis (brain, bone or other pertinent site). For patients with multiple mets, SBRT should also be added as an option for patients with up to 3 to 5 mets.</p>					
<p>KID-3 Internal request: Institutional review comment to reassess the inclusion of sorafenib as a first-line therapy for relapsed or stage IV and surgically unresectable with predominant clear cell histology.</p>	<p>Based on panel discussion, the consensus was to remove sorafenib as a first-line therapy for relapsed or stage IV and surgically unresectable with predominant clear cell histology due to its limited use.</p>	19	1	1	6
<p>KID-3 and KID-4 External request: Submission request from the American Society for Radiation Oncology (ASTRO): On page KID-3 and KID-4, radiation therapy is not included for treatment after relapse or in stage IV patients who are unresectable. The use of local aggressive therapy such as SBRT for treatment of oligometastases (up to 3 to 5 lesions) or oligoprogression should be included in both the algorithms and the Discussion.</p>	<p>Based on panel discussion, the consensus was not to include radiation therapy as a treatment option after relapse or in stage IV patients who are unresectable due to limited available data. However, “ablative techniques for oligometastatic disease” was added to footnote j, “Best supportive care can include palliative RT, metastasectomy, ablative techniques for oligometastatic disease, bisphosphonates, or RANK ligand inhibitors for bony metastases.”</p>	0	21	0	6
<p>KID-2 and KID-3 External request: Submission request from the American Society for Radiation Oncology (ASTRO): Intraoperative radiation is not included on pages KID-2 and KID-3 as an option after surgery for locally recurrent or advanced tumors undergoing resection and should be added for these scenarios.</p>	<p>Based on panel discussion, the consensus was not to include intraoperative radiation as an option after surgery for locally recurrent or advanced tumors undergoing resection due to limited available data.</p>	0	21	0	6

<p>KID-3 Internal request: Institutional review comment to consider the inclusion of cabozantinib as a first-line therapy for relapsed or stage IV and surgically unresectable with predominant clear cell histology.</p> <p>External request: Submission request from Exelixis to recommend the addition of cabozantinib as a first-line treatment option for advanced renal cell carcinoma (RCC) patients with clear cell component.</p>	<p>Based on panel discussion and noted reference, the consensus was to include cabozantinib for poor- and intermediate-risk groups as a first-line therapy for relapsed or stage IV and surgically unresectable with predominant clear cell histology. Cabozantinib was added with a category 2A designation.</p> <p>Choueiri TK, Halabi S, Sanford BL, et al. Cabozantinib Versus Sunitinib As Initial Targeted Therapy for Patients With Metastatic Renal Cell Carcinoma of Poor or Intermediate Risk: The Alliance A031203 CABOSUN Trial. J Clin Oncol 2017;35:591-597.</p>	21	0	0	6
<p>KID-5 Internal request: Institutional review comment to consider the inclusion of both bevacizumab + erlotinib and bevacizumab + everolimus for HLRCC patients as systemic therapy options for relapsed or stage IV and surgically unresectable with predominant non-clear cell histology.</p>	<p>Based on panel discussion and noted references, the consensus was to add both bevacizumab + erlotinib and bevacizumab + everolimus for HLRCC patients as systemic therapy options for relapsed or stage IV and surgically unresectable with predominant non-clear cell histology. These were both added with a category 2A designation.</p> <ul style="list-style-type: none"> Voss MH, Molina AM, Chen YB, et al. Phase II Trial and Correlative Genomic Analysis of Everolimus Plus Bevacizumab in Advanced Non-Clear Cell Renal Cell Carcinoma. J Clin Oncol 2016;34:3846-3853. Srinivasan R, et al. Mechanism based target therapy for hereditary leiomyomatosis and renal cell cancer (HLRCC) and sporadic papillary renal cell carcinoma: interim results from a phase 2 study of bevacizumab and erlotinib. Euro J Cancer 2014;50:Abstract 5. 	21	0	0	6
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<p>External request: Submission request from the American Society for Radiation Oncology (ASTRO): The guideline does not provide a “Principles of Radiation Therapy” section comparable to the “Principles of Surgery” on page KID-A and offers limited information on palliative RT for metastases. A description of RT principles should be added and should address palliative RT, including for brain and spine metastases and oligometastases. The description of palliative RT in the Discussion (page MS-23) should also be expanded to include oligometastases.</p>	<p>Based on the panel discussion, the consensus was to consider adding a Principles of Radiation Therapy to a future version of the guidelines.</p>	<p>21</p>	<p>0</p>	<p>0</p>	<p>6</p>
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