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β Internal medicine
ω Urology
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NCCN Guidelines Panel Disclosures

Continue
Table of Contents

NCCN Kidney Cancer Panel Members
Summary of Guidelines Updates - click here

Workup, Primary Treatment, and Follow-up (KID-1)
First-Line Therapy for Relapse and Stage IV Medically or Surgically Unresectable Disease (KID-2)
Subsequent Therapy for Predominant Clear Cell Histology (KID-3)
Principles of Surgery (KID-A)
Surveillance Protocol Based on UISS Risk (KID-B)
Predictors of Short Survival (KID-C)

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Staging

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### INITIAL WORKUP

- H&P
- CBC, comprehensive metabolic panel, LDH
- Urinalysis
- Abdominal/pelvic CT or abdominal MRI with or without contrast depending on renal insufficiency
- Chest imaging
- Bone scan, if clinically indicated
- Brain MRI, if clinically indicated
- If urothelial carcinoma suspected (eg, central mass), consider urine cytology, ureteroscopy
- Consider needle biopsy, if clinically indicated

### PRIMARY TREATMENT

#### Stage I, II, III<sup>b</sup>
- Surgical excision
  - See KID-A

#### Stage IV
- Potentially surgically resectable solitary metastatic site
- Nephrectomy + surgical metastasectomy<sup>e</sup>
- Cytoreductive nephrectomy in select patients prior to systemic therapy

### FOLLOW-UP<sup>d,e</sup> (category 2B)

- Every 6 mo for 2 y, then annually for 5 y:
  - H&P
  - Comprehensive metabolic panel, LDH
  - Chest and abdominal CT or abdominal/renal ultrasound and chest x-ray

- Relapse
  - See First-Line Therapy (KID-2)

- Relapse
  - See First-Line Therapy (KID-2)

- Relapse
  - See First-Line Therapy (KID-2)

- Relapse
  - See First-Line Therapy (KID-2)

### Notes
- Biopsy of small lesions may be considered to confirm diagnosis of malignancy and guide surveillance strategies.
- Patients are encouraged to participate in clinical trials.
- Individualized treatment based upon symptoms and extent of metastatic disease.
- UCLA Integrated Staging System (UISS) surveillance protocol based on risk group stratification of high, intermediate, low, or nodal status has been published and may be considered as an alternate to the listed follow-up for patients with localized or locally advanced RCC. See Surveillance Protocol Based on UISS Risk (KID-B)
- No single follow-up plan is appropriate for all patients. Follow-up should be individualized based on patient and tumor characteristics.
FIRST-LINE THERAPY

Clinical trial
or
Sunitinib (category 1)
or
Temsolimus (category 1 for poor-prognosis patients,\textsuperscript{g} category 2B for selected patients of other risk groups)
or
Bevacizumab + IFN (category 1)
or
Pazopanib (category 1)
or
High dose IL-2 for selected patients
or
Sorafenib for selected patients
and
Best supportive care:\textsuperscript{h} See NCCN Palliative Care Guidelines

Relapse or Stage IV and medically or surgically unresectable

Predominant clear cell histology

Clinical trial (preferred)
or
Temsolimus (category 1 for poor-prognosis patients,\textsuperscript{g} category 2A for other risk groups)
or
Sorafenib
or
Sunitinib
or
Pazopanib (category 3)
or
Chemotherapy (category 3): gemcitabine or capecitabine or flouxuridine or 5-FU or doxorubicin (in sarcomatoid only)
and
Best supportive care:\textsuperscript{h} See NCCN Palliative Care Guidelines

Non clear cell histology

See Subsequent Therapy (KID-3)

\textsuperscript{f}Category 1 recommendations are listed in order of FDA approval.

\textsuperscript{g}Poor-prognosis patients, defined as those with \( \geq 3 \) predictors of short survival. See Predictors of Short Survival (KID-C).

\textsuperscript{h}Best supportive care can include palliative RT, metastasectomy, or bisphosphonates for bony metastases.
SUBSEQUENT THERAPY

| Predominant clear cell histology |

Clinical trial  
or  
Everolimus (category 1 following tyrosine kinase inhibitor\(^i\))  
or  
Sorafenib (category 1 following cytokine therapy and category 2A following other tyrosine kinase inhibitor\(^i\))  
or  
Sunitinib (category 1 following cytokine therapy and category 2A following other tyrosine kinase inhibitor\(^i\))  
or  
Pazopanib (category 1 following cytokine therapy and category 3 following other tyrosine kinase inhibitor\(^i\))  
or  
Temsirolimus (category 2A following cytokine therapy and category 2B following tyrosine kinase inhibitor\(^i\))  
or  
Bevacizumab (category 2B)  
or  
IFN or IL-2 (category 2B)  
and  
Best supportive care:  

\(^{h}\)See NCCN Palliative Care Guidelines

\(^{h}\)Best supportive care can include palliative RT, metastasectomy, or bisphosphonates for bony metastases.  
\(^{i}\)Tyrosine kinase inhibitors with a category 1 designation are listed in order of FDA approval.  
\(^{j}\)For example, sorafenib, sunitinib, or pazopanib.
PRINCIPLES OF SURGERY

- Nephron-sparing surgery is appropriate in selected patients, for example:
  - Multiple primaries
  - Uninephric state
  - Renal insufficiency
  - Selected patients with small unilateral tumors

- Regional lymph node dissection is optional.

- Adrenal gland may be left if uninvolved and tumor is not high risk, on the basis of size and location.

- Special teams may be required for extensive inferior vena cava involvement.

- Observation or emerging energy ablative techniques (eg, cryosurgery or radiofrequency ablation) can be considered for patients who are not surgical candidates.

- Emerging energy ablative techniques (eg, cryosurgery or radiofrequency ablation) are currently considered an option by some experts for selected small tumors. Though a rigorous comparison with surgical resection (ie, total or partial nephrectomy by open or laparoscopic techniques) has not been done. Biopsy of small lesions may be considered to confirm diagnosis of malignancy and guide surveillance strategies.
## SURVEILLANCE PROTOCOL BASED ON UISS RISK

UISS Risk Group Based Surveillance Protocol for Patients Following Surgical Resection for Localized and Locally Advanced Renal Cell Cancer  
See Risk Group Stratification (KID-B 2 of 2)

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Surveillance Protocol</th>
<th>Months Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk:</td>
<td></td>
<td>3 6 12 18 24 30 36 48 60 84 108</td>
</tr>
<tr>
<td>• History and physical examination</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Laboratory studies*</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Chest CT</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Abdominal CT</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Intermediate risk:</td>
<td></td>
<td>3 6 12 18 24 30 36 48 60 84 108</td>
</tr>
<tr>
<td>• History and physical examination</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Laboratory studies*</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Chest CT†</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Abdominal CT</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>High risk:</td>
<td></td>
<td>3 6 12 18 24 30 36 48 60 84 108</td>
</tr>
<tr>
<td>• History and physical examination</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Laboratory studies*</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Chest CT†</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Abdominal CT</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Nodal disease:</td>
<td></td>
<td>3 6 12 18 24 30 36 48 60 84 108</td>
</tr>
<tr>
<td>• History and physical examination</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Laboratory studies*</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Chest CT†</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>• Abdominal CT</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

* Includes complete blood count, serum chemistries and liver function tests.
† A chest radiograph can be alternated with a chest CT after 3 years of follow-up.


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**Note:** All recommendations are category 2A unless otherwise indicated. Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.
Flow chart for determination of UISS risk group assignment of patients with localized or locally advanced RCC. Start from left to right using 1997 AJCC N stage and T stage, Fuhrman grade, and ECOG-PS.


Note: All recommendations are category 2A unless otherwise indicated. Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.
**Predictors of Short Survival**

Poor-prognosis patients are defined as those with ≥ 3 predictors of short survival.

- Lactate dehydrogenase level > 1.5 times upper limit of normal
- Hemoglobin level < lower limit of normal
- Corrected serum calcium level > 10 mg/dl (2.5 mmol/liter)
- Interval of less than a year from original diagnosis to the start of systemic therapy
- Karnofsky performance score ≤ 70
- ≥ 2 sites of organ metastasis


**Note:** All recommendations are category 2A unless otherwise indicated.

Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.
### Table 1

**AJCC Staging of Renal Cell Carcinoma**

<table>
<thead>
<tr>
<th>Primary Tumor (T)</th>
<th>Distant Metastasis (M)</th>
<th>Stage Grouping</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TX</strong></td>
<td><strong>MX</strong></td>
<td>Distal metastasis cannot be assessed</td>
</tr>
<tr>
<td><strong>T0</strong></td>
<td><strong>M0</strong></td>
<td>No distant metastasis</td>
</tr>
<tr>
<td><strong>T1</strong></td>
<td><strong>M1</strong></td>
<td>Distant metastasis</td>
</tr>
<tr>
<td><strong>T1a</strong></td>
<td><strong>T1</strong></td>
<td>Tumor 4 cm or less in greatest dimension, limited to the kidney</td>
</tr>
<tr>
<td><strong>T1b</strong></td>
<td><strong>T2</strong></td>
<td>Tumor more than 4 cm but not more than 7 cm in greatest dimension, limited to the kidney</td>
</tr>
<tr>
<td><strong>T2</strong></td>
<td><strong>T3</strong></td>
<td>Tumor more than 7 cm in greatest dimension, limited to the kidney</td>
</tr>
<tr>
<td><strong>T3</strong></td>
<td><strong>T3a</strong></td>
<td>Tumor extends into major veins or invades adrenal gland or perinephric tissues but not beyond Gerota's fascia</td>
</tr>
<tr>
<td><strong>T3a</strong></td>
<td><strong>T3b</strong></td>
<td>Tumor directly invades the adrenal gland or perirenal and/or renal sinus fat but not beyond Gerota's fascia</td>
</tr>
<tr>
<td><strong>T3b</strong></td>
<td><strong>T3c</strong></td>
<td>Tumor grossly extends into the renal vein or its segmental (muscle-containing) branches, or vena cava below the diaphragm</td>
</tr>
<tr>
<td><strong>T3c</strong></td>
<td><strong>T4</strong></td>
<td>Tumor grossly extends into vena cava above diaphragm or invades the wall of the vena cava</td>
</tr>
<tr>
<td><strong>T4</strong></td>
<td><strong>Stage IV</strong></td>
<td>Tumor invades beyond Gerota's fascia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>*<em>Regional Lymph Nodes (N)</em></th>
<th><strong>Stage</strong></th>
<th><strong>T</strong></th>
<th><strong>N</strong></th>
<th><strong>M</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NX</strong></td>
<td>Stage I</td>
<td>T1</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td><strong>N0</strong></td>
<td>Stage II</td>
<td>T2</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td><strong>N1</strong></td>
<td>Stage III</td>
<td>T1</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td><strong>N2</strong></td>
<td>Stage III</td>
<td>T2</td>
<td>N1</td>
<td>M0</td>
</tr>
</tbody>
</table>

*Note: Laterality does not affect the N classification

*Note: If a lymph node dissection is performed, then pathologic evaluation would ordinarily include at least eight nodes.

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NCCN Categories of Evidence and Consensus

**Category 1:** The recommendation is based on high-level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus.

**Category 2A:** The recommendation is based on lower-level evidence and there is uniform NCCN consensus.

**Category 2B:** The recommendation is based on lower-level evidence and there is nonuniform NCCN consensus (but no major disagreement).

**Category 3:** The recommendation is based on any level of evidence but reflects major disagreement.

All recommendations are category 2A unless otherwise noted.