

**American College of Radiology  
ACR Appropriateness Criteria®**

**Clinical Condition:**                      **Renal Cell Carcinoma Staging**

**Variant 1:**                                      **Tumor ≤3 cm.**

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
CT abdomen without and with contrast	9	Should include precontrast and postcontrast phases, including nephrographic phase. Multiplanar reconstructions and 3D volume-rendered images are helpful for surgical planning.	☼☼☼☼
CT abdomen with contrast	8		☼☼☼
X-ray chest	8	Asymptomatic patient.	☼
MRI abdomen without and with contrast	8	See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI abdomen without contrast	6	If iodinated and gadolinium base contrasts are contraindicated.	O
CT chest without contrast	5	Patient with solitary nodule on chest radiograph or respiratory symptoms.	☼☼☼
CT chest with contrast	5		☼☼☼
CT pelvis with contrast	4		☼☼☼
US abdomen	4	More appropriate in patients with contrast sensitivity or renal insufficiency.	O
CT abdomen without contrast	2		☼☼☼
CT chest without and with contrast	2		☼☼☼
CT pelvis without contrast	2		☼☼☼
CT pelvis without and with contrast	2		☼☼☼☼
MRI head without and with contrast	1		O
MRI head without contrast	1		O
FDG PET skull base to mid-thigh	1	Attenuation correction by radionuclide methods or, more commonly, with computed tomography (CT) is considered part of the examination.	☼☼☼☼
Tc-99m bone scan whole body	1		☼☼☼
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Clinical Condition:****Renal Cell Carcinoma Staging****Variant 2:****Tumor >3 cm.**

<b>Radiologic Procedure</b>	<b>Rating</b>	<b>Comments</b>	<b><u>RRL*</u></b>
CT abdomen without and with contrast	9	Should include precontrast and postcontrast, including nephrographic phase. Multiplanar reconstructions and 3D volume-rendered images are helpful for surgical planning.	⊕⊕⊕⊕
CT abdomen with contrast	8		⊕⊕⊕
X-ray chest	8		⊕
CT chest without contrast	8	Can identify subtle pulmonary nodules, mediastinal lymphadenopathy, and bone and subcutaneous metastases. Confirms or excludes metastases seen on chest radiograph.	⊕⊕⊕
CT chest with contrast	8		⊕⊕⊕
MRI abdomen without and with contrast	8	See statement regarding contrast in text under "Anticipated Exceptions."	○
MRI abdomen without contrast	6	If iodinated and gadolinium base contrasts are contraindicated.	○
CT pelvis with contrast	5		⊕⊕⊕
US abdomen	3		○
Tc-99m bone scan whole body	3	More appropriate if tumor >7 cm or locally advanced; if bone pain present. Additional confirmatory imaging with radiographs, CT or MRI may be obtained if indicated.	⊕⊕⊕
MRI head without and with contrast	3		○
MRI head without contrast	3		○
CT abdomen without contrast	2		⊕⊕⊕
CT chest without and with contrast	2		⊕⊕⊕
CT pelvis without contrast	2		⊕⊕⊕
CT pelvis without and with contrast	2		⊕⊕⊕⊕
Arteriography kidney	2	Appropriate as part of renal tumor embolization prior to surgery in hypervascular tumors to reduce blood loss at surgery and for palliation of hematuria in inoperable tumors.	⊕⊕⊕
FDG-PET skull base to mid-thigh	2	Attenuation correction by radionuclide methods or, more commonly, with computed tomography (CT) is considered part of the examination.	⊕⊕⊕⊕
<b><u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate</b>			<b>*Relative Radiation Level</b>

# RENAL CELL CARCINOMA STAGING

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## **Summary of Literature Review**

### **Introduction/Background**

Renal cell carcinoma (RCC) accounts for 2%-3% of all visceral malignancies. It is estimated that approximately 53,500 new cases of RCC are diagnosed per year in the U.S, resulting in approximately 13,040 deaths [1] due to cancers of the kidney and renal pelvis. The incidence in men is 1.6 times greater than in women. Metastatic disease at presentation varies with the patient series but typically occurs in about one in 10 patients [2-5]. The most common sites of distant metastases in descending order are the lung, bone, retroperitoneal and mediastinal nodes, liver, and brain, or in multiple sites [6-7].

Partial nephrectomy is now increasingly used in many patients with RCC. Radical nephrectomy, usually reserved for locally advanced RCC, involves node dissection and complete removal of the kidney and Gerota's fascia.

### **Staging**

The traditional Robson system ([Appendix 1](#)) used for staging renal cancers has significant limitations because it groups venous tumoral involvement and lymph node metastases in the same stage. In recent times the TNM staging system ([Appendixes 2 and 3](#)) developed by the American Joint Committee on Cancer (AJCC) has

become more commonly used and is regarded as more accurate and of greater prognostic value [8-12].

The TNM system, which was introduced in 1978, has been revised several times, most recently in 2010, to reflect evolving knowledge of the prognostic indicators over the decades. Significant changes from the 2002 version reflect the importance of tumor size, adrenal involvement, and the extent of renal vein involvement. Tumors between 7 cm and 10 cm are now classified as T2a lesions. Tumors >10 cm are now classified as T2b lesions. Tumors involving renal vein or its segmental branches (muscle-containing branches) are now reclassified as T3a. Tumors involving the inferior vena cava (IVC) below the diaphragm are considered T3b disease, whereas tumors involving the IVC above the diaphragm or invading the wall of the IVC are classified as T3c. Ipsilateral adrenal involvement is classified as T4 if the invasion is contiguous invasion and M1 if it is not contiguous. Nodal involvement is simplified to N0 versus N1. These changes reflect improved survival predictability over the previous versions of TNM staging.

Prior to the widespread use of ultrasound (US), computed tomography (CT), and magnetic resonance imaging (MRI), patients with renal cancers were more likely to be symptomatic at discovery, and consequently the tumors were larger and of a higher stage, with approximately 33% of RCCs presenting in stage I, 10% in stage II, 25% in stage III, and 33% in stage IV [4]. More recently, however, RCCs are increasingly discovered when they are small and therefore at lower stage. As many more tumors are identified serendipitously on cross-sectional imaging, a stage migration has been observed, with a greater proportion of newly diagnosed patients with RCC currently presenting with stage I disease [13-14]. This trend is also associated with a decrease in the size of tumors in stage I RCCs. Based on the data of 31,233 kidney cancer patients from the National Cancer Data Base (NCDB) in the U.S. for the year 2007, the distribution of stage I, II, III and IV tumors was 60%, 10%, 14% and 16%, respectively, based on the 2002 TNM staging [5]. With recent advancements in diagnosis and treatment, median 5-year cancer-specific survival rates have improved to 90%-95% for stage I, 75%-85% for stage II, 60%-70% for stage III, and 20%-30% for stage IV [9,15].

### **Prognosis**

Prognosis is related to several factors, including the tumor subtype, the size of the primary tumor, the stage, and the nuclear grade. In one large study evaluating 47,909 cases from the national cancer database, patients with tumors <4 cm in diameter had a 75% 5-year survival rate, whereas tumors >10 cm in diameter yielded a median survival rate of 47.5% at 5 years [16-17]. Although incidentally discovered small tumors have a much better prognosis than symptomatic tumors [2-3] nonaggressive biologic behavior cannot be assumed. In one study of 50

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lesions <3 cm in diameter, 38% had extension outside the renal capsule with T3/T4 disease [18]. In another series, 12% of 318 T1 tumors had higher staging due to nodal and distant metastases [15] which was likely related to other factors such as tumor subtype and nuclear grade.

### **Imaging in Staging**

#### *Staging of Primary Tumor*

Preoperative imaging can provide important staging and anatomic information to the surgeon. Both CT and MRI are equally accurate in staging of the primary tumor [19-20]. It is important to be aware that changes in pathologic stage of malignant renal neoplasms postoperatively is common, mainly due to changes seen in the size and renal sinus fat invasion on imaging studies [21]. RCC is commonly multifocal. One of the important roles of preoperative imaging studies is also to look for synchronous primaries. Several studies have shown that both CT and US are suboptimal in detecting small synchronous primaries <1 cm in diameter [22-24], with detection rates ranging from 22% to 58%. However, an adequately designed CT protocol that includes the nephrographic phase appears to increase the detectability of small lesions [25].

Perinephric tumor extension (T3a) is difficult to discriminate from nonspecific perinephric stranding from edema, vascular engorgement, or fibrosis. High-resolution CT using thin sections appears to improve detection of perinephric infiltration, although false positives can be problematic [19-20,26]. Breath-hold MRI showing lack of perinephric fat involvement is reported to have a high negative predictive value of no perinephric tumor invasion [27]. In a study of 73 RCCs, Roy et al [28] showed that the presence of a pseudocapsule on MRI had an accuracy of 93% for clear-cell carcinomas in separating T1/T2 tumors from T3a tumors.

Renal sinus fat invasion, staged as T3a in the current TNM staging system, can be difficult to accurately detect on CT [29]. It is considered as the most common site for extrarenal extension of RCC. The clinical significance of this finding is controversial. Several authors believe that the presence of renal sinus fat invasion heralds a poorer prognosis when compared to perinephric fat invasion [30-32]. However, Margulis et al [33] found no significant difference in outcomes. Nevertheless, presence of renal sinus fat invasion poses special challenges in planning nephron-sparing procedures and hence special caution should be taken when evaluating these structures. Many urologists rely on intraoperative frozen section, when available, to make these determinations.

Direct contiguous spread to the adrenal, previously classified as T3a, now is classified as T4 in the latest TNM staging system. CT has a high sensitivity and nearly a 100% negative predictive value in detecting direct contiguous spread to the ipsilateral adrenal gland [15,34]. However, the positive predictive value of CT is lower, as it may be difficult to distinguish abutment from direct invasion.

The extent of venous invasion of tumor is an important factor in the T staging in the current TNM staging system. Tumor extension into segmental branches or the main the renal vein is seen in approximately 20% of cases and has been reclassified as T3a in light of recent evidence that this group of patients tend to have a better prognosis when compared to those with extension of tumor to the IVC, which is seen in up to 10% of patients [35-37]. Not only must the involvement of the renal veins and IVC be identified, but the cephalic extent of the tumor must also be correctly assessed for preoperative planning. Depending on the level of an IVC thrombus, the surgeon may need to perform a thoracoabdominal incision instead of an abdominal incision. Intra-atrial thrombus may require cardiac bypass. Intrahepatic caval thrombus may require open thrombectomy or, if there is transmural invasion of the caval wall, a graft placement. Thrombus limited to the renal vein ostia may be “milked” back into the vein without the need to open the vein. Therefore, accurate assessment of caval thrombus is important. The prognostic significance of the extent of venous thrombus is still a topic of controversy, but recent evidence show that supradiaphragmatic extension of IVC thrombus heralds a poorer prognosis than subdiaphragmatic extension [35,37-38].

Venous thrombus in the renal vein or IVC can usually be identified on the venous phase or delayed phase of the examination on the initial diagnostic CT. In cases where the findings are equivocal, MRI may be helpful. Tumor thrombus in the segmental branches of the renal vein may be more difficult to determine than thrombus in the main renal vein and IVC [29]. Both contrast-enhanced multidetector CT and MRI have equal sensitivity in detecting venous involvement, particularly in the main renal vein and the IVC [26,39]. Signs suggestive of renal vein or caval thrombus include filling defects, enlargement of the vessel, and rim enhancement. The pitfalls in CT occur with technically inadequate boluses of contrast media, motion, and flow artifact.

Due to its higher tissue contrast, noncontrast MRI has a higher sensitivity and specificity in detecting venous extension than a nonenhanced CT. Pitfalls of MRI include the potential for large tumors to compress the vena cava and cause flow-related artifacts. Such artifacts can be reduced with appropriate saturation pulses. With bright blood techniques, rapid or turbulent flow can also lead to artifacts. Diagnostic accuracy is improved with gadolinium-enhanced MR venography [40]. The highest sensitivity and specificity in assessing venous involvement are achieved with gradient echo sequence [20,41]. Bland thrombus featuring low, uniform signal intensity and lack of enhancement after gadolinium can be distinguished from tumor thrombus, which exhibits intermediate or high signal intensity, heterogeneous intensity, and more reliably, the presence of small vessels [40]. However, if a good-quality CT is obtained at several phases after contrast administration and the vein is clearly seen, MRI is usually not needed.

Venous anomalies should be sought, specifically the presence of a retroaortic left renal vein or circumaortic

left renal vein, as these have surgical implications. CT and MR angiograms can be incorporated in any staging study to determine any arterial or venous anomalies that may be helpful in surgical planning. US and color duplex US may be used to study the venous invasion and venous anatomy, but this technique is of limited value in obese patients and in the presence of bowel gas, which interferes with the ability to image the renal vein-IVC junction. US is also highly dependent on the expertise of the operator.

Catheter angiography is insensitive for tumor thrombus [42]. Its main roles are for preoperative embolization to reduce blood loss in hypervascular tumors and for palliation of hematuria in inoperable tumors.

Including the pelvis in routine staging examination is of limited value and is not likely to yield any significant results unless in rare instances of ectopic kidneys located in the pelvis. Two retrospective studies looking at a total of 519 staging CTs including both abdomen and pelvis reported that none of the pelvic CTs offered management altering information not already known to the clinical team [43-44].

#### *Nodal Staging*

As the current methodology for detecting lymph node metastases is based only on size, all imaging is suboptimal for N staging. Cross-sectional imaging criteria for diagnosing metastatic lymph nodes include a short-axis diameter of >1 cm and disruption of the normal lymph node architecture. However, based on this criterion, CT has a false negative rate of about 10%, and nearly 50% of enlarged lymph nodes tend to be benign [45]. MR lymphography with iron oxide nanoparticles shows promise, but the agent is not yet available in the United States [46]. CT-guided aspiration biopsies are an alternative and can be performed if desired for documenting nodal metastases.

Contiguous invasion of the adrenal gland, liver, diaphragm, psoas muscles, pancreas, and bowel is seen in advanced T4 tumors and usually portends a poor prognosis. Both CT and MRI suffer with a poor positive predictive value, as it is occasionally difficult to distinguish mere abutment from invasion. However CT offers a high negative predictive value in excluding direct contiguous invasion [15,34].

#### **Distant Metastases**

Distant metastases are commonly seen in lungs, bone, liver, and brain. Routine chest radiographs are considered necessary, but the routine use of chest CT is more controversial. For small primary lesions (<3 cm) the risk of metastases is small enough that the high cost and radiation of a chest CT may not be justified. The risk of pulmonary metastases increases with the size of the primary tumor, and although universally accepted guidelines do not yet exist [2,18,47], chest CT is justified for larger primary tumors. When the chest radiograph is suspicious or positive, chest CT is useful for confirming or excluding metastases and defining the extent of disease. Inclusion of CT scan of the pelvis with the abdomen rarely adds any valuable information. In a study

of 119 patients undergoing preoperative CT staging, routine pelvic CT yielded no findings related to the RCC [43].

Neither routine bone scans nor bone surveys appear routinely justified [48]. However, if the patient has an elevated alkaline phosphatase, bone pain, or an extremely large and aggressive tumor, bone scans may be helpful [48-49]. Furthermore, use of brain MRI routinely cannot be justified, but it is indicated when neurologic symptoms are present, if the primary tumor is large, or if other metastatic disease is already present [50].

Positron emission tomography (PET) does not yet have an established role in staging renal cancer. Early studies using PET with the tracer fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG-PET) suggest that it may be difficult to even detect primary renal cancers against the normal background of high activity in the kidneys. PET may be helpful for establishing metastatic disease in lesions detected by CT, MRI, or bone scan, and it may be used to detect unsuspected metastases in high-risk patients [51-52]. Although negative PET results cannot exclude metastatic disease, a positive PET scan should be considered highly suspicious for local recurrence or metastatic disease due its high specificity.

#### **Summary**

- Staging of renal cancer depends on the size of the primary tumor.
- For small or incidentally detected tumors ( $\leq 3$  cm), multidetector, multiphase CT of the abdomen with either CT of the chest or chest radiography is usually sufficient. MRI of the abdomen is a suitable substitute when the patient cannot undergo contrast-enhanced CT. Bone scan or MRI of the brain may be used in symptomatic patients.
- For larger primary tumors ( $> 3$  cm), multidetector, multiphase CT of the abdomen with chest CT is the diagnostic modality of choice. If the status of the renal veins and IVC cannot be determined on CT, contrast-enhanced multiphase 3D MR venography should be performed. MRI of the abdomen is a suitable substitute for staging renal cancer when the patient cannot undergo contrast-enhanced CT.
- Prior to any major surgery to remove a locally advanced primary tumor, brain MRI and bone scan should be performed.
- Lesions detected by any modality that are suspicious for metastatic disease should be biopsied. FDG-PET scan may be considered as a noninvasive alternative.
- CTA and MRA could be incorporated into any staging study of the renal cancer to obtain information regarding the vascular supply, which can be helpful to surgeons in planning a resection.
- Catheter angiography can be performed to embolize large tumors prior to resection [53-56].

#### **Anticipated Exceptions**

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of

manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (ie, <30 mL/min/1.73m<sup>2</sup>), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73m<sup>2</sup>. For more information, please see the [ACR Manual on Contrast Media](#) [57].

### Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria<sup>®</sup> [Radiation Dose Assessment Introduction](#) document.

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv

\*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as NS (not specified).

### Supporting Document(s)

- [ACR Appropriateness Criteria<sup>®</sup> Overview](#)
- [Procedure Information](#)
- [Evidence Table](#)

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

### Appendix 1. Robson's Staging System for Renal Cell Carcinoma

Robson	Disease Extent
I	Tumor confined within the renal capsule
II	Tumor spread to perinephric fat or ipsilateral adrenal gland
IIIA	Venous tumor thrombus (renal vein or IVC)
IIIB	Regional lymph node metastases
IIIC	Venous tumor thrombus and regional lymphadenopathy
IVA	Direct invasion of adjacent organs outside Gerota's fascia
IVB	Distant metastases

### Appendix 2. 2010 TNM Staging System for the Kidney

#### Primary tumor (T)

Stage	Definition
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
T1	Tumor 7 cm or less in greatest dimension, limited to the kidney
T1a	Tumor 4 cm or less in greatest dimension, limited to the kidney
T1b	Tumor more than 4 cm but not more than 7 cm in greatest dimension limited to the kidney
T2	Tumor more than 7 cm in greatest dimension, limited to the kidney
T2a	Tumor more than 7 cm but less than or equal to 10 cm in greatest dimension, limited to the kidney
T2b	Tumor more than 10 cm, limited to the kidney
T3	Tumor extends into major veins or perinephric tissues but not into the ipsilateral adrenal gland and not beyond Gerota's fascia
T3a	Tumor grossly extends into the renal vein or its segmental (muscle containing) branches, or tumor invades perirenal and/or renal sinus fat but not beyond Gerota's fascia
T3b	Tumor grossly extends into the vena cava below the diaphragm
T3c	Tumor grossly extends into the vena cava above the diaphragm or invades the wall of the vena cava
T4	Tumor invades beyond Gerota's fascia (including contiguous extension into the ipsilateral adrenal gland)

#### Regional lymph nodes (N)

Stage	Definition
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in regional lymph node(s)

#### Distant metastasis (M)

Stage	Definition
M0	No distant metastasis
M1	Distant metastasis

### Appendix 3. Stage Grouping

Stage I	T1, N0, M0
Stage II	T2, N0, M0
Stage III	T1 or T2, N1, M0
	T3, N0 or N1, M0
Stage IV	T4, any N, M0
	Any T, any N, M1