

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

**Clinical Condition:** Renal Cell Carcinoma Staging

**Variant 1:** Tumor ≤3 cm.

Radiologic Procedure	Rating	Comments	<a href="#"><u>RRL*</u></a>
CT abdomen without and with contrast	9	Should include pre- and post-contrast phases including arteriographic phase. Multiplanar reconstructions and 3D volume rendered images are helpful for surgical planning.	High
X-ray chest	8	Asymptomatic patient.	Min
MRI abdomen without and with contrast	8	See comments regarding contrast in text under "Anticipated Exceptions."	None
CT chest without contrast	5	Patient with solitary nodule on chest radiograph or respiratory symptoms.	Med
US abdomen	4	More appropriate in patients with contrast sensitivity or renal insufficiency.	None
MRI head with or without contrast	1		None
FDG-PET whole body	1		High
NUC Tc-99m bone scan whole body	1		Med
INV arteriography kidney	1		Med
INV venacavography inferior	1		Med
X-ray radiographic survey whole body	1		Med
<b>Rating Scale:</b> 1=Least appropriate, 9=Most appropriate			<b>*Relative Radiation Level</b>

An 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 exams 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.

**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 pre- and post-contrast phases including arteriographic phase. Multiplanar reconstructions and 3D volume rendered images are helpful for surgical planning.	High
X-ray chest	8		Min
CT chest without contrast	8	Can identify subtle pulmonary nodules, mediastinal lymphadenopathy, bone and subcutaneous metastases. Confirms or excludes metastases seen on chest radiograph.	Med
MRI abdomen without and with contrast	8	See comments regarding contrast in text under "Anticipated Exceptions."	None
FDG-PET whole body	4		High
US abdomen	3		None
INV venacavography inferior	3		Med
NUC Tc-99m bone scan whole body	3	More appropriate if tumor >7 cm or locally advanced; if bone pain present.	Med
MRI head with or without contrast	3	More appropriate if tumor >7 cm or locally advanced; or if neurologic symptoms present.	None
INV 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.	Med
X-ray radiographic survey whole body	1		Med
<b>Rating Scale: 1=Least appropriate, 9=Most appropriate</b>			<b>*Relative Radiation Level</b>

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## RENAL CELL CARCINOMA STAGING

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### **Summary of Literature Review**

Renal cell carcinoma (RCC) accounts for 2%-3% of all visceral malignancies. Approximately 36,000 new cases are diagnosed per year in the U.S., resulting in approximately 12,500 deaths [1]. The incidence in men is nearly twice that in women. Metastatic disease at presentation varies with the patient population but typically occurs in about one-third of patients [2-4]. The most common sites of distant metastases in descending order are the lung, bone, skin, liver, and brain, or in multiple sites [3].

The traditional treatment for RCC is radical nephrectomy, which involves node dissection and complete removal of the kidney and Gerota's fascia. Nephron-sparing surgery is increasingly used for small tumors. Prognosis is related to tumor size and stage [4,5]. Robson's staging system (Appendix 1) was introduced in the 1960s and was much less complex than the TNM system first introduced in 1978 and revised in 1987, 1997 and 2002 [6].

The Robson classification has significant limitations in that venous tumoral involvement and lymph node metastases are grouped in the same stage. There are now strong advocates for use of the revised 2002 TNM staging system (Appendix 2 and 3), which is regarded as more accurate and of greater prognostic value [7-10]. Significant changes from the 1987 and 1997 versions of the TMN system reflect the importance of tumor size and the extent of inferior vena cava (IVC) involvement. Tumors larger than 7 cm have been upgraded to T2 lesions. For surgical planning of partial elective nephrectomy, further division of T1 tumors into T1a and T1b was added, with a 4.0-cm cutoff separating them, for lesions confined to the kidney. T3a disease includes renal sinus fat invasion. Tumor involving the renal vein or its

segmental (muscle containing branches) with or without IVC involvement below the diaphragm is considered T3b disease, whereas tumor involving the IVC above the diaphragm or invading the wall of the IVC is classified as T3c. These changes have improved survival predictability although further refinements are likely in the future.

Approximately 33% of RCCs present in stage I, 10% in stage II, 25% in stage III, and 33% in stage IV [3]. 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 [7,11].

Prognosis is related to the size of the primary tumor as well. In one large study, patients with tumors <2.5 cm had a 100% 5-year survival rate, whereas tumors >10 cm in diameter yielded a median survival rate of 27% at 5 years [5]. Only 5%-10% of patients present with the classic triad of flank mass, hematuria, and pain. Since the widespread use of ultrasound (US), computed tomography (CT), and magnetic resonance imaging (MRI), RCCs are increasingly discovered when they are small and therefore at lower stage. Although these incidentally discovered small tumors have a much better prognosis than symptomatic tumors [12-14] nonaggressive biologic behavior cannot be assumed. In one study of 50 lesions smaller than 3 cm, 38% had extension outside the renal capsule with T3/T4 disease [15]. In another series, 12% of 318 T1 tumors had higher staging due to nodal and distant metastases [11] which was likely related to other factors such as tumor subtype and nuclear grade.

Preoperative staging is important to the surgeon in planning the procedure. Tumor size is accurately determined by CT, MRI, and US. Perinephric tumor extension (T3a) is difficult to discriminate from nonspecific perinephric stranding from edema, vascular engorgement, or fibrosis. High-resolution CT using thin sections (~1 mm) can demonstrate perinephric stranding with 96% sensitivity, 93% specificity, and 95% accuracy [16], although false positives can be problematic [16-18]. This determination is often not critical since the tumor and perinephric fat are usually removed at the time of radical nephrectomy. The presence of T3a disease should be excluded, however, if nephron-sparing surgery is planned [17-19]. CT shows a 100% negative predictive value for T3a disease involving the adrenal gland [20]. Breath-hold MRI showing lack of perinephric fat involvement has high negative predictive value and predicts whether a tumor can be removed by nephron-sparing surgery [21,22]. In a study of 73 RCCs Roy et al [22] showed that the presence of a pseudocapsule on MRI

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had an accuracy of 93% for clear-cell carcinoma in separating T1/T2 tumors from T3a tumors.

Tumor extends into the renal vein in 20% of cases and into renal vein and IVC in 10%, yet with proper surgical treatment, patients with T3b or T3c disease may have survival rates similar to those for stages I and II disease [23]. Not only must the involvement of the renal veins and inferior vena 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.

Dynamic enhanced CT is the most commonly employed method of identifying caval thrombus. Studies have shown that the technique used influences the success of CT, particularly with regard to the speed of scanning and rate of contrast media administration [24]. Multi-detector-row CT shows very high accuracy rates, achieving equivalence with MRI [16,17]. Signs suggestive of renal vein or caval thrombus include filling defects, enlargement of the vessel, and rim enhancement. With good technique, helical CT achieves 85%-91% sensitivity routinely [16-19,25-27]. Problems occur with technically inadequate boluses of contrast media, motion and flow artifact (especially with foot injections), and renal insufficiency. Venous anomalies should be sought, specifically the presence of a retroaortic left renal vein or circumaortic left renal vein, as these have surgical implications.

MRI is 83%-100% sensitive for tumor thrombus but routinely achieves 90%-100% sensitivity with modern equipment and may be slightly more accurate than CT in assessing the cephalic extent of the thrombus [16-18,28,29]. Pitfalls of MRI include large tumors compressing the vena cava and flow-related artifacts, which can be reduced with appropriate saturation pulses. With bright blood techniques, rapid or turbulent flow can also lead to artifacts. Intravenous contrast may be helpful in this setting [30]. The highest sensitivity and specificity in assessing venous involvement are achieved with gradient echo sequence [18,31]. Bland thrombus (low signal intensity) can be distinguished from tumor thrombus, which exhibits intermediate-signal intensity [31]. 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.

Other techniques include US, which is approximately 50%-75% sensitive for caval thrombus [12,25,32] and can

be helpful for quickly identifying the cephalad extent of a tumor thrombus. US is limited in obese patients and in the presence of bowel gas, which interferes with the ability to image the renal vein-IVC junction.

Cavography is approximately 85%-100% sensitive for detecting caval thrombus and is equal to MRI in accuracy [23,33]. However, multidetector, multiphasic CT or MRI suffices to diagnose caval thrombus, and thus catheter cavography is rarely needed.

Angiography has proved insensitive for tumor thrombus [34]. Its main roles are preoperative embolization to reduce blood loss in hypervascular tumors and for palliation of hematuria in inoperable tumors.

For TxN+ disease (lymph node involvement), CT and MRI are approximately equal, and both are superior to US [24,35,36]. All imaging is suboptimal for N staging because of the reliance on node size for assessing metastases [31]. MR lymphography with iron oxide nanoparticles shows promise as a methodology to identify tumor within lymph nodes regardless of their size. The agent is not yet available in the United States, however, and there is no large reported experience with its use in renal cell carcinoma [37]. From a surgical perspective, the identification of nodes is less important because the nodes must be sampled at the time of surgery.

CT-guided aspiration biopsies can be performed if desired for documenting nodal metastases; however, they are rarely needed. Imaging is important for the preoperative detection of bulky adenopathy, which might complicate the surgical approach. This is especially true for laparoscopic nephrectomies in which both the vascular anatomy and the nodal pathology may be poorly visualized. Accurate preoperative information becomes even more important, especially for centrally located renal tumors, emphasizing the need for computed tomography angiography (CTA) or magnetic resonance angiography (MRA) prior to such a procedure [16-18].

The presence of T4M0-1 disease (metastatic disease with contiguous invasion) is also important to the surgeon. Common sites of contiguous organ invasion include the liver, diaphragm, psoas muscles, pancreas, and bowel. Neither CT nor MRI is ideal, because it is impossible at times to distinguish lack of a fat plane from immediately adjacent but not invasive tumor or from directly invasive tumor; however, both techniques perform well, with a sensitivity and specificity >90% [36]. The multiplanar capabilities of MRI can be useful in this regard; however, neither technique always assesses liver or diaphragmatic invasion correctly [38,39]. Angiography can also be misleading, since tumors can recruit vessels from the liver or elsewhere without the tumor actually invading the organ.

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T4M1N+ disease (distant metastases) principally affects the chest, bone, liver, and brain. Routine chest radiographs are considered necessary, but the routine use of chest CT is more controversial. For small lesions (<3 cm) the risk of metastases is so small as to eliminate the need for chest CT; however, the risk increases with the size of the primary tumor, and although universally accepted guidelines do not yet exist [2,13,15,40] chest CT is justified for larger tumors. When the chest radiograph is suspicious or positive, chest CT is useful for confirming or excluding metastases and defining the extent of disease.

In a study of 119 patients undergoing preoperative CT staging, routine pelvic CT yielded no findings related to the renal cell carcinoma [41].

Similarly, neither routine bone scans nor bone surveys appear routinely justified [25]. However, if the patient has an elevated alkaline phosphatase, bone pain, or an extremely large and aggressive tumor, bone scans may be helpful [25,42]. Furthermore, brain MRI does not appear routinely justified, but it is indicated when neurologic symptoms are present, if the primary tumor is large, or if other metastatic disease is already present.

Positron emission tomography (PET) does not yet have an established role in staging renal cancer. Early studies using 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 [43,44]. 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

Thus, the routine staging of renal cancer should depend 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. If symptoms of bone pain or neurologic symptoms exist, bone scan or MRI of the brain may be employed.

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 inferior vena cava cannot be resolved on CT, contrast-enhanced multiphase 3D MR venography (MRV) should be performed. MRI of the abdomen is a suitable substitute for staging renal cancer when the patient cannot undergo contrast-enhanced CT.

US may be performed prior to surgery to ascertain the cephalad extent of a previously identified caval tumor thrombus but cannot be relied upon to detect small renal vein or IVC thrombus. Cavography is employed only in unusual circumstances. 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 either biopsied or examined with an FDG-PET scan.

Although not strictly staging, CTA and MRA should be incorporated into any staging study of the renal cancer, as the vascular information can be helpful to surgeons in planning a resection. Catheter angiography can be performed to embolize large tumors prior to resection [14,45-47].

### Anticipated Exceptions

In patients with history of adverse reaction to contrast media or renal insufficiency, MRI and/or US may be preferred to CT. MRI is superior to US in evaluating lymphadenopathy, determining the organ of origin of the mass, diagnosing intracaval and renal venous thrombus, and demonstrating bone metastases.

Nephrogenic systemic fibrosis (NSF), also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF [48-50], a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (eg,  $>0.2$  mM/kg) and to agents in which the gadolinium is least strongly chelated. The FDA has recently issued a “black box” warning concerning these contrast agents ([http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca\\_200705HCP.pdf](http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705HCP.pdf)).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated GFR  $<30$  mL/min/1.73m<sup>2</sup>), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s) [49].

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## 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. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document.

Relative Radiation Level Designations	
Relative Radiation Level	Effective Dose Estimate Range
None	0
Minimal	< 0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

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## Appendix 1. Robson's Staging System for Renal Cell Carcinoma [2]

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. Staging Renal Cell Carcinoma [10]

### Primary tumor (T)

Stage	Sub-Stage	Definition
T1		Tumor 7.0 cm or less in greatest dimension, limited to kidney
	T1a	Tumor < 4.0 cm
	T1b	Tumor 4.0 cm to 7.0 cm
T2		Tumor > 7.0 cm in greatest dimension, limited to kidney
T3		Tumor extends into major veins or invades adrenal gland or perinephric tissues but not beyond Gerota's fascia
	T3a	Tumor directly invades adrenal gland or perirenal and/or renal sinus fat but not beyond Gerota's fascia
	T3b	Tumor grossly extends into the renal vein or its segmental (muscle containing) branches, or IVC below the diaphragm
	T3c	Tumor grossly extends into IVC above the diaphragm or invades the wall of the vena cava
T4		Tumor invades beyond Gerota's fascia

### Regional lymph nodes (N)

Stage	Sub-Stage	Definition
N0		No regional lymph node metastasis
N1		Metastasis to a single regional lymph node
N2		Metastasis in more than 1 regional lymph node

### Distant metastasis (M)

Stage	Sub-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, N1, M0
	T2, N1, M0
	T3, N0, M0
	T3, N1, M0
Stage IV	T4, N0, M0
	T4, N1, M0
	Any T, N2, M0
	Any T, any N, M1

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